

CLEVELAND BIOLABS INC  
Form 10-Q  
November 14, 2008

**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, 2008

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 x No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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 14, 2008, there were 13,695,676 shares outstanding of registrant's common stock, par value \$0.005 per share.

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CLEVELAND BIOLABS INC  
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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, 2008 (unaudited) and December 31, 2007

	September 30 2008 (unaudited)	December 31 2007
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 3,666,169	\$ 14,212,189
Short-term investments	1,000,000	1,000,000
Accounts receivable:		
Trade	1,368,618	163,402
Interest	5,399	50,042
Other prepaid expenses	575,373	325,626
Total current assets	6,615,559	15,751,259
<b>EQUIPMENT</b>		
Computer equipment	295,025	258,089
Lab equipment	1,081,729	966,517
Furniture	276,009	274,903
	1,652,763	1,499,509
Less accumulated depreciation	552,828	313,489
	1,099,935	1,186,020
<b>OTHER ASSETS</b>		
Intellectual property	722,386	459,102
Deposits	23,482	25,445
	745,868	484,547
<b>TOTAL ASSETS</b>	<b>\$ 8,461,362</b>	<b>\$ 17,421,826</b>

See accompanying notes

## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

September 30, 2008 (unaudited) and December 31, 2007

	September 30 2008 (unaudited)	December 31 2007
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,771,536	\$ 710,729
Deferred revenue	2,431,107	1,670,610
Dividends payable	44,320	396,469
Accrued expenses	351,926	449,774
Total current liabilities	4,598,889	3,227,582
<b>STOCKHOLDERS' EQUITY</b>		
Series B convertible preferred stock, \$.005 par value		
Authorized - 10,000,000 shares at September 30, 2008 and December 31, 2007		
Issued and outstanding 3,301,373 and 3,870,267 shares at September 30, 2008 and December 31, 2007, respectively	16,507	19,351
Additional paid-in capital	20,792,287	24,383,695
Common stock, \$.005 par value		
Authorized - 40,000,000 shares at September 30, 2008 and December 31, 2007		
Issued and outstanding 13,635,406 and 12,899,241 shares at September 30, 2008 and December 31, 2007, respectively	68,177	64,496
Additional paid-in capital	35,530,556	30,764,914
Accumulated deficit	(52,545,054)	(41,038,212)
Total stockholders' equity	3,862,473	14,194,244
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 8,461,362</b>	<b>\$ 17,421,826</b>

See accompanying notes

## CLEVELAND BIOLABS, INC.

## STATEMENT OF OPERATIONS

Three Months and Nine Months Ending September 30, 2008 and 2007 (unaudited)

	Three Months Ended		Nine Months Ended	
	September 30 2008 (unaudited)	September 30 2007 (unaudited)	September 30 2008 (unaudited)	September 30 2007 (unaudited)
<b>REVENUES</b>				
Grant and contract	\$ 1,851,419	\$ 540,544	\$ 3,082,119	\$ 1,327,996
Service	-	120,000	120,000	290,000
	1,851,419	660,544	3,202,119	1,617,996
<b>OPERATING EXPENSES</b>				
Research and development	3,485,430	4,105,480	9,719,519	11,663,054
Selling, general and administrative	1,240,142	1,442,669	4,425,792	6,968,565
Total operating expenses	4,725,572	5,548,149	14,145,311	18,631,619
<b>LOSS FROM OPERATIONS</b>	<b>(2,874,153)</b>	<b>(4,887,605)</b>	<b>(10,943,192)</b>	<b>(17,013,623)</b>
<b>OTHER INCOME</b>				
Interest income	49,450	305,568	244,593	761,648
Buffalo relocation reimbursement	-	-	220,000	-
Sublease revenue	2,656	1,771	7,970	1,771
Gain on disposal of fixed assets	-	-	1,394	-
Gain on investment	-	-	3,292	-
Total other income	52,106	307,339	477,249	763,419
<b>OTHER EXPENSE</b>				
Corporate relocation	8,933	901,964	142,638	1,152,643
Loss on Investment	-	305,479	-	305,479
Interest expense	-	-	-	1,087
Total other expense	8,933	1,207,443	142,638	1,459,209
<b>NET LOSS</b>	<b>\$ (2,830,980)</b>	<b>\$ (5,787,709)</b>	<b>\$ (10,608,581)</b>	<b>\$ (17,709,413)</b>
<b>DIVIDENDS ON CONVERTIBLE PREFERRED STOCK</b>	<b>(317,814)</b>	<b>(807,913)</b>	<b>(898,260)</b>	<b>(807,913)</b>
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (3,148,794)</b>	<b>\$ (6,595,622)</b>	<b>\$ (11,506,841)</b>	<b>\$ (18,517,326)</b>
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED</b>	<b>\$ (0.23)</b>	<b>\$ (0.54)</b>	<b>\$ (0.86)</b>	<b>\$ (1.54)</b>

WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	13,605,822	12,148,718	13,415,376	12,010,177
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See accompanying notes

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## CLEVELAND BIOLABS, INC.

## STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2008 and 2007 (unaudited)

	September 30 2008 (unaudited)	September 30 2007 (unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (10,608,581)	\$ (17,709,413)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	239,339	110,979
Noncash salaries and consulting expense	1,150,692	4,445,737
Loss on investments	-	305,479
Changes in operating assets and liabilities:		
Accounts receivable - trade	(1,205,216)	(484,789)
Accounts receivable - interest	44,643	(7,008)
Other prepaid expenses	(249,748)	167,907
Deposits	1,964	(12,392)
Accounts payable	1,060,807	320,563
Deferred revenue	760,497	1,846,763
Accrued expenses	(97,848)	269,424
Milestone payments	-	(50,000)
Total adjustments	1,705,130	6,912,663
Net cash (used in) provided by operating activities	(8,903,451)	(10,796,750)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Sale of short-term investments	-	19,999,968
Purchase of short-term investments	-	(19,003,837)
Issuance of notes receivable	-	(250,000)
Purchase of equipment	(153,253)	(831,430)
Costs of patents pending	(263,284)	(153,417)
Net cash (used in) provided by investing activities	(416,537)	(238,716)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Issuance of preferred stock	-	30,020,984
Financing costs	-	(1,152,857)
Dividends	(1,250,410)	(807,913)
Issuance of common stock	-	-
Exercise of stock options	24,378	101,300
Exercise of warrants	-	90,515
Net cash (used in) provided by financing activities	(1,226,032)	28,252,029
INCREASE (DECREASE) IN CASH AND EQUIVALENTS	(10,546,020)	17,216,563
CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	14,212,189	3,061,993
CASH AND EQUIVALENTS AT END OF PERIOD	\$ 3,666,169	\$ 20,278,556

## Supplemental disclosures of cash flow information:

Cash paid during the period for interest	\$	-	\$	1,087
Cash paid during the year for income taxes	\$	-		

## Supplemental schedule of noncash financing activities:

Conversion of preferred stock to common stock	\$	3,594,242	\$	-
Issuance of stock options to employees, consultants, and independent board members	\$	1,929,432	\$	2,745,287
Expense recapture of expense for options expensed in 2007 but issued in 2008	\$	1,459,425	\$	-
Issuance of shares to consultants and employees	\$	626,500	\$	1,700,450
Amortization of restricted shares issued to employees and consultants	\$	54,185	\$	-
Accrual of preferred stock dividends	\$	44,320	\$	-

See accompanying notes

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2007 to December 31, 2007 and to  
September 30, 2008 (unaudited)

	Stockholders' Equity		
	Shares	Common Stock Amount	Additional Paid-in Capital
Balance at January 1, 2007	11,826,389	\$ 59,132	\$ 18,314,097
Issuance of options	-	-	3,401,499
Options to be issued in 2008	-	-	2,687,355
Issuance of shares - Series B financing	-	-	-
Fees associated with Series B Preferred offering	-	-	-
Issuance of restricted shares	190,000	950	1,699,500
Exercise of options	126,046	630	110,650
Exercise of warrants	48,063	240	90,275
Conversion of Series B Preferred Shares to Common	708,743	3,544	4,461,537
Dividends on Series B Preferred shares	-	-	-
Net Loss	-	-	-
Other comprehensive income			
Unrealized gains (losses) on short term investments			
Changes in unrealized holding gains (losses) arising during period	-	-	-
Less reclassification adjustment for (gains) losses included in net loss	-	-	-
Comprehensive loss			
Balance at December 31, 2007	12,899,241	64,496	\$ 30,764,914
Issuance of options	-	-	1,929,433
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-	(1,459,425)

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Issuance of restricted shares	130,000	650	625,850
Restricted stock awards	-	-	54,185
Exercise of options	37,271	186	24,191
Conversion of Series B Preferred Shares to Common	568,894	2,844	3,591,408
Dividends on Series B Preferred shares	-	-	-
Net Loss	-	-	-
Other comprehensive income			
Unrealized gains (losses) on short term investments			
Changes in unrealized holding gains (losses) arising during period	-	-	-
Less reclassification adjustment for (gains) losses included in net loss	-	-	-
Comprehensive loss			
Balance at September 30, 2008	13,635,406	\$ 68,177	\$ 35,530,556

See accompanying notes

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2007 to December 31, 2007 and to  
September 30, 2008 (unaudited)

	Stockholders' Equity		
	Shares	Preferred Stock Amount	Additional Paid-in Capital
Balance at January 1, 2007	-	\$ -	\$ -
Issuance of options	-	-	-
Options to be issued in 2008	-	-	-
Issuance of shares - Series B financing	4,579,010	22,895	32,030,175
Fees associated with Series B Preferred offering	-	-	(3,184,943)
Issuance of restricted shares	-	-	-
Exercise of options	-	-	-
Exercise of warrants	-	-	-
Conversion of Series B Preferred Shares to Common	(708,743)	(3,544)	(4,461,537)
Dividends on Series B Preferred shares	-	-	-
Net Loss	-	-	-
Other comprehensive income			
Unrealized gains (losses) on short term investments			
Changes in unrealized holding gains (losses) arising during period	-	-	-
Less reclassification adjustment for (gains) losses included in net loss	-	-	-
Comprehensive loss			
Balance at December 31, 2007	3,870,267	\$ 19,351	\$ 24,383,695
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	(568,894)	(2,844)	(3,591,408)
Dividends on Series B Preferred shares	-	-	-
Net Loss	-	-	-
Other comprehensive income			
Unrealized gains (losses) on short term investments	-	-	-
Changes in unrealized holding gains (losses) arising during period			
Less reclassification adjustment for (gains) losses included in net loss	-	-	-
Comprehensive loss			
Balance at September 30, 2008	3,301,373	\$ 16,507	\$ 20,792,287

See accompanying notes

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2007 to December 31, 2007 and to  
September 30, 2008 (unaudited)

	Stockholders' Equity			Comprehensive Income (Loss)
	Other Comprehensive Income/(Loss)	Accumulated Deficit	Total	
Balance at January 1, 2007	\$ (4,165)	\$ (12,775,910)	\$ 5,593,154	
Issuance of options	-	-	3,401,499	
Options to be issued in 2008	-	-	2,687,355	
Issuance of shares - Series B financing	-	-	32,053,070	
Fees associated with Series B Preferred offering	-	-	(3,184,943)	
Issuance of restricted shares	-	-	1,700,450	
Exercise of options	-	-	111,280	
Exercise of warrants	-	-	90,515	
Conversion of Series B Preferred Shares to Common	-	-	-	
Dividends on Series B Preferred shares	-	(1,265,800)	(1,265,800)	
Net Loss	-	(26,996,502)	(26,996,502)	(26,996,502)
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses) arising during period	-	-	-	\$ -
Less reclassification adjustment for (gains) losses included in net loss	4,165	-	4,165	\$ 4,165
Comprehensive loss				\$ (26,992,337)
Balance at December 31, 2007	\$ -	\$ (41,038,212)	\$ 14,194,244	
Issuance of options	-	-	1,929,433	

Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-	(1,459,425)	
Issuance of restricted shares	-	-	626,500	
Restricted stock awards	-	-	54,185	
Exercise of options	-	-	24,378	
Conversion of Series B Preferred Shares to Common	-	-	-	
Dividends on Series B Preferred shares	-	(898,261)	(898,261)	
Net Loss	-	(10,608,581)	(10,608,581)	(10,608,581)
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses) arising during period	-	-	-	\$ -
Less reclassification adjustment for (gains) losses included in net loss	-	-	-	\$ -
Comprehensive loss				\$ (10,608,581)
Balance at September 30, 2008	\$ -	\$ (52,545,054)	\$ 3,862,473	

See accompanying notes



**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. The Company's initial technological development efforts are intended to be used as powerful antidotes with a broad spectrum of applications including protection from cancer treatment side effects, radiation and hypoxia. A significant discovery found that one of the Company's compounds increases the number of progenitor (originator) stem cells in mouse bone marrow. To date, the Company has not developed any commercial products. The Company has developed and produced biological compounds under a single commercial development contract.

**Note 2. Summary of Significant Accounting Policies**

A. Basis of Presentation - The information at September 30, 2008 and September 30, 2007, and for the quarter and nine months ended September 30, 2008 and September 30, 2007, 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, 2007, 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, 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, 2008 and December 31, 2007.

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 \$82,252, and \$49,298 for the quarters ended September 30, 2008 and 2007, respectively. Depreciation expense was \$239,317 and \$110,979 for the nine months ended September 30, 2008 and 2007, respectively.

F.

Impairment of Long-Lived Assets - In accordance with Statements of Financial Accounting Standards, or SFAS, No. 144, Accounting for the Impairment or Disposal 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 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 certain intellectual property rights. Capitalized intellectual property is reviewed annually for impairment.

A portion of this intellectual property is owned by the Cleveland Clinic Foundation, or 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. If the patent application is approved, the costs paid by the Company are 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 with the preparation, filing and maintenance of the patent application by the Company on behalf of CCF will be expensed as part of selling, general and administrative expenses. Gross capitalized patents pending costs were \$656,693 and \$407,425 for these 13 patent applications as of September 30, 2008 and December 31, 2007, respectively. All of the CCF patent applications are still pending approval.

The Company also has submitted five patent applications as a result of intellectual property exclusively developed and owned by the Company. 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 with the preparation, filing and maintenance of the patent application will be expensed as part of selling, general and administrative expenses at that time. Gross capitalized patents pending costs were \$65,693 and \$51,677 for these five patent applications as of September 30, 2008 and December 31, 2007, respectively. The patent applications are still pending approval.

H. Line of Credit - The Company has a working capital line of credit that is fully secured by short-term investments. This fully-secured, working capital line of credit carries an interest rate of prime minus 1%, a borrowing limit of \$1,000,000, and expires on September 25, 2009. At September 30, 2008, there were no outstanding borrowings under this credit facility.

I. 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.

In September 2006, The Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements." SFAS No. 157 provides enhanced guidance for using fair value to measure assets and liabilities and expands disclosure with respect to fair value measurements. This statement was originally effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FSP157-2 which allows companies to elect a one-year deferral of adoption of SFAS No. 157 for non-recurring assets and non-financial liabilities that are recognized or disclosed at fair value in the financial statements on a non-recurring basis. The Company has adopted SFAS No. 157 as of January 1, 2008.

SFAS No. 157 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, 2008.

J. 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.

K. Revenue Recognition - The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition", or SAB 104, and Statement of Financial Accounting Standards No. 116, or SFAS 116. 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 per SAB 104. 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 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 has recognized grant revenue from the following agencies: the Department of Defense (DoD), the Defense Threat Reduction Agency (DTRA), the U.S. Army (DARPA), National Aeronautics and Space Administration (NASA), the National Institutes of Health (NIH) and the Department of Health and Human Services (HHS).

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) in accordance with SFAS 116. The principles of SFAS 116 result 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.

Commercial development revenues are recognized when the service or development is delivered.

L. 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 the Roswell Park Cancer Institute during the second quarter of 2007. The Company received an additional \$1,000,000 in funds from the State of New York through the Roswell Park Cancer Institute 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 as the services are performed and the prepaid asset is recognized as expense. For the nine months ended September 30, 2008, the Company recognized \$760,497 as revenue resulting in a balance of deferred revenue of \$2,431,107 at September 30, 2008. At December 31, 2007, the balance in deferred revenue was \$1,670,610.

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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.

N.2006 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 expires on May 26, 2016 and the aggregate number of shares of stock which may be delivered under the Plan shall 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 2006 Plan, and contains updates that reflect changes and developments in federal tax laws. For the quarter ended September 30, 2008, there were 43,456 stock options and granted under the Amended Plan, and as of September 30, 2008 there were 1,663,380 stock options and 335,000 shares granted under the Amended Plan leaving 2,001,620 shares of stock to be awarded under the Amended Plan.

O. Stock-Based Compensation - The FASB issued SFAS No. 123(R) (revised December 2004), Share Based Payment, which is a revision of SFAS No. 123 Accounting for Stock-Based Compensation. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. The Company values employee stock-based compensation under the provisions of SFAS 123(R) and related interpretations.

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 an adequate trading history to rely solely on the volatility of the Company. The Company recognizes the fair value of stock-based compensation in net income on a straight-line basis over the requisite service period.

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

	2008 YTD	2007
Risk-free interest rate	2.61-3.58%	3.38-5.11%
Expected dividend yield	0%	0%
Expected life	5-6 years	2.74-6 years
Expected volatility	64.31-80.25%	71.86-76.29%

During the quarter ended September 30, 2008, the Company granted 43,456 additional stock options pursuant to stock award agreements. The Company recognized a total of \$355,800 in expense related to stock options for the quarter ended September 30, 2008. During the quarter ended September 30, 2007, the Company granted 18,000 stock options pursuant to stock award agreements to certain employees and key consultants and recognized a total of \$395,129 in expense related to options.

During the nine months ended September 30, 2008, the Company granted 958,380 additional stock options pursuant to stock award agreements. The Company recognized a total of \$1,929,433 in expense related to stock options for the

nine months ended September 30, 2008. The Company also recaptured \$1,459,425 of previously recognized expense due to the stock options awarded under the 2007 Executive Compensation Plan. These options were originally expensed based on the December 31, 2007 variables, but were not issued until February 4, 2008. The change in dates resulted in a difference in valuation assumptions used in the Black-Scholes model causing a reduction in the grant date fair value. This reduction in the grant date fair value from \$5.34 to \$2.44 per share resulted in the recapture of \$1,459,425 in expense and a net expense for options for the nine months ended September 30, 2008 of \$470,008.



During the nine months ended September 30, 2007, the Company granted 543,000 stock options pursuant to stock award agreements and expensed \$2,745,287 related to stock options.

The weighted average, estimated grant date fair values of stock options granted during the quarters ended September 30, 2008 and 2007 was \$2.76 and \$4.95, respectively.

The following tables summarize the stock option activity for the nine months ended September 30, 2008 and September 30, 2007, respectively.

	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

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2006	483,490	\$ 2.17	
Granted	543,000	\$ 9.82	
Exercised	124,000	\$ 1.35	
Forfeited, Canceled	-	n/a	
Outstanding, September 30, 2007	902,490	\$ 6.89	8.77
Exercisable, September 30, 2007	599,930	\$ 6.58	8.78

The Company also recognized \$5,627 in expense for shares issued under the Amended Plan to a consultant during the quarter ended September 30, 2008. In addition, the Company recognized \$18,333 in consulting expense related to the amortization of restricted shares.

For the nine months ended September 30, 2008, the Company recognized a total of \$626,500 in expense for shares issued under the Amended Plan and a total of \$54,185 in expense related to the amortization of restricted shares. For the nine months ended September 30, 2007 the Company recognized a total of \$1,700,450 in expense for shares issued under the Plan to various consultants.

P. 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, 2008 and 2007:

	Quarter Ended September 30, 2008	Quarter Ended September 30, 2007	Nine-Months Ended September 30, 2008	Nine-Months Ended September 30, 2007
Net loss available to common stockholders	\$ (3,148,794)	\$ (6,595,622)	\$ (11,506,841)	\$ (18,517,326)
Net loss per share, basic and diluted	\$ (0.23)	\$ (0.54)	\$ (0.86)	\$ (1.54)
Weighted-average shares used in computing net loss per share, basic and diluted	13,605,822	12,148,718	13,415,376	12,010,177

The Company has excluded all outstanding 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 *warrants*, was 3,453,268 for both periods ended September 30, 2008 and 2007, 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 1,927,586 and 902,490 for the periods ended September 30, 2008 and 2007, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

Q. Concentrations of Risk - Grant revenue was comprised wholly from grants and contracts issued by the federal and NY state government and accounted for 100.0% and 81.8% of total revenue for the quarter ended September 30, 2008 and 2007, respectively. Grant revenue accounted for 96.3% and 82.1% for the nine months ended September 30, 2008 and 2007, 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.

R. 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 and the Great British Pound, or GBP. As of September 30, 2008, the Company is obligated to make payments under the agreements of 1,033,262 Euros and 281,548 GBP. As of September 30, 2007, the Company has commitments for 100,000 Euros and 0 GBP.

S. Comprehensive Income/(Loss) - The Company applies Statement of Financial Accounting Standards (SFAS) No. 130, "Reporting Comprehensive Income." SFAS No. 130 requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

**Note 3. Stock Transactions**

On February 1, 2006, the Company paid a common stock dividend of 91,776 shares to holders of the Series A preferred stock to satisfy the dividend requirement of the preferred stock issuance.

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On March 1, 2006, the Company issued 116,750 stock options to various employees and consultants of the Company under non-qualified stock option agreements. These options allow for the purchase of 116,750 shares of common stock at a price of \$4.50. These options have a three-year vesting schedule and expire on February 29, 2016.

On June 21, 2006, after the expiration of the 115-day extension and an additional 30-day period, the Company incurred one additional penalty period in which 60,000 shares of Series A preferred stock were earned at \$120,000 and 15,295 shares of common stock were earned at \$30,590. The Company has not incurred any further obligation to issue penalty shares since these issuances.

On July 20, 2006, the Company sold 1,700,000 shares of common stock in its initial public offering at \$6.00 per share. The net proceeds to the Company from this offering were approximately \$8,300,000. Beginning July 21, 2006, the Company's shares were quoted on the NASDAQ Capital Market and listed on the Boston Stock Exchange under the symbols "CBLI" and "CFB" respectively. On August 28, 2007, trading of the Company's common stock moved from the NASDAQ Capital Market to the NASDAQ Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange. In connection with its initial public offering, the Company sold warrants to purchase 170,000 shares of common stock to the underwriters and their designees at a cost of \$100.00. The warrants have an exercise price of \$8.70 per share.

On July 20, 2006, the effective date of the Company's initial public offering, the Company issued 92,407 shares of common stock as accumulated dividends to the Series A preferred stockholders. On the same date, all of the Company's Series A Preferred shares automatically converted on a one-for-one basis into 3,351,219 shares of common stock and notes of the Company in the principal amount of \$283,500 plus accrued interest of \$29,503 automatically converted into 124,206 shares of common stock. In connection with their appointment to the Board, the Company issued to each of the Company's three new independent directors, options to purchase 15,000 shares of common stock with an exercise price of \$6.00 per share.

On September 21, 2006, the SEC declared effective a registration statement of the Company registering up to 4,453,601 shares of common stock for resale from time to time by the selling stockholders named in the prospectus contained in the registration statement. The Company will not receive any proceeds from the sale of the underlying shares of common stock, although to the extent the selling stockholders exercise warrants for the underlying shares of common stock, the Company will receive the exercise price of those warrants. The registration statement was filed to satisfy registration rights that the Company had previously granted.

On November 16, 2006 the Company issued 50,000 warrants to an outside consultant. These warrants are immediately exercisable into common shares of the Company and have an exercise price of \$6.00 per share and an expiration date of November 16, 2011.

On February 14, 2007, the Company issued 99,500 stock options to various employees and consultants of the Company under non-qualified stock option agreements. These options allow for the purchase of 99,500 shares of common stock at a price of \$9.14. These options have various vesting schedules from immediate vesting to three years and expire on February 14, 2017.

On February 26, 2007, the Company issued 55,000 warrants at an exercise price of \$9.19 per share, to a placement agent as incentive for work on the private placement offering.

On March 16, 2007, the Company entered into a Securities Purchase Agreement with various accredited investors (the Buyers), pursuant to which the Company agreed to sell to the Buyers Series B Convertible Preferred Stock (Series B Preferred) convertible into an aggregate of 4,288,712 shares of common stock and Series B Warrants that are exercisable for an aggregate of 2,144,356 shares of common stock. The Series B Preferred have an initial conversion price of \$7.00 per share, and in the event of a conversion at such conversion price, one share of Series B Preferred

would convert into one share of common stock. The Series B Warrants have an exercise price of \$10.36 per share, the closing bid price on the day prior to the private placement. To the extent, however, that the conversion price of the Series B Preferred or the exercise price of the Series B Warrants is reduced as a result of certain anti-dilution protections, the number of shares of common stock into which the Series B Preferred are convertible and for which the Series B Warrants are exercisable may increase.

The Company also issued to the placement agents in the private placement (the Agents), as compensation for their services, Series B Preferred, Series B Warrants, and Series C Warrants. The Agents collectively received Series B Preferred that are convertible into an aggregate of 290,298 shares of common stock, Series B Warrants that are exercisable for an aggregate of 221,172 shares of the Company's common stock, and Series C Warrants that are exercisable for 267,074 shares of the Company's common stock. The Series C Warrants have an exercise price of \$11.00 per share, and are also subject to anti-dilution protections that could increase the number of shares of common stock for which they are exercisable.

In total, the securities issued in the private placement will be convertible into, or exercisable for, up to approximately 7,211,612 shares of common stock, which amount is subject to adjustment in the event of certain corporate events such as stock splits or issuances of securities at a price below the conversion price of the Series B Preferred or exercise price of the warrants, as the case may be. On September 13, 2007, the Company paid \$807,913 to the Series B Preferred stockholders for the semiannual dividend.

On March 19, 2007, the Company issued 20,000 stock options to members of the Scientific Advisory Board of the Company under non-qualified stock option agreements. These options are immediately exercisable and allow for the purchase of 20,000 shares of common stock at a price of \$8.82. These options expire on March 18, 2017.

On April 6, 2007, the Company issued 152,500 stock options to officers and consultants under non-qualified stock option agreements. These options are immediately exercisable and allow for the purchase of 152,500 shares of common stock at a price of \$8.36. These options expire on April 5, 2017. The Company also issued 115,000 shares of common stock to consultants under the Plan.

On June 12, 2007, 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 are immediately exercisable and allow for the purchase of 140,000 shares of common stock at a price of \$9.40. These options expire on June 11, 2017.

On June 15, 2007, the Company issued 110,000 stock options to various key employees and consultants under non-qualified stock option agreements. These options have various vesting schedules including immediate vesting, up to three year vesting, and vesting upon the company stock price obtaining certain levels. These options allow for the purchase of 110,000 shares of common stock at a price ranging from \$9.93 to \$17.00. These options expire on June 14, 2017. The Company also issued 30,000 shares of common stock to the same consultants under the Plan.

On June 21, 2007, the Company issued 3,000 stock options to a consultant under a non-qualified stock option agreement. These options vest over a six month period and allow for the purchase of 3,000 shares of common stock at a price of \$10.84. These options expire on June 20, 2017.

On June 27, 2007, the Company issued 30,000 shares of common stock to various outside consultants under the Plan.

On July 18, 2007, the Company issued 15,000 shares of common stock to an outside consultant under the Plan. On that date, the Company also issued 18,000 stock options to another consultant under a non-qualified stock option agreement. These options are immediately exercisable and allow for the purchase of 18,000 shares of common stock at a price of \$10.61. These options expire on December 31, 2012.

On December 4, 2007, the Company issued 117,000 stock options to various key employees and consultants under non-qualified stock option agreements. These options have up to three year vesting. These options allow for the purchase of 117,000 shares of common stock at an exercise price of \$10.00 per share. These options expire on or before December 3, 2017.

On December 11, 2007, the SEC declared effective a registration statement of the Company registering up to 5,514,999 shares of common stock for resale from time to time by the selling stockholders named in the prospectus contained in the registration statement. This number represents 5,514,999 shares of common stock issuable upon the conversion or exercise of the securities issued the Company's March 2007 private placement at the current conversion and exercise prices. Of these 5,514,999 shares of common stock, 3,717,515 shares are issuable upon conversion of Series B Preferred and 1,797,484 shares are issuable upon exercise of the Series B Warrants. The Company will not receive any proceeds from the sale of the underlying shares of common stock, although to the extent the selling stockholders exercise warrants for the underlying shares of common stock, the Company will receive the exercise price of those warrants. The registration statement was filed to satisfy registration rights that the Company had

previously granted. Subsequent to the effectiveness of the registration statement, 708,743 Series B Preferred were converted and \$61,418 in dividends earned were paid as of December 31, 2007. At December 31, 2007, \$396,469 in dividends were accrued on the outstanding Series B Preferred.

On January 1, 2008, the Company issued 100,000 options to a recently-hired employee and 60,000 options to a key consultant of the Company under the Plan. 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. 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 Plan. 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. These options 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 unrestricted shares of common stock to a key consultant under the Plan.

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 \$5.88 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. 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. 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 15, 2018.

On September 22 2008, the Company issued 15,000 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 15,000 shares of common stock at an exercise price of \$4.51 per share. These options expire on September 22, 2018.



For the nine months ending September 30, 2008, Series B Preferred Shares were converted into 568,894 shares of common stock. At September 30, 2008, there were 3,301,373 outstanding Series B Preferred for which \$44,320 in dividends had been accrued.

**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, similar submissions to foreign regulatory authorities 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.

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, 2008, \$350,000 in milestone payments have been made under one of these agreements.

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

The Company currently has operating lease commitments in place for facilities in Buffalo, New York and Chicago, Illinois as well as office equipment. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. The operating lease expenses recognized were \$83,213 and \$79,054 for the quarters ended September 30, 2008 and 2007, respectively and the operating lease expense recognized were \$249,267 and \$166,986 for the nine months ended September 30, 2008 and 2007, respectively.

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

	Operating Leases
2008 Remaining Quarter	\$ 83,317
2009	349,782
2010	343,657
2011	311,803
2012	144,375
	\$ 1,232,934

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, subject to the terms applicable in the agreement.

The following tables summarize the stock option activity for the nine months ended September 30, 2008 and 2007:

	Shares	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	0	n/a
Outstanding, September 30, 2008	1,927,586	\$ 6.23

	Shares	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2006	483,490	\$ 2.17
Granted	543,000	\$ 9.82
Exercised	124,000	\$ 1.35
Forfeited, Canceled	0	n/a
Outstanding, September 30, 2007	902,490	\$ 6.89

The Company has entered into warrant agreements with strategic partners, consultants and investors with 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 six 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, 2007	3,453,268	\$ 8.86
Granted	0	n/a
Exercised	0	n/a
Forfeited, Canceled	0	n/a
Outstanding, September 30, 2008	3,453,268	\$ 8.86

	Warrants	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2006	814,424	\$ 3.36
Granted	2,687,602	\$ 10.40
Exercised	48,758	\$ 2.00
Forfeited, Canceled	-	n/a
Outstanding, September 30, 2007	3,543,268	\$ 8.86

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, 2008.

## 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. 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, 2007.*

### 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. Our common stock is currently listed on the NASDAQ Global Market under the symbol "CBLI."

### Technology

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

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

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

On the other hand, if the need is to destroy cancerous cells, we focus our research efforts on restoring apoptotic mechanisms that are suppressed in tumors, so that those cancerous cells will once again become vulnerable to

apoptotic death. In this regard, we believe that our drug candidates could have significant potential for improving, and becoming vital to, the treatment of cancer patients.

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

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- 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, or 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 21 to 33 months. Another drug candidate, Curaxin CBLC102, entered Phase IIa clinical trials earlier last year. The results of this trial are anticipated to be available in the fourth quarter of 2008. From our inception to September 30, 2008, we spent \$39,815,429 on research and development.

## **RESEARCH AND DEVELOPMENT**

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

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

- the number and outcome of clinical studies we are planning to conduct; for example, our research and development expenses may increase based on the number of late-stage clinical studies that we may be required to conduct;
- the performance of our research and development 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 research and development and implement technological improvements would be diminished, which would negatively impact our ability to fund research and development 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 research and development that we may record as research and development expense; or

· future levels of revenue; research and development 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 research and development 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 research and development, that will be required for the next several years. We expect to spend substantial additional sums on the continued research and development 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 (or 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.

There are significant risks and uncertainties inherent in the preclinical and clinical studies associated with our research and development 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.

## **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 anticipate having a developed drug submitted for FDA approval for these non-medical applications within 15-27 months.

- *Leveraging our relationship with leading research and clinical development institutions.* The Cleveland Clinic Foundation, or CCF, 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 clinical trials are performed on our drug candidates. In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute, or 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 and help fund our programs.* 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, as well as an additional resource for funding. 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 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.

## **PRODUCTS IN DEVELOPMENT**

### **Protectans**

We are exploring a new natural source of factors that 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 20<sup>th</sup> century. We have established a technological process for screening of such factors, named protectans, and their rapid preclinical evaluation. These inhibitors can 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).

Ten sets of patent applications have been filed over the past five years around various aspects and qualities of the protectan family of compounds. The first of these patents was recently granted by the nine members of the Eurasian Patent Organization and two additional countries totaling eleven overall. The issued patent covers the method of protecting a mammal from radiation using flagellin or its derivatives, including Protectan CBLB502.

We spent \$11,828,423 and \$4,185,678 on research and development for Protectans overall in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007 we spent \$2,295,574 and \$2,734,261, respectively. For the nine months ended September 30, 2008 and September 30, 2007 we spent \$6,064,505 and \$7,987,478, respectively. From our inception to September 30, 2008, we spent \$23,256,915 on research and development 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 significant survival benefits at a single dose. 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.

We spent \$10,701,175 and \$3,718,962 on research and development for Protectan CBLB502 in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007 we spent \$2,007,124 and \$2,576,698 respectively on research and development for Protectan CBLB502. For the nine months ended September 30, 2008 and September 30, 2007, we spent \$5,189,400 and \$7,337,462 respectively on R&D for Protectan CBLB502. From our inception to September 30, 2008, we spent \$20,546,485 on research and development for the biodefense applications of Protectan CBLB502.

We intend to enter into contracts to purchase Protectan CBLB502 with various U.S. and international 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.

#### *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, or GI, tract, which are 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 relatively inexpensive, due to its high yield bacterial producing strain and simple purification process.

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

- Performing a Phase I dose-escalation human study on a small number of volunteers. We expect to complete this study in March 2009 at an approximate cost of \$1,500,000.
- Conducting pivotal animal efficacy studies with the GMP manufactured drug candidate. We expect to complete these studies in mid 2010. At the present time, the costs of these studies cannot be approximated with any level of certainty.
- Performing a 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.

·Filing a Biologic License Application, or 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.

We have successfully established cGMP quality manufacturing for Protectan CBLB502 and it 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. Phase I is the only stage of human testing required for approval in this indication.

The FDA gave us permission to start safety testing on humans on August 7, 2008. The first healthy volunteer in the dose escalation safety study was dosed on October 14, 2008. The initial safety study will involve single injections of Protectan CBLB502 in ascending dose groups of six healthy volunteers each. Participants in the study will be assessed for adverse side effects over a two-week time period and blood samples will be obtained to assess the effects of Protectan CBLB502 on various biomarkers. The study is currently projected to take approximately six months to complete. The second safety study in a larger number of healthy volunteers is planned to start in mid-2009.

We are working towards filing a Biologic License Application for FDA approval of Protectan CBLB502 for non-medical applications in 15-27 months.

In March 2008, the U.S. Department of Defense, or DoD, awarded us a contract valued at up to \$8.9 million through the Chemical Biological Medical Systems Joint Project Management Office Broad Agency Announcement, or 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.

On September 12, 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. The grant program, Medical Countermeasures to Enhance Platelet Regeneration and Increase Survival Following Radiation Exposure, is funded through the Project BioShield Act of 2004 and administered by the Department of Health and Human Services.

On September 16, 2008, the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services (DHHS) awarded us a contract under the Broad Agency Announcement 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 is \$13.3 million over a three-year period, with the first year's award of \$3.4 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.

Protectan CBLB502's unprecedented efficacy, unique ability to address both hematopoietic and gastrointestinal damage, broad time window of use, and mitigation effects that do not require additional supportive care and set it apart from any other existing or potential therapies.

We spent \$9,885,776 and \$3,574,593 on research and development for the biodefense applications of Protectan CBLB502 in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007 we spent \$1,846,094 and \$2,423,658 respectively on research and development for biodefense applications of Protectan CBLB502. For the nine months ended September 30, 2008 and September 30, 2007, we spent \$4,638,905 and \$6,927,442 respectively on research and development for biodefense applications of Protectan CBLB502, respectively. From our inception to September 30, 2008, we spent \$18,975,288 on research and development for the biodefense applications of Protectan CBLB502.



Protectan CBLB502 is a candidate for procurement by the DoD, HHS/BARDA and 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 recent contract award from the DoD and the solicitation from 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 will be well positioned to fulfill both of these needs, with its demonstrated unprecedented efficacy and survival benefits, unique ability to address both hematopoietic and gastrointestinal damage, broad window of efficacy relative to radiation exposure, and suitability for both military and civilian delivery scenarios. We believe that Protectan CBLB502 is the only radiation countermeasure with these capabilities in advanced development that can be self or buddy-administered, without the need of additional supportive care in a battlefield or civilian community setting.

We intend to enter into contracts to sell Protectan CBLB502 to various U.S. government agencies 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*

In addition to its military or other non-medical applications, we have found that Protectan CBLB502 has been observed to dramatically increase the efficacy of radiotherapy on 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 2009. The 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, recent studies funded by a grant from the Department of Defense 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 toxicities of radiation treatment and anticancer drugs will be subject to the full FDA approval process.

In order for us to receive final FDA approval 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 cannot estimate with any certainty when the FDA may allow the application. We expect to make this submission in early 2009 at an approximate cost of \$100,000.
- Performing a Phase I/II human efficacy study on a small number of cancer patients. We expect to complete this study in the third quarter of 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.

We spent \$815,399 and \$144,369 on research and development for the medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007, we spent \$161,030 and \$153,040 respectively on R&D for the medical applications of Protectan CBLB502. For the nine months ended September 30, 2008 and September 30, 2007, we spent \$550,495 and \$410,020 respectively on research and development for the medical applications of Protectan CBLB502. From our inception to September 30, 2008, we spent \$1,571,197 on research and development for the medical applications of Protectan CBLB502.

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to the medical applications of Protectan CBLB502, estimating the completion dates or cost to complete our research and development is highly speculative and subjective and so the estimates above are subject to change.

Nor can we be certain when any net cash flow from products validated under our research and development, if any, will commence. Even if we successfully develop and market the medical applications of Protectan CBLB502, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

### ***Protectan CBLB612***

Protectan CBLB612 is a proprietary synthetic analogue of mycoplasma lipopeptides that acts as a powerful stimulator and mobilizer of hematopoietic (bone marrow/blood production) stem cells, or 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 HSC into peripheral blood in primate model (Rhesus macaques). A single injection of 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 G-CSF (Neupogen®, Amgen, Inc., Thousand Oaks, California), the market leading drug used for stimulation of blood regeneration, demonstrated that Protectan CBLB612 showed a stronger efficacy as a propagator and mobilizer of HSC in peripheral blood. In mice experimental models, a single injection of Protectan CBLB612 gave several times higher yields of HSC in peripheral blood than the standard course of G-CSF treatment.

Protectan CBLB612 also has been shown to provide protection in a mouse model from lethal hematopoietic-induced ARS when administered between 48 hours prior and 24 hours after radiation exposure. Protectan CBLB612 does not display any significant toxicity at its therapeutic doses in rodents and non-human primates.

More recent studies demonstrated Protectan CBLB612's ability to substantially reduce myelosuppression (the most common rate limiting adverse effect of chemotherapy) caused by a widely used chemotherapeutic drug, cyclophosphamide (Cytosan, Neosar, CTX).

In these experiments, mice bearing syngeneic melanomas were treated once a week for two weeks with a 500 mg/kg, or near maximum tolerable dose, of cyclophosphamide, alone or in combination with Protectan CBLB612. Protectan CBLB612 was administered 24 hours after each cyclophosphamide administration. Complete blood counts and tumor growth were evaluated over a three-week period.

Peripheral white blood cell counts were in the range of normal in Protectan CBLB612 treated animals following two independent cyclophosphamide injections, while untreated animals suffered severe leukopenia. The deepest drop of white blood cells in the Protectan CBLB612 treated group on average was to  $2.66 \times 10^3/\mu\text{L}$  compared to  $-0.432.66 \times 10^3/\mu\text{L}$  in the control group ( $p < 0.05$ ).

Moreover, treatment with Protectan CBLB612 did not interfere with the anti-cancer efficacy of cyclophosphamide and tumor growth was equally reduced in the chemotherapy-treated groups regardless of co-administration with Protectan CBLB612.

Tumor growth was partially diminished in mice that received Protectan CBLB612 alone, compared to animals that were injected only with the vehicle control. This intrinsic anti-tumor effect of Protectan CBLB612 may be related to its immune stimulation properties.

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. We expect to file an IND application with the FDA in the second half of 2009 to begin human studies. The development of our Protectan CBLB612 has been supported by a grant from the Defense Advanced Research Projects Agency of the Department of Defense.

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

- Conducting pivotal animal safety studies with 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; and

Filing a New Drug Application.

We spent \$1,127,248 and \$466,715 on research and development for Protectan CBLB612 in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007, we spent \$288,450 and \$157,563 respectively on R&D for Protectan CBLB612. For the nine months ended September 30, 2008 and September 30, 2007, we spent \$875,105 and \$650,016 respectively on the research and development for CBLB612, respectively. From our inception to September 30, 2008, we spent \$3,031,020 on research and development for Protectan CBLB612. Further development and extensive testing will be required to determine its technical feasibility and commercial viability.

Because of the uncertainties at this early stage of development of Protectan CBLB612, estimating the completion dates or cost to complete our research and development would be highly speculative and subjective. The risks and uncertainties associated with developing our products, including significant and changing governmental regulation and the uncertainty of future clinical study results increase the difficulty associated with supplying timing and cost estimates.

Nor can we be certain when any net cash flow from products validated under our research and development, if any, will commence. Even if we successfully develop and market Protectan CBLB612, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

## **Curaxins**

Curaxins are small molecules that destroy tumor cells by simultaneously targeting multiple regulators of apoptosis. Our initial test results indicate that curaxins can be effective against a number of malignancies, including hormone-refractory prostate cancer, multiple myeloma, renal cell carcinoma, or RCC and soft-tissue sarcoma.

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 research and development efforts and improving the probability of success.

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

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

We spent \$4,708,773 and \$2,426,014 on research and development for Curaxins overall in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007, we spent \$886,852 and \$1,087,215 respectively on R&D for Curaxins. For the nine months ended September 30, 2008 and September 30, 2007, we spent \$2,726,527 and \$2,918,940 respectively on research and development for Curaxins. From our inception to September 30, 2008, we spent \$11,134,247 on research and development 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- $\kappa$ B suppressor and activator of p53 in these types of cancer cells. It has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates. These features make Curaxin CBLC102 our prime IND drug candidate among other curaxins.

We have applied for a patent covering the use of Curaxin CBLC102 as an anticancer agent based on a newly-discovered mechanism of action. 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.

A Phase II efficacy clinical trial using Curaxin CBLC102 in patients with advanced hormone-refractory (androgen-independent) prostate cancer started in January 2007 at the University of Chicago, Cleveland Clinic, University of Pittsburgh and Case Western Reserve University Hospitals. We are applying CBLC102 as the monotherapy to patients who have failed to respond satisfactorily after undergoing established cancer treatments and will use the suppression of tumor growth and prolonged patient survival as major endpoints. Reducing the prostate-specific antigen, or PSA, level is an additional endpoint (elevated PSA levels are indicative of the progression of prostate cancer).

The planned enrollment of 32 patients was completed on April 29, 2008. The results of this trial are anticipated to be available in the fourth quarter of 2008.

We intend to decide on the scope of future development efforts for CBLC102 once the results from this trial are analyzed. 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.

We spent \$2,712,521 and \$1,372,998 on research and development for Curaxin CBLC102 in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007, we spent \$466,088 and \$626,806 respectively on research and development for Curaxin CBLC102. For the nine months ended September 30, 2008 and September 30, 2007, we spent \$1,431,077 and \$1,714,109 respectively on research and development for Curaxin CBLC102. From our inception to September 30, 2008, we spent \$6,156,366 on research and development 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. In

February 2008, three lead candidates were chosen for preclinical development based on their efficacy, low toxicity profiles, high stability and suitability for human administration. We expect to file an IND application with the FDA in 2009 for one of these three lead candidates.



We spent \$1,996,252 and \$1,053,016 on research and development for other Curaxins in the fiscal years ended December 31, 2007 and December 31, 2006, respectively. For the quarters ended September 30, 2008 and 2007, we spent \$420,764 and \$460,409 respectively on R&D for other Curaxins. For the nine months ended September 30, 2008 and September 30, 2007, we spent \$1,295,449 and \$1,204,831 respectively on research and development for other Curaxins. From our inception to September 30, 2008, we spent \$4,977,881 on research and development for other Curaxins.

These other Curaxin candidates are at a very early stage of their development and, as a result, it is premature to estimate when any development of any of them may be completed, the cost of development or when any cash flow could be realized from development.

## **FINANCIAL OVERVIEW**

We were incorporated in Delaware and commenced business operations in June 2003. Beginning July 21, 2006, our common stock was listed on the NASDAQ Capital Market and on the Boston Stock Exchange under the symbols "CBLI" and "CFB" respectively. On August 28, 2007, trading of our stock moved from the NASDAQ Capital Market to the NASDAQ Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange.

On March 16, 2007, we consummated a transaction with various accredited investors pursuant to which we agreed to sell to the investors, in a private placement, an aggregate of approximately 4,288,712 shares of Series B Convertible Preferred Stock, par value \$0.005 per share, and Series B Warrants to purchase approximately 2,144,356 shares of our common stock pursuant to a Securities Purchase Agreement of the same date. The aggregate purchase price paid by the investors for the Series B Preferred and Series B Warrants was approximately \$30,000,000. After related fees and expenses, we received net proceeds of approximately \$29,000,000. We intend to use the proceeds for general corporate and working capital purposes.

The Series B Preferred have an initial conversion price of \$7.00 per share, and in the event of a conversion at such conversion price, one share of Series B Preferred would convert into one share of common stock. Based on the closing price of our common stock on March 16, 2007 of \$10.19, the Series B Preferred sold to investors and issued to certain of the Agents had a market value of \$46,660,112. The Series B Warrants have an exercise price of \$10.36 per share, the closing bid price on the day prior to the private placement. To the extent, however, that the conversion price of the Series B Preferred or the exercise price of the Series B Warrants is reduced as a result of certain anti-dilution protections, the number of shares of common stock into which the Series B Preferred are convertible and for which the Series B Warrants are exercisable may increase.

We also issued to the placement agents in the private placement, as compensation for their services, Series B Preferred, Series B Warrants, and Series C Warrants. The agents collectively received Series B Preferred that are convertible into an aggregate of 290,298 shares of common stock, Series B Warrants that are exercisable for an aggregate of 221,172 shares of our common stock, and Series C Warrants that are exercisable for 267,074 shares of our common stock. The Series C Warrants have an exercise price of \$11.00 per share, and are also subject to antidilution protections that could increase the number of shares of common stock for which they are exercisable.

In total, the securities issued in the private placement were convertible into, or exercisable for, up to approximately 7,211,612 shares of common stock (subject to adjustments for stock splits, anti-dilution, etc.). As of September 30, 2008 the securities issued in the transaction, in the aggregate, were convertible into or exercisable for approximately 5,933,975 shares of common stock (subject to adjustments for stock splits, anti-dilution, etc.).

Proceeds from these transactions, together with grants we have received, have supported our research and development activities to date. We are actively seeking new grants and co-development contacts with premier pharmaceutical partners to support further development of other promising leads resulting from our research and

development program.

On December 11, 2007, the SEC declared effective a registration statement of the Company registering up to 5,514,999 shares of common stock for resale from time to time by the selling stockholders named in the prospectus contained in the registration statement. This number represents 5,514,999 shares of common stock issuable upon the conversion or exercise of the securities issued the Company's March 2007 private placement at the current conversion and exercise prices. Of these 5,514,999 shares of common stock, 3,717,515 shares are issuable upon conversion of Series B Preferred and 1,797,484 shares are issuable upon exercise of the Series B Warrants. We will not receive any proceeds from the sale of the underlying shares of common stock, although to the extent the selling stockholders exercise warrants for the underlying shares of common stock, we will receive the exercise price of those warrants. Subsequent to the effectiveness of the registration statement, 1,277,637 shares of Series B Preferred were converted and \$2,119,741 in dividends earned were paid as of September 30, 2008. At September 30, 2008 there were 3,301,373 remaining outstanding Series B Preferred shares for which \$44,320 in dividends had been accrued.

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## **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 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. While all decisions regarding accounting policies are important, we believe that our policies regarding revenue recognition, research and development expenses, intellectual property related costs and stock-based compensation expense could be considered critical.

### ***Revenue Recognition***

We recognize revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition", and Statement of Financial Accounting Standards No. 116, or SFAS 116. 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 the Roswell Park Cancer Institute in accordance with SFAS 116. The principles of SFAS 116 result 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 research and development expenses are incurred during the period and according to the terms of the contract. Commercial development revenues are recognized when the service or development is delivered.

### ***Research and Development Expenses***

Research and development costs are expensed as incurred. These expenses consist primarily of our proprietary research and development efforts, including salaries and related expenses for personnel, costs of materials used in our research and development 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 research and development arrangements are expensed when the specific milestone has been achieved. As of September 30, 2008, \$50,000 has

been paid to the CCF for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102, \$250,000 has been paid to the CCF as a result of commencing Phase II clinical trials for Curaxin CBLC102 and \$50,000 has been paid to the 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 research and development 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, 2007, we have capitalized \$459,102 in expenditures associated with the preparation, filing and maintenance of certain of our patents, which were incurred through the year ended December 31, 2007. We capitalized an additional \$263,284 relating to these costs incurred for the nine months ended September 30, 2008, totaling \$722,386.

### ***Stock-based Compensation***

We value stock-based compensation pursuant to the provisions of SFAS 123(R). Accordingly, effective January 1, 2005, all stock-based compensation, including grants of employee stock options, are recognized in the statement of operations based on their fair values.

The Financial Accounting Standards Board (FASB) issued SFAS No. 123(R) requiring all share-based payments to employees, including grants of employee stock options, be recognized in the statement of operations based at their fair values. The Company values employee stock-based compensation under the provisions of SFAS 123(R) and related interpretations.

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, 2008, the Company granted 958,380 additional stock options pursuant to stock award agreements. The Company recognized a total of \$1,929,433 in expense related to options for the nine months ended September 30, 2008. The Company also recaptured \$1,459,425 of previously recognized expense due to the stock options awarded under the 2007 executive compensation program. These options were originally expensed based on the December 31, 2007 variables, but were not issued until February 4, 2008. The change in dates resulted in a difference in valuation assumptions used in the Black-Scholes model causing a reduction in the grant date fair value. This reduction in the grant date fair value from \$5.34 to \$2.44 per share resulted in the recapture of \$1,459,425 in expense and a net expense for options for the nine-months ended September 30, 2008 of \$470,008.

During the nine months ended September 30, 2007, the Company granted 543,000 stock options pursuant to stock award agreements and expensed \$2,745,287 related to stock options.

For the nine months ended September 30, 2008 the Company also recognized a total of \$626,500 expense for shares issued under the Plan and a total of \$54,185 in expense related to the amortization of restricted shares. For the nine

months ended September 30, 2007, the Company recognized a total of \$1,700,450 in expense for shares issued under the Plan to various consultants.

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During the quarters ended September 30, 2008 and September 30, 2007, the Company granted 43,456 and 18,000 additional stock options pursuant to stock award agreements, respectively. We recognized a total of \$355,800 and \$395,129 in expense related to options for the quarters ended September 30, 2008 and September 30, 2007, respectively. The weighted average, estimated grant date fair values of stock options granted during the quarters ended September 30, 2008 and 2007 was \$2.76 and 4.95, respectively.

### **Impact of Recently Issued Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standard (“SFAS”) No. 157, “Fair Value Measurements.” SFAS No. 157 provides enhanced guidance for using fair value to measure assets and liabilities and expands disclosure with respect to fair value measurement. This statement was originally effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued Staff Position FSP 157-2 which allows companies to elect a one year deferral of adoption of SFAS No. 157 for non-financial assets and non-financial liabilities that are recognized or disclosed at fair values in the financial statements on a non-recurring basis. The Company has adopted SFAS No. 157 as of January 1, 2008. There has been no material impact to our financial statements due to the adoptions of SFAS No. 157.

In March 2008, the FASB issued SFAS No. 161. “Disclosures about Derivative Instruments and Hedging Activities,” (SFAS No. 161). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities.” SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit-risk-related contingent features in derivative agreements. SFAS No. 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008. The adoption of SFAS No.161 will not affect our consolidated financial condition and results of operations, but may require additional disclosures if we enter into derivative and hedging activities.

In April 2008, the FASB issued FASB Staff Position No. FAS 142-3, “Determination of the Useful Life of Intangible Assets” (“FSP FAS 142-3”). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “Goodwill and Other Intangible Assets”. The FSP is intended to improve the consistency between the useful life of a recognized intangible asset under Statement 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(R) and other U.S. generally accepted accounting principles. The new standard is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. We are currently evaluating the impact, if any of FSP FAS 142-3 upon adoption on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *Hierarchy of Generally Accepted Accounting Principles* (“SFAS No. 162”). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements. SFAS No. 162 is effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles. The implementation of this standard is not expected to have a material impact on our financial position and results of operations.

### **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 quarter and nine months ended September 30, 2008 and September 30, 2007, and the years ended December 31, 2007 and December 31, 2006, 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, 2007.

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	<b>Quarter Ended 30-Sep-08 (unaudited)</b>	<b>Quarter Ended 30-Sep-07 (unaudited)</b>	<b>Nine Months Ended 30-Sep-08 (unaudited)</b>	<b>Nine Months Ended 30-Sep-07 (unaudited)</b>	<b>Year Ended December 31, 2007</b>	<b>Year Ended December 31, 2006</b>
Revenues	\$ 1,851,419	\$ 660,544	\$ 3,202,119	\$ 1,617,996	\$ 2,018,558	\$ 1,708,214
Operating expenses	4,725,572	5,548,149	14,145,311	18,631,619	27,960,590	9,126,315
Other expense (income)	6,277	1,206,672	(90,018)	1,456,351	2,058,236	-
Net interest expense (income)	(49,450)	(305,568)	(244,593)	(760,561)	(1,003,766)	(195,457)
Net income (loss)	\$ (2,830,980)	\$ (5,787,709)	\$ (10,608,581)	\$ (17,709,413)	\$ (26,996,502)	\$ (7,222,644)

The following table summarizes research and development expenses for the quarter and nine months ended September 30, 2008 and September 30, 2007 and the years ended December 31, 2007 and 2006 and since inception:

	<b>Quarter Ended 30-Sep-08 (unaudited)</b>	<b>Quarter Ended 30-Sep-07 (unaudited)</b>	<b>Nine Months Ended 30-Sep-08 (unaudited)</b>	<b>Nine Months Ended 30-Sep-07 (unaudited)</b>	<b>Year Ended December 31, 2007</b>	<b>Year Ended December 31, 2006</b>	<b>Total Since Inception</b>
Research and development	\$ 3,485,430	\$ 4,105,480	\$ 9,719,519	\$ 11,663,054	\$ 17,429,652	\$ 6,989,804	\$ 39,815,429
General	\$ 303,004	\$ 284,004	\$ 928,488	\$ 756,636	\$ 892,456	\$ 378,113	\$ 5,103,677
Protectan CBLB502 - medical applications	\$ 1,846,094	\$ 2,423,658	\$ 4,638,905	\$ 6,927,442	\$ 9,885,776	\$ 3,574,593	\$ 18,975,287
Protectan CBLB502 - non-medical applications	\$ 161,030	\$ 153,040	\$ 550,495	\$ 410,020	\$ 815,399	\$ 144,369	\$ 1,571,197
Protectan CBLB612	\$ 288,450	\$ 157,563	\$ 875,105	\$ 650,016	\$ 1,127,248	\$ 466,715	\$ 3,031,020
Curaxin CBLC102	\$ 466,088	\$ 626,806	\$ 1,431,077	\$ 1,714,109	\$ 2,712,521	\$ 1,372,998	\$ 6,156,366
Other Curaxins	\$ 420,764	\$ 460,409	\$ 1,295,449	\$ 1,204,831	\$ 1,996,252	\$ 1,053,016	\$ 4,977,882

### Three Months Ended September 30, 2008 Compared to Three Months Ended September 30, 2007

#### Revenue

Revenue increased from \$660,544 for the three months ended September 30, 2007 to \$1,851,419 for the three months ended September 30, 2008 representing an increase of \$1,190,875 or 180.3% resulting primarily from an increase in revenue from various federal grants and contracts including the Department of Defense contract and the Collaborative Research Agreement with the Roswell Park Cancer Institute.

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

<b>Agency</b>	<b>Program</b>	<b>Amount</b>	<b>Period of Performance</b>	<b>Revenue 2008 (July 1 thru Sept. 30)</b>	<b>Revenue 2007 (July 1 thru Sept. 30)</b>	<b>Revenue 2007</b>
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				(unaudited)		(unaudited)	
<b>DoD</b>	DTRA Contract	\$ 1,263,836	03/2007-02/2009	\$ -	\$ 114,952	\$ 466,322	
	Phase II NIH SBIR						
<b>NIH</b>	program	\$ 750,000	07/2006-06/2008	\$ -	\$ 139,867	\$ 459,621	
	Phase I NASA						
<b>NASA</b>	STTR program	\$ 100,000	01/2006-01/2007	\$ -	\$ -	\$ 33,197	
<b>NY</b>	Sponsored Research						
<b>State/RPCI</b>	Agreement	\$ 3,000,000	03/2007-02/2012	\$ 84,792	\$ 153,238	\$ 329,390	
<b>NIH</b>	NCI Contract	\$ 750,000	09/2006-08/2008	\$ 71,363	\$ 132,487	\$ 440,028	
			05/2008 -				
<b>DoD</b>	DOD Contract	\$ 8,900,000	09/2009	\$ 1,635,868	\$ -	\$ -	
<b>HHS</b>	BARDA Contract	\$ 13,300,000	09/2008-09/2011	\$ 2,115	\$ -	\$ -	
<b>NIH</b>	NIAID Grant	\$ 774,183	09/2008-02/2010	\$ 57,281	\$ -	\$ -	
<b>Totals</b>				\$ 1,851,419	\$ 540,544	\$ 1,728,558	

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

### ***Operating Expenses***

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

Operating expenses decreased from \$5,548,149 for the three months ended September 30, 2007 to \$4,725,572 for the three months ended September 30, 2008, a decrease of \$822,577 or 14.8%. We recognized a total of \$379,760 of non-cash, stock-based compensation for the three months ended September 30, 2008 compared to \$554,279 for the three months ended September 30, 2007. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have decreased from \$4,993,870 for the three months ended September 30, 2007 to \$4,345,812 for the three months ended September 30, 2008. This represents a decrease in operating expenses of \$648,058 or 13.0%.

Research and development costs decreased from \$4,105,480 for the three months ended September 30, 2007 to \$3,485,430 for the three months ended September 30, 2008. This represents a decrease of \$620,050 or 15.1%. We recognized a total of \$201,848 of non-cash, stock based compensation under research and development costs for the three months ended September 30, 2008 compared to \$96,554 for the three months ended September 30, 2007. Without the non-cash, stock-based compensation, the research and development expenses decreased from \$4,008,926 for the three months ended September 30, 2007 to \$3,283,582 for the three months ended September 30, 2008; a decrease of \$725,344 or 18.1%.

Selling, general and administrative costs decreased from \$1,442,669 for the three months ended September 30, 2007 to \$1,240,142 for the three months ended September 30, 2008. This represents a decrease of \$202,527 or 14.0%. We recognized a total of \$177,912 of non-cash, stock-based compensation under selling, general and administrative costs for the three months ended September 30, 2008 compared to \$477,557 for the three months ended September 30, 2007. Without the non-cash, stock-based compensation, the selling, general and administrative expenses increased from \$965,112 for the three months ended September 30, 2007 to \$1,062,230 for the three months ended September 30, 2008; an increase of \$97,118 or 10.1%.

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.

### **Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007**

#### ***Revenue***

Revenue increased from \$1,617,996 for the nine months ended September 30, 2007 to \$3,202,119 for the nine months ended September 30, 2008 representing an increase of \$1,584,122 or 97.9% resulting primarily from an increase in revenue from various federal grants and contracts including the Department of Defense contract and the Collaborative Research Agreement with the Roswell Park Cancer Institute.

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



Agency	Program	Amount	Period of Performance	Revenue 2008 (thru Sept. 30) (unaudited)	Revenue 2007 (thru Sept. 30) (unaudited)	Revenue 2007
<b>DoD</b>	DTRA Contract	\$ 1,263,836	03/2007-02/2009	\$ 323,826	\$ 466,322	\$ 466,322
<b>NY State/RPCI</b>	Sponsored Research Agreement	\$ 3,000,000	03/2007-02/2012	\$ 239,503	\$ 153,238	\$ 329,390
<b>NIH</b>	Phase II NIH SBIR program	\$ 750,000	07/2006-06/2008	\$ 77,971	\$ 280,461	\$ 459,621
<b>NIH</b>	NCI Contract	\$ 750,000	09/2006-08/2008	\$ 228,579	\$ 394,780	\$ 440,028
<b>NASA</b>	Phase I NASA STTR program	\$ 100,000	01/2006-01/2007	\$ 290,075	\$ 33,196	\$ 33,197
<b>DOD</b>	DOD Contract	\$ 8,900,000	05/2008 - 09/2009	\$ 1,862,769	\$ -	\$ 0
<b>HHS</b>	BARDA Contract	\$ 13,300,000	09/2008-09/2011	\$ 2,115	\$ -	\$ -
<b>NIH</b>	NIAID Grant	\$ 774,183	09/2008-02/2010	\$ 57,281	\$ -	\$ -
Totals				\$ 3,082,119	\$ 1,327,997	\$ 1,728,558

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

### *Operating Expenses*

Operating expenses decreased from \$18,631,619 for the nine months ended September 30, 2007 to \$14,145,311 for the nine months ended September 30, 2008, a decrease of \$4,486,308 or 24.1%. We recognized a total of \$1,150,692 of non-cash, stock-based compensation for the nine months ended September 30, 2008 compared to \$4,445,737 for the nine months ended September 30, 2007. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have decreased from \$14,185,882 for the nine months ended September 30, 2007 to \$12,994,619 for the nine months ended September 30, 2008. This represents a decrease in operating expenses of \$1,191,263 or 8.4%.

Research and development costs decreased from \$11,663,054 for the nine months ended September 30, 2007 to \$9,719,519 for the nine months ended September 30, 2008. This represents a decrease of \$1,943,535 or 16.7%. We recognized a total of \$416,750 of non-cash, stock based compensation under research and development costs for the nine months ended September 30, 2008 compared to \$711,296 for the nine months ended September 30, 2007. Without the non-cash, stock-based compensation, the research and development expenses decreased from \$10,951,758 for the nine months ended September 30, 2007 to \$9,302,769 for the nine months ended September 30, 2008; a decrease of \$1,648,989 or 15.1%.

Selling, general and administrative costs decreased from \$6,968,565 for the nine months ended September 30, 2007 to \$4,425,792 for the nine months ended September 30, 2008. This represents a decrease of \$2,542,773 or 36.5%. We recognized a total of \$733,942 of non-cash, stock-based compensation under selling, general and administrative costs for the nine months ended September 30, 2008 compared to \$3,754,273 for the nine months ended September 30, 2007. Without the non-cash, stock-based compensation, the selling, general and administrative expenses increased from \$3,214,292 for the nine-months ended September 30, 2007 to \$3,691,850 for the nine months ended September 30, 2008; an increase of \$477,558 or 14.9%. The higher general and administrative expenses were incurred as a result of increased investor relations activities and continuing to improve the infrastructure of the Company.

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.

**Year Ended December 31, 2007 Compared to Year Ended December 31, 2006**

***Revenue***

Revenue increased from \$1,708,214 for the year ended December 31, 2006 to \$2,018,558 for the year ended December 31, 2007, representing an increase of \$310,344 or 18.2%, resulting primarily from an increase in revenue from various grants including the sponsored research agreement with RPCI, the DTRA contract, and the NCI contract. As the term of the BioShield grant ended, the proceeds from the BioShield grant were \$0 for the year ended December 31, 2007 as compared to \$1,100,293 for the year ended December 31, 2006.

### ***Operating Expenses***

Operating expenses increased from \$9,126,315 for the year ended December 31, 2006 to \$27,960,590 for the year ended December 31, 2007. This represents an increase of \$18,834,275 or 206.4%. We recognized a total of \$7,789,305 of non-cash, stock based compensation for the year December 31, 2007 compared to \$506,078 for the year ended December 31, 2006. If these non-cash, stock based compensation expenses were excluded, operating expenses would have increased from \$8,620,237 for the year ended December 31, 2006 to \$20,171,285 for the year ended December 31, 2007. This represents an increase in operating expenses of \$11,551,048 or 134.0%.

This increase resulted primarily from an increase in research and development expenses from \$6,989,804 for the year ended December 31, 2006 to \$17,429,652 for the year ended December 31, 2007, an increase of \$10,439,848 or 149.4%. The higher research and development expenses were incurred as a result of increasing the number of research and development personnel, commencing clinical trials for CBLC102 and completing the cGMP manufacturing of CBLB502. We recognized a total of \$250,682 of non-cash, stock based compensation for research and development for the year ended December 31, 2006 compared to \$1,836,787 for the year ended December 31, 2007. Without the non-cash, stock based compensation, the research and development expenses increased from \$6,739,122 for the year ended December 31, 2006 to \$15,592,865 for the year ended December 31, 2007; an increase of \$8,853,743 or 131.4%.

In addition, general and administrative expenses increased from \$2,136,511 for the year ended December 31, 2006 to \$10,530,938, for the year ended December 31, 2007. This represents an increase of \$8,394,427 or 392.9%. These higher general and administrative expenses were incurred as a result of creating and improving the infrastructure of the company and the costs associated with being a publicly traded company. We recognized a total of \$255,396 of non-cash, stock-based compensation for general and administrative compensation for the year ended December 31, 2006 compared to \$5,952,517 for the year ended December 31, 2007. Without the non-cash, stock based compensation, the general and administrative expenses increased from \$1,881,115 for the year ended December 31, 2006 to \$4,578,421 for the year ended December 31, 2007; an increase of \$2,697,306 or 143.4%.

### **Liquidity and Capital Resources**

We have incurred annual operating losses since our inception, and, as of September 30, 2008, we had an accumulated deficit of \$52,545,054. 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 research and development 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 \$8,903,451 for the nine months ended September 30, 2008, compared to \$10,796,750 used in operating activities for the nine months ended September 30, 2007. Net cash used in operating activities totaled \$16,607,922 for the year ended December 31, 2007, compared to \$6,653,602 used in operating activities for the same period in 2006. For all periods, the increase in cash used was primarily attributable to increased research and development activities and maintaining and improving the infrastructure necessary to support these research and development activities.

Net cash used in investing activities was \$416,537 for the nine months ended September 30, 2008 and net cash used in investing activities was \$238,716 for the nine months ended September 30, 2007. Net cash used in investing activities was \$442,523 for the year ended December 31, 2007 and \$14,281 used for the same period in 2006. The increase in cash used for investing activities resulted primarily from purchasing capital assets and investing in intellectual property.





Net cash used in financing activities totaled \$1,226,032 for the nine months ended September 30, 2008, compared to net cash provided by financing activities of \$28,252,029 for the nine months ended September 30, 2007. The decrease in cash provided by financing activities was attributed to the payment of dividends in the first nine months of 2008 as compared to the proceeds from the issuance of preferred stock and warrants in the private placement offering which occurred during the first nine months of 2007. Net cash provided by financing activities totaled \$28,200,591 for the year ended December 31, 2007, compared to \$8,523,414 provided by financing activities for the year ended December 31, 2006. The increase in cash provided by financing activities was attributed to the proceeds from the issuance of Series B Preferred in connection with our private placement offering.

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, 2008, 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 research and development 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.

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.

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***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 and the Great British Pound or GBP. As of September 30, 2008, we are obligated to make payments under the agreement of 1,033,262 Euros and 281,548 GBP. We also expect to enter into additional agreements with foreign third parties, increasing the risk. As a result, our financial results could be affected by changes in foreign currency exchange rates. We have established means to purchase forward contracts to hedge against this risk. As of September 30, 2008, the Company has commitments for 100,000 Euros and 0 GBP

***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, 2008 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, 2008, 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, 2008 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, 2008, we were not a party to any litigation or other legal proceeding.

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

None.

### **Item 3. Defaults Upon Senior Securities**

None.

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

None.

### **Item 5. Other Information**

None.

### **Item 6. Exhibits**

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

<b>Exhibit Number</b>	<b>Description of Document</b>
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 14, 2008

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

Dated: November 14, 2008

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