

CLEVELAND BIOLABS INC  
Form 10-Q  
May 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 March 31, 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  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):

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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 May 14, 2008 there were 13,479,432 shares outstanding of registrant's common stock, par value \$0.005 per share.

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CLEVELAND BIOLABS INC  
10-Q  
5/14/2008

## TABLE OF CONTENTS

	PAGE
PART I - FINANCIAL INFORMATION	
ITEM 1: Financial Statements	
Balance Sheets as of March 31, 2008 and December 31, 2007	3-4
Statements of Operations For Three Months Ended March 31, 2008 and 2007	5
Statements of Cash Flows For Three Months Ended March 31, 2008 and 2007	6
Statement of Stockholders' Equity from January 1, 2007 to December 31, 2007 and to March 31, 2008	7
Notes to Financial Statements	10
ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations	21
ITEM 3: Quantitative and Qualitative Disclosures About Market Risk	35
ITEM 4: Controls and Procedures	35
PART II - OTHER INFORMATION	
ITEM 1: Legal Proceedings	36
ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds	36
ITEM 3: Defaults Upon Senior Securities	36
ITEM 4: Submission of Matters to a Vote of Securities Holders	36
ITEM 5: Other Information	36
ITEM 6: Exhibits	36
Signatures	37

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

March 31, 2008 (unaudited) and December 31, 2007

<u>ASSETS</u>	March 31 2008 (unaudited)	December 31 2007
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 9,102,383	\$ 14,212,189
Short-term investments	1,000,000	1,000,000
Accounts receivable:		
Trade	527,476	163,402
Interest	42,634	50,042
Other prepaid expenses	440,020	325,626
<b>Total current assets</b>	<b>11,112,513</b>	<b>15,751,259</b>
<b>EQUIPMENT</b>		
Computer equipment	263,344	258,089
Lab equipment	1,016,331	966,517
Furniture	274,904	274,903
	1,554,579	1,499,509
Less accumulated depreciation	390,298	313,489
	1,164,281	1,186,020
<b>OTHER ASSETS</b>		
Intellectual property	609,846	459,102
Deposits	26,327	25,445
	636,173	484,547
<b>TOTAL ASSETS</b>	<b>\$ 12,912,967</b>	<b>\$ 17,421,826</b>

## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

March 31, 2008 (unaudited) and December 31, 2007

	March 31 2008 (unaudited)	December 31 2007
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,266,391	\$ 710,729
Milestone payable	50,000	-
Deferred revenue	1,579,860	1,670,610
Dividends payable	51,462	396,469
Accrued expenses	249,236	449,774
Total current liabilities	3,196,949	3,227,582
<b>STOCKHOLDERS' EQUITY</b>		
Series B convertible preferred stock, \$.005 par value Authorized - 10,000,000 shares at March 31, 2008 and December 31, 2007		
Issued and outstanding 3,524,687 and 3,870,267 shares at March 31, 2008 and December 31, 2007, respectively	17,623	19,351
Additional paid-in capital	22,208,269	24,383,695
Common stock, \$.005 par value Authorized - 40,000,000 shares at March 31, 2008 and December 31, 2007		
Issued and outstanding 13,355,657 and 12,899,241 shares at March 31, 2008 and December 31, 2007, respectively	66,778	64,496
Additional paid-in capital	32,747,897	30,764,914
Accumulated other comprehensive income (loss)	-	-
Accumulated deficit	(45,324,549)	(41,038,212)
Total stockholders' equity	9,716,018	14,194,244
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 12,912,967</b>	<b>\$ 17,421,826</b>

## CLEVELAND BIOLABS, INC.

## STATEMENT OF OPERATIONS

Three Months Ending March 31, 2008 and 2007 (unaudited)

	Three Months Ended	
	March 31 2008 (unaudited)	March 31 2007 (unaudited)
<b>REVENUES</b>		
Grant and contract	\$ 556,324	\$ 271,445
Service	120,000	50,000
	676,324	321,445
<b>OPERATING EXPENSES</b>		
Research and development	3,551,386	3,528,600
Selling, general and administrative	1,193,114	994,319
Total operating expenses	4,744,500	4,522,919
<b>LOSS FROM OPERATIONS</b>	(4,068,176)	(4,201,474)
<b>OTHER INCOME</b>		
Interest income	145,127	96,429
Sublease revenue	2,656	-
Gain on disposal of fixed assets	1,394	-
Gain on investment	3,292	-
Total other income	152,469	96,429
<b>OTHER EXPENSE</b>		
Corporate relocation	54,344	-
Interest expense	-	1,088
Total other expense	54,344	1,088
<b>NET LOSS</b>	\$ (3,970,051)	\$ (4,106,133)
<b>DIVIDENDS ON CONVERTIBLE PREFERRED STOCK</b>	(316,286)	-
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>	\$ (4,286,337)	\$ (4,106,133)
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED</b>	\$ (0.33)	\$ (0.35)
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED</b>	13,143,686	11,854,027



## CLEVELAND BIOLABS, INC.

## STATEMENTS OF CASH FLOWS

For the Three Months Ended March 31, 2008 and 2007 (unaudited)

	March 31 2008 (unaudited)	March 31 2007 (unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (3,970,051)	\$ (4,106,133)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	76,809	27,666
Noncash salaries and consulting expense	(192,626)	375,301
Changes in operating assets and liabilities:		
Accounts receivable - trade	(364,074)	(54,298)
Accounts receivable - interest	7,407	(10,605)
Other prepaid expenses	(114,394)	(78,293)
Deposits	(881)	-
Accounts payable	555,663	467,030
Deferred revenue	(90,749)	-
Accrued expenses	(200,539)	98,866
Milestone payments	50,000	250,000
Total adjustments	(273,384)	1,075,667
Net cash (used in) provided by operating activities	(4,243,435)	(3,030,466)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Sale of short-term investments	-	1,300,000
Purchase of short-term investments	-	(17,999,965)
Issuance of notes receivable	-	(250,000)
Purchase of equipment	(55,070)	(11,640)
Costs of patents pending	(150,743)	(93,193)
Net cash (used in) provided by investing activities	(205,813)	(17,054,798)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Issuance of preferred stock	-	30,020,984
Financing costs	-	(1,148,106)
Dividends	(661,295)	-
Issuance of common stock	-	118,410
Exercise of stock options	737	-
Net cash (used in) provided by financing activities	(660,558)	28,991,288
<b>INCREASE (DECREASE) IN CASH AND EQUIVALENTS</b>	<b>(5,109,806)</b>	<b>8,906,024</b>
<b>CASH AND EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>14,212,189</b>	<b>3,061,993</b>
<b>CASH AND EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 9,102,383</b>	<b>\$ 11,968,017</b>



## Supplemental disclosures of cash flow information:

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

## Supplemental schedule of noncash financing activities:

Issuance of stock options to employees, consultants, and independent board members	\$	728,077	\$	375,301
Conversion of preferred stock to common stock	\$	2,177,154	\$	-
Expense recapture of expense for options expensed in 2007 but issued in 2008	\$	(1,459,425)	\$	-
Issuance of shares to consultants and employees	\$	521,000	\$	-
Accrual of preferred stock dividends	\$	316,287	\$	-
Amortization of restricted shares issued to employees	\$	17,722	\$	-

## CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

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

	Stockholders' Equity		Additional Paid-in Capital
	Shares	Common Stock Amount	
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	-	-	728,077
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-	(1,459,425)
Issuance of restricted shares	105,000	525	520,475

Amortization of restricted shares	-	-	17,722
Exercise of options	5,836	29	708
Conversion of Series B Preferred Shares to Common	345,580	1,728	2,175,426
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 March 31, 2008	13,355,657	\$ 66,778	\$ 32,747,897

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

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

	Stockholders' Equity		Preferred Stock	Additional Paid-in Capital
	Shares	Amount		
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	-	-	-	-

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Amortization of restricted shares	-	-	-
Exercise of options	-	-	-
Conversion of Series B Preferred Shares to Common	(345,580)	(1,728)	(2,175,426)
Dividends on Series B Preferred shares	-	-	-
Net Loss	-	-	-
<b>Other comprehensive income</b>			
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	-	-	-
<b>Comprehensive loss</b>			
Balance at March 31, 2008	3,524,687	\$ 17,623	\$ 22,208,269

8

CLEVELAND BIOLABS,  
INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND  
COMPREHENSIVE LOSS

Period From January 1, 2007 to  
December 31, 2007 and to  
March 31, 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	4,165	-	4,165	\$ 4,165
for (gains) losses				

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included in net loss				
Comprehensive loss				\$ (26,992,337)
Balance at December 31, 2007	\$	-	\$ (41,038,212)	\$ 14,194,244
Issuance of options		-	-	728,077
Partial recapture of expense for options expensed in 2007 but issued in 2008		-	-	(1,459,425)
Issuance of restricted shares		-	-	521,000
Amortization of restricted shares		-	-	17,722
Exercise of options		-	-	737
Conversion of Series B Preferred Shares to Common		-	-	-
Dividends on Series B Preferred shares		-	(316,286)	(316,286)
Net Loss		-	(3,970,051)	(3,970,051) (3,970,051)
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses) arising during person		-	-	- \$ -
Less reclassification adjustment for (gains) losses included in net loss		-	-	- \$ -
Comprehensive loss				\$ (3,970,051)
Balance at March 31, 2008	\$	-	\$ (45,324,549)	\$ 9,716,018

**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 toxicities, radiation and hypoxia. A recent discovery found that one of its 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 March 31, 2008 and March 31, 2007, and for the three-months ended March 31, 2008 and March 31, 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 March 31, 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 \$76,809, and \$27,666 for the three-months ended March 31, 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 17 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 \$546,931 and \$407,425 on behalf of CCF for 13 patent applications as of March 31, 2008 and December 31, 2007, respectively. All of the CCF patent applications are still pending approval.

The Company also has submitted three 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 17 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 \$62,915 and \$51,677 on behalf of the Company for three patent applications as of March 31, 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, 2008. At March 31, 2008 and December 31, 2007, 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. The carrying amounts of the convertible notes payable approximate their respective fair values as they bear terms that are comparable to those available under current market conditions.

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 March 31, 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 at the time of submitting the invoice to the government agency. 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 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 periodically upon delivery of an invoice for allowable R&D expenses according to the terms of the contract. The Company has recognized grant revenue from the following agencies: 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 in 2007 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 and 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 three-months ended March 31, 2008, the Company recognized \$90,749 as revenue resulting in a balance of deferred revenue of \$1,579,860 at March 31, 2008. At December 31, 2007, the balance in deferred revenue was \$1,670,610.

M. Research and Development - Research and development expenses consist primarily of costs associated with salaries and related expenses for personnel, costs of materials used in R&D, 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. For the three-months ended March 31, 2008, there were 719,948 options and 120,000 shares granted under the Plan, and as of March 31, 2008 there were 1,424,948 stock options and 310,000 shares granted under the Plan leaving 265,052 shares of stock to be awarded under the Plan. A proposed amendment and restatement of the Plan, which among other things, reserved an additional 2,000,000 shares, was submitted to the stockholders for approval at the 2008 Annual Meeting.

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

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	53.44-80.25%	71.86-76.29%

During the three-months ended March 31, 2008, the Company granted 719,948 additional stock options pursuant to stock award agreements. The Company recognized a total of \$728,077 in expense related to options for the three-months ended March 31, 2008. The Company also recaptured \$1,459,425 of previously recognized expense for 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 three-months ended March 31, 2008 of (\$731,348).

The weighted average, estimated grant date fair values of stock options granted during the three-months ended March 31, 2008 was \$2.86.

The following tables summarize the stock option activity for the three-months ended March 31, 2008 and March 31, 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	719,948	\$ 4.89	
Exercised	11,099	\$ 1.87	
Forfeited, Canceled	0	n/a	
Outstanding, March 31, 2008	1,720,589	\$ 6.32	9.09
Exercisable, March 31, 2008	1,256,747	\$ 5.75	9.13

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2006	483,490	\$ 2.17	
Granted	119,500	\$ 9.09	
Exercised	20,000	\$ 2.50	
Forfeited, Canceled	0	n/a	
Outstanding, March 31, 2007	582,990	\$ 3.58	8.81
Exercisable, March 31, 2007	301,120	\$ 3.57	8.81

The Company also recognized \$521,000 in expense for shares issued under the Plan to an employee and a consultant during the three-months ended March 31, 2008. In addition, the Company recognized \$17,722 in compensation expense related to the amortization of restricted shares.

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-months ended March 31, 2008 and 2007:

	Quarter Ended March 31, 2008	Quarter Ended March 31, 2007
Net loss available to common stockholders	\$ (4,286,337)	\$ (4,106,133)
Net loss per share, basic and diluted	\$ (0.33)	\$ (0.35)
Weighted-average shares used in computing net loss per share, basic and diluted	13,143,686	11,854,027

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 and 3,402,821 for the three-months ended March 31, 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 1,720,589 and 582,990 for the three-months ended March 31, 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 and contract revenue was comprised wholly from grants and contracts issued by the federal government and accounted for 82.3% and 84.4% of total revenue for the three-months ended March 31, 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 March 31, 2008, the Company is obligated to make payments under the agreements of 74,350 Euros and 144,323 GBP. The Company has established means to purchase forward contracts to hedge against this risk. As of March 31, 2008, the Company has no commitments for Euros or 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.

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 were 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.

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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 at a price of \$8.00 per share. 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 3, 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.

During the three-months ended March 31, 2008 an additional 345,580 Series B Preferred were converted and \$661,295 in dividends were paid to Series B Preferred stockholders. At March 31, 2008, there were 3,524,687 outstanding Series B Preferred for which \$51,462 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 March 31, 2008, \$300,000 in milestone payments have been made under one of these agreements and an additional \$50,000 has been accrued 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 Rosemont, 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 \$83,045, and \$43,598 for the three-months ended March 31, 2008 and 2007, respectively.

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

		Operating Leases
2008	Remaining Three Quarters	\$ 249,539
2009		349,782
2010		343,657
2011		311,803
2012		144,375
		\$ 1,399,156

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 three-months ended March 31, 2008 and 2007:

	Shares	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2007	1,011,740	\$ 7.29
Granted	719,948	\$ 4.89
Exercised	11,099	\$ 1.87
Forfeited, Canceled	0	n/a
Outstanding, March 31, 2008	1,720,589	\$ 6.32

	Shares	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2006	483,490	\$ 2.17
Granted	119,500	\$ 9.09
Exercised	20,000	\$ 2.50
Forfeited, Canceled	0	n/a
Outstanding, March 31, 2007	582,990	\$ 3.58

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, March 31, 2008	3,453,268	\$ 8.86

	Warrants	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2006	814,424	\$ 3.36
Granted	2,632,602	\$ 10.42
Exercised	44,205	\$ 2.00
Forfeited, Canceled	-	n/a
Outstanding, March 31, 2007	3,402,821	\$ 8.84

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

On April 29, 2008, at the Annual Meeting of Stockholders of the Company, the stockholders of CBLI approved the amendment and restatement of the Cleveland BioLabs, Inc. 2006 Equity Incentive Plan, or the Amended Plan. The Amended Plan increased the number of shares available for issuance by an additional 2,000,000 shares, clarified other aspects of the Amended Plan, and added updates that reflect changes and developments in federal tax laws.



## 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, or R&D, efforts and clinical trials, product demand, market acceptance and other factors discussed in the Company's other SEC filings under the heading "Risk Factors." 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 radiation drug discovery. 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 agents.

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 often severe 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:

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

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

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 24 to 36 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.

## **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 18-30 months.
- *Leveraging our relationship with leading research and clinical development institutions.* The Cleveland Clinic Foundation, 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 pipeline 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).

#### *Protectan CBLB502*

Protectan CBLB502 is our leading radioprotectant molecule in the protectans series. 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 protecting 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 intestine. Protectan CBLB502 is a single agent anti-radiation therapy with significant survival benefits at a single dose. Results indicate safety of Protectan CBLB502, which protects animals 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, each of which is substantially effective on its own. 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.

#### *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. 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. Manufacture of Protectan CBLB502 is relatively inexpensive, due to its high yield bacterial producing strain and simple purification process.

We have successfully established cGMP quality manufacturing for Protectan CBLB502 and plan to initiate a first Phase I human safety study in 2008 for Protectan CBLB502 in ARS, which is the only stage of human testing required for approval in this indication. The ARS indication follows an abbreviated approval pathway through the FDA's two-animal rule, which requires efficacy in two species and only safety in humans. This makes the start of the first Phase I in ARS especially important and although it will need to be followed with a much larger cohort of volunteers prior to submission for FDA approval, this initial trial will provide indications of human safety and therapeutic

efficacy, through the identification of predicted changes in certain cytokines, which function as biomarkers.

We are working towards filing a Biologic License Application for FDA approval of Protectan CBLB502 for non-medical applications in 18 months.

In March 2008, the U.S. Department of Defense, or DoD, awarded us a letter contract valued at up to \$8.9 million through the Chemical Biological Medical Systems (CBMS) 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.

We also submitted a proposal for the BAA for "Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting from Acute Exposure to Ionizing Radiation" published on March 6, 2008, by the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services (HHS). 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 disperse device (such as a dirty bomb), or exposure to radioactive material with or without combined injury or trauma. Among certain other criteria, the BAA specified that any medical countermeasures submitted must be efficacious when administered at or later than 24 hours after exposure. According to the BAA, it is anticipated that multiple awards will result from the announcement and those awards will be multi-year, cost-reimbursement, completion type contracts. BARDA anticipates awarding 5-6 contracts on or about September 16, 2008. BARDA estimates that the total cost (direct and indirect cost combined) for these contracts (estimate to be 3 years in duration) will be up to \$13.5 million per contract, out of which up to \$3.4 million will be available in fiscal year 2008.

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.

#### *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 of experimental tumors in mice. Protectan CBLB502 appears to increase the tolerance of mice to radiation while having no effect on the radiosensitivity of tumors, thus opening the possibility of combining radiotherapy with Protectan CBLB502 treatment to improve the overall anticancer efficacy of radiotherapy. Our animal efficacy studies have demonstrated that up to 100% of mice treated with Protectan CBLB502 prior to being exposed to radiation survived without any associated signs of toxicity. This compares to a 100% mortality rate in the animal group that received a placebo drug.

Another recent study demonstrated the ability of Protectan CBLB502 to reduce the toxicities of a chemotherapeutic drug, Platinol (cisplatin), broadly used for the treatment of ovarian, endometrial, head and neck, lung, stomach and other types of cancer. Platinol treatment was used in the study as an example of chemotherapy-associated toxicity. Platinol 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.

We plan to initiate a Phase I/II study in the second half of 2008 for Protectan CBLB502 in head and neck cancer patients. 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 actually result in better outcomes for patients with cancers of the head and neck.



Protectan CBLB502 has also shown efficacy as a potential adjuvant for radiation therapy in mouse models of sarcoma and 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.

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.

### ***Protectan CBLB612***

Protectan CBLB612 is a modified lipopeptide mycoplasma that acts as a powerful stimulator and mobilizer of hematopoietic (bone marrow/blood production) stem cells, 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 hematopoietic stem cells into peripheral blood in primate model (Rhesus macaques).

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

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

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. Its first human trials are projected for 2009. The development of our Protectan CBLB612 has been supported by a grant from the Defense Advanced Research Projects Agency of the Department of Defense.

### **Curaxins**

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

The original focus of our drug development program was to develop drugs to treat one of the most treatment-resistant types of cancer, RCC. Unlike many cancer types that frequently mutate or delete p53, one of the major tumor suppressor genes, RCC belongs to a rare category of cancers that typically maintain a wild type form of this protein. Nevertheless, RCC cells are resistant to apoptosis, suggesting that in spite of its normal structure, p53 is functionally disabled. The work of our founders has shown that p53 function is indeed inhibited in RCC by an unknown dominant factor. We have established a drug discovery program to identify small molecules that selectively destroy tumor cells by restoring the normal function to functionally impaired p53 in RCC. This program yielded a series of chemicals

with the desirable properties named curaxins (CBLC100 series). We have isolated three chemical classes of curaxins. One of them includes relatives of 9-aminoacridine, the compound that is the core structure of many existing drugs. Pre-existing information about this compound has allowed us to bypass the preclinical development and Phase I studies and bring one of our drug candidates into Phase IIa clinical trials, saving years of R&D efforts and improving the probability of success.

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

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

### **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.

### **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.

## **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 March 31, 2008 the securities issued in the transaction, in the aggregate, were convertible into or exercisable for approximately 6,157,289 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 R&D 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 R&D 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, 708,743 Series B Preferred were converted and \$60,789 in dividends earned were paid as of December 31, 2007.

During the three-months ended March 31, 2008 an additional 345,580 shares of the Series B Preferred were converted and \$661,295 in dividends were paid during the three-months ended March 31, 2008. At March 31, 2008 there were 3,524,687 remaining outstanding Series B Preferred shares for which \$51,462 in dividends had been accrued.

### **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, R&D 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 at the time of submitting the invoice to the government agency.

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 periodically upon delivery of an invoice for allowable R&D expenses according to the terms of the contract. Commercial development revenues are recognized when the service or development is delivered.

### ***R&D Expenses***

R&D costs are expensed as incurred. These expenses consist primarily of our proprietary R&D efforts, including salaries and related expenses for personnel, costs of materials used in our R&D, costs of facilities and costs incurred in connection with our third-party collaboration efforts. Pre-approved milestone payments made by us to third parties under contracted R&D arrangements are expensed when the specific milestone has been achieved. As of March 31, 2008, \$50,000 has been paid for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102 and \$250,000 has been paid as a result of commencing Phase II clinical trials for Curaxin CBLC102. An additional \$50,000 has been accrued for a milestone payment relating to the filing of an IND with the FDA for Protectan CBLB502. Once a drug receives regulatory approval, we will record any subsequent milestone payments in identifiable intangible assets, less accumulated amortization, and amortize them evenly over the remaining agreement term or the expected drug life cycle, whichever is shorter. We expect our R&D expenses to increase as we continue to develop our drug candidates.

### ***Intellectual Property Related Costs***

We capitalize costs associated with the preparation, filing and maintenance of our intellectual property rights. Capitalized intellectual property is reviewed annually for impairment. If a patent application is approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be amortized on a straight line basis over the shorter of 17 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 \$150,744 relating to these costs incurred for the three months ended March 31, 2008, totaling \$609,846.



### ***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 traded history of the Company. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

During the three-months ended March 31, 2008, the Company granted 719,948 additional stock options pursuant to stock award agreements. The Company recognized a total of \$728,077 in expense related to options for the three months ended March 31, 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 terms and conditions, but were not awarded 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 necessitated the recapture of the \$1,459,425 in expense. This recapture resulted in a net expense for options for the three-months ended March 31, 2008 of (\$731,348).

During the three-months ended March 31, 2007, the Company granted 119,500 options pursuant to stock award agreements to employees and key consultants. We recognized a total of \$375,301 in expense for options for the three-months ended March 31, 2007. The weighted average, estimated grant date fair values of stock options granted during the three-months ended March 31, 2008 and 2007 were \$2.86 and \$5.88, 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.

**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 quarters ended March 31, 2008 and March 31, 2007, and the year 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.

	<b>Quarter Ended 31-Mar-08 (unaudited)</b>	<b>Quarter Ended 31-Mar-07 (unaudited)</b>	<b>Year Ended December 31, 2007</b>	<b>Year Ended December 31, 2006</b>
Revenues	\$ 676,324	\$ 321,445	\$ 2,018,558	\$ 1,708,214
Operating expenses	4,744,500	4,522,919	27,960,590	9,126,315
Other expense (income)	47,002	-	2,058,236	-
Net interest expense (income)	(145,127)	(95,341)	(1,003,766)	(195,457)
Net income (loss)	\$ (3,970,051)	\$ (4,106,133)	\$ (26,996,502)	\$ (7,222,644)

**Three Months Ended March 31, 2008 Compared to Three Months Ended March 31, 2007****Revenue**

Revenue increased from \$321,445 for the three-months ended March 31, 2007 to \$676,324 for the three-months ended March 31, 2008 representing an increase of \$354,879 or 110.4% resulting primarily from an increase in revenue from various federal grants and contracts including the Collaborative Research Agreement with the Roswell Park Cancer Institute, the DTRA contract, and the NCI contract.

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 (thru March 31) (unaudited)</b>	<b>Revenue 2007 (thru March 31) (unaudited)</b>	<b>Revenue 2007</b>
<b>DoD</b>	DTRA Contract	\$ 1,263,836	03/2007-02/2009	\$ 323,826	\$ -	\$ 466,322
<b>NY State/RPCI</b>	Sponsored Research Agreement	\$ 3,000,000	03/2007-02/2012	\$ 90,749	\$ -	\$ 329,390
<b>NIH</b>	Phase II NIH SBIR program	\$ 750,000	07/2006-06/2008	\$ 77,971	\$ 140,593	\$ 459,621
<b>NIH</b>	NCI Contract	\$ 750,000	09/2006-08/2008	\$ 63,778	\$ 130,852	\$ 440,028
<b>NASA</b>	Phase I NASA	\$ 100,000	01/2006-01/2007	\$ -	\$ -	\$ 33,197

STTR  
program

Totals	\$ 556,324	\$ 271,445	\$ 1,728,558
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We anticipate our revenue over the next year to be derived mainly from government grants and contracts. In addition, it is common in our industry for companies to enter into licensing agreements with large pharmaceutical companies. To the extent we enter into such licensing arrangements, we may receive additional revenue from licensing fees.

### ***Operating Expenses***

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

Operating expenses increased from \$4,522,919 for the three-months ended March 31, 2007 to \$4,744,500 for the three-months ended March 31, 2008, an increase of \$221,581 or 4.9%. We recognized a total of (\$192,626) of non-cash, stock-based compensation for the three-months ended March 31, 2008 compared to \$375,301 for the three-months ended March 31, 2007. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have increased from \$4,147,618 for the three-months ended March 31, 2007 to \$4,937,126 for the three-months ended March 31, 2008. This represents an increase in operating expenses of \$789,508 or 19.0%.

Research and development costs increased from \$3,528,600 for the three-months ended March 31, 2007 to \$3,551,386 for the three-months ended March 31, 2008. This represents an increase of \$22,786 or 0.6%. We recognized a total of \$315,630 of R&D non-cash, stock based compensation for the three-months ended March 31, 2007 compared to \$46,862 for the three-months ended March 31, 2008. Without the non-cash, stock-based compensation, the R&D expenses increased from \$3,212,970 for the three-months ended March 31, 2007 to \$3,504,524 for the three-months ended March 31, 2008; an increase of \$291,554 or 9.1%.

Selling, general and administrative costs increased from \$994,319 for the three-months ended March 31, 2007 to \$1,193,114 for the three-months ended March 31, 2008. This represents an increase of \$198,795 or 20.0%. We recognized a total of \$59,670 of non-cash, stock-based compensation under selling, general and administrative costs for the three-months ended March 31, 2007 compared to (\$239,488) for the three-months ended March 31, 2008. Without the non-cash, stock-based compensation, the selling, general and administrative expenses increased from \$934,649 for the three-months ended March 31, 2007 to \$1,432,602 for the three months ended March 31, 2008; an increase of \$497,953 or 53.3%. 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 have historically consisted of costs relating to R&D and general and administrative expenses. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at the Roswell Park Cancer Institute and the 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 expect 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 also to support the expansion of our business.

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 compensation for 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 R&D 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 R&D 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 compensation for R&D stock based compensation 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 R&D 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 March 31, 2008, we had an accumulated deficit of \$45,324,549. Our principal sources of liquidity have been cash provided by sales of our securities and government grants, contracts and agreements. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government grants, equity financing, licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties.

Net cash used in operating activities totaled \$4,243,435 for the three-months ended March 31, 2008, compared to \$3,030,466 used in operating activities for the three-months ended March 31, 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

R&D activities and maintaining and improving the infrastructure necessary to support these R&D activities.

Net cash used in investing activities was \$205,813 for the three months ended March 31, 2008 and net cash used in investing activities was \$17,054,798 for the three months ended March 31, 2007. The decrease in cash used in investing activities resulted primarily from a reduction in the purchase of short term investments of \$17,999,965 from the funds received from the issuance of Series B Preferred in connection with our private placement offering that took place in the first quarter of 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 the maturing of short-term investments that converted to cash.



Net cash used in financing activities totaled \$660,558 for the three-months ended March 31, 2008, compared to net cash provided by financing activities of \$28,991,288 for the three-months ended March 31, 2007. The decrease in cash provided by financing activities was attributed to the payment of dividends in the first three 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 three 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 March 31, 2008, we have paid \$50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102 and \$250,000 for commencing Phase II clinical trials for Curaxin CBLC102. The \$50,000 milestone payment was made May 3, 2007 and the \$250,000 milestone was paid on August 21, 2007 as per the terms of the agreement. In addition, the Company has accrued an additional \$50,000 related to the filing of an IND application related to Protectan CBLB502 that occurred in February 2008.

Our agreement with the CCF also provides for payment by us to CCF of royalty payments calculated as a percentage of the net sales of the drug candidates ranging from 1-2%, and sublicense royalty payments calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%. However, any royalty payments and sublicense royalty payments assume that we will be able to commercialize our drug candidates, which are subject to numerous risks and uncertainties, including those associated with the regulatory approval process, our R&D process and other factors. Each of the above milestone payments, royalty payments and sublicense royalty payments was accrued until CCF owns less than five percent of our common stock on a fully-diluted basis or we receive more than \$30,000,000 in funding and/or revenues from sources other than CCF, which have occurred with the completion of the private offering.

Although we believe that existing cash resources will be sufficient to finance our currently planned operations for the near-term (6-18 months), such amounts will not be sufficient to meet our longer-term cash requirements, including our cash requirements for the commercialization of certain of our drug candidates currently in development. We may be required to issue equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

The following factors, among others, could cause actual results to differ from those indicated in the above forward-looking statements: the results of our R&D efforts, the timing and success of preclinical testing, the timing and success of any clinical trials we may commence in the future, the timing of and responses to regulatory submissions, the amount of cash generated by our operations, the amount of competition we face and how successful we are in obtaining any required licenses and entering into collaboration arrangements.

***Impact of Inflation***

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

***Impact of Exchange Rate Fluctuations***

We believe that our results of operations are somewhat dependent upon moderate changes in foreign currency exchange rates. We have entered into a manufacturing agreement with a foreign third party to produce one of its drug compounds and are required to make payments in the foreign currency. 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. Currently, our exposure primarily exists with the Euro and the Great British Pound or GBP. As of March 31, 2008, we are obligated to make payments under the agreement of 74,350 Euros and 144,323 GBP. We have established means to purchase forward contracts to hedge against this risk. As of March 31, 2008, the Company has no commitments for Euros or 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 March 31, 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 March 31, 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 March 31, 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 March 31, 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

**Signatures**

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

CLEVELAND BIOLABS, INC.

Dated: May 14, 2008

By:

/s/ MICHAEL FONSTEIN.

Michael Fonstein  
Chief Executive Officer  
(Principal Executive Officer)

Dated: May 14, 2008

By:

/s/ JOHN A. MARHOFER, JR.

John A. Marhofer, Jr.  
Chief Financial Officer  
(Principal Financial Officer)