

CLEVELAND BIOLABS INC  
Form 10QSB  
November 14, 2007

**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-QSB**

(Mark one)

**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Quarterly Period Ended September 30, 2007

or

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934**

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

**Commission File Number 001-12465**

**CLEVELAND BIOLABS, INC.**  
(Exact name of small business issuer 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 14203**  
(Address of principal executive offices and zip code)

**(716) 849-6810**  
(Issuer's telephone number)

Check whether the issuer (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 shell company (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

As of September 30, 2007 there were 12,182,748 shares of registrant's common stock, \$0.005 par value

Transitional Small Business Disclosure Format (Check One): YES  NO

---

CLEVELAND BIOLABS INC  
 10-QSB  
 11/14/2007

TABLE OF CONTENTS

	PAGE
<b>PART I - FINANCIAL INFORMATION</b>	
<b>ITEM 1:</b>	<b>Financial Statements</b>
	Balance Sheets as of September 30, 2007 and December 31, 2006 3-4
	Statements of Operations For Three and Nine Months Ended September 30, 2007 and 2006 5
	Statement of Stockholders' Equity January 1, 2006 to December 31, 2006 and to September 30, 2007 6
	Statements of Cash Flows For Nine Months Ended September 30, 2007 and 2006 9
	Notes to Financial Statements 10
<b>ITEM 2:</b>	<b>Management's Discussion and Analysis of Financial Condition and Results of Operations 20</b>
<b>ITEM 3:</b>	<b>Controls and Procedures 33</b>
<b>PART II - OTHER INFORMATION</b>	
<b>ITEM 1:</b>	<b>Legal Proceedings 34</b>
<b>ITEM 2:</b>	<b>Unregistered Sales of Equity Securities and Use of Proceeds 34</b>
<b>ITEM 3:</b>	<b>Defaults Upon Senior Securities 34</b>
<b>ITEM 4:</b>	<b>Submission of Matters to a Vote of Securities Holders 34</b>
<b>ITEM 5:</b>	<b>Other Information 34</b>
<b>ITEM 6:</b>	<b>Exhibits 34</b>
	Signatures 35

In this report, "Cleveland BioLabs," "CBLI," "we," "us" and "our" refer to Cleveland BioLabs, Inc. "common stock" refers to Cleveland BioLabs, Inc.'s common stock, par value \$0.005 per share.

## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

September 30, 2007 (unaudited) and December 31, 2006

<u>ASSETS</u>	September 30 2007 (unaudited)	December 31 <u>2006</u>
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 20,278,556	\$ 3,061,993
Short-term investments	1,003,869	1,995,836
Accounts receivable:		
Trade	644,539	159,750
Interest	44,179	42,479
Notes receivable - Orbit Brands	-	50,171
Prepaid expenses	266,769	434,675
Total current assets	22,237,912	5,744,904
<b>EQUIPMENT</b>		
Computer equipment	250,527	132,572
Lab equipment	886,731	347,944
Furniture	91,885	65,087
	1,229,143	545,603
Less accumulated depreciation	252,990	142,011
Construction in progress	147,889	-
	1,124,042	403,592
<b>OTHER ASSETS</b>		
Intellectual property	406,395	252,978
Deposits	27,447	15,055
	433,842	268,033
<b>TOTAL ASSETS</b>	<b>\$ 23,795,796</b>	<b>\$ 6,416,529</b>

## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

September 30, 2007 (unaudited) and December 31, 2006

	September 30 2007 (unaudited)	December 31 <u>2006</u>
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 965,369	\$ 644,806
Deferred revenue	1,846,763	-
Accrued expenses	397,991	128,569
Total current liabilities	3,210,123	773,375
<b>LONG-TERM LIABILITIES</b>		
Milestone payable (long-term)	-	50,000
Total long-term liabilities	-	50,000
<b>STOCKHOLDERS' EQUITY</b>		
Series B convertible preferred stock, \$.005 par value		
Authorized - 10,000,000 shares at September 30, 2007 and December 31, 2006		
Issued and outstanding 4,579,010 and 0 shares at September 30, 2007 and December 31, 2006, respectively	22,895	-
Additional paid-in capital	28,845,232	-
Common stock, \$.005 par value		
Authorized - 40,000,000 shares at September 30, 2007 and December 31, 2006		
Issued and outstanding 12,182,748 and 11,826,389 shares at September 30, 2007 and December 31, 2006, respectively	60,914	59,132
Additional paid-in capital	22,949,868	18,314,097
Accumulated other comprehensive income (loss)	-	(4,165)
Accumulated deficit	(31,293,236)	(12,775,910)
Total stockholders' equity	20,585,673	5,593,154
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 23,795,796</b>	<b>\$ 6,416,529</b>

## CLEVELAND BIOLABS, INC.

## STATEMENT OF OPERATIONS

Three Months and Nine Months Ending September 30, 2007 and 2006 (unaudited)

	Three Months Ended		Nine Months Ended	
	September 30 2007 (unaudited)	September 30 2006 (unaudited)	September 30 2007 (unaudited)	September 30 2006 (unaudited)
<b>REVENUES</b>				
Grant	\$ 540,544	\$ 263,368	\$ 1,327,996	\$ 1,271,787
Service	120,000	60,000	290,000	205,000
	660,544	323,368	1,617,996	1,476,787
<b>OPERATING EXPENSES</b>				
Research and development	4,105,480	1,281,055	11,663,054	4,341,535
Selling, general and administrative	1,442,669	708,776	6,968,565	1,367,457
Total operating expenses	5,548,149	1,989,831	18,631,619	5,708,992
<b>LOSS FROM OPERATIONS</b>	(4,887,605)	(1,666,463)	(17,013,623)	(4,232,205)
<b>OTHER INCOME</b>				
Interest income	305,568	81,189	761,648	125,719
Sublease revenue	1,771	-	1,771	-
<b>OTHER EXPENSE</b>				
Interest expense	-	2,257	1,087	11,198
Corporate relocation	901,964	-	1,152,643	-
Loss on investment	305,479	-	305,479	-
<b>NET LOSS</b>	(5,787,709)	(1,587,531)	(17,709,413)	(4,117,684)
<b>DIVIDENDS ON CONVERTIBLE PREFERRED STOCK</b>				
	(807,913)	(22,035)	(807,913)	(215,933)
<b>NET LOSS AVAILABLE TO COMMON STOCKHOLDERS</b>	\$ (6,595,622)	\$ (1,609,566)	\$ (18,517,326)	\$ (4,333,617)
<b>NET LOSS AVAILABLE TO COMMON STOCKHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED</b>				
	\$ (0.54)	\$ (0.15)	\$ (1.54)	\$ (0.55)
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED</b>				

IN CALCULATING NET LOSS  
PER SHARE,  
BASIC AND DILUTED

12,148,718

10,681,032

12,010,177

7,922,195

5

---

CLEVELAND BIOLABS,  
INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND  
COMPREHENSIVE LOSS

Period From January 1, 2006 to  
December 31, 2006 and to  
September 30, 2007 (unaudited)

	Stockholders' Equity		Common Stock	
	Shares	Amount	Additional Paid-in Capital	Penalty Shares
Balance at January 1, 2006	6,396,801.00	31,984	3,338,020	81,125
Issuance of shares - previously accrued penalty shares	54,060	270	80,855	(81,125)
Issuance of shares - stock dividend	184,183	922	367,445	-
Issuance of penalty shares	15,295	76	(76)	-
Issuance of shares - initial public offering	1,700,000	8,500	10,191,500	-
Fees associated with initial public offering	-	-	(1,890,444)	-
Conversion of preferred stock to common stock	3,351,219	16,756	5,291,385	-
Conversion of notes payable to common stock	124,206	621	312,382	-
Issuance of options	-	-	506,078	-
Exercise of options	625	3	2,810	-
Issuance of warrants	-	-	114,032	-
Proceeds from sales of warrants	-	-	110	-
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	-	-	-	-
<b>Comprehensive loss</b>				
Balance at December 31, 2006	11,826,389	\$ 59,132	\$ 18,314,097	\$ -
Issuance of options	-	-	2,745,287	-
Issuance of Series B Preferred Shares	-	-	-	-
Fees associated with Series B Preferred offering	-	-	-	-
Issuance of restricted shares	190,000	950	1,699,500	-
Exercise of options	118,296	591	100,709	-
Exercise of warrants	48,063	240	90,275	-
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	-	-	-	-
<b>Comprehensive loss</b>				
Balance at September 30, 2007	12,182,748	\$ 60,914	\$ 22,949,868	\$ -

CLEVELAND BIOLABS,  
INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND  
COMPREHENSIVE LOSS

Period From January 1, 2006 to  
December 31, 2006 and to  
September 30, 2007  
(unaudited)

	Stockholders' Equity		Preferred Stock	
	Shares	Amount	Additional Paid-in Capital	Penalty Shares
Balance at January 1, 2006	3,051,219	15,256	4,932,885	360,000
Issuance of shares - previously accrued penalty shares	240,000	1,200	358,800	(360,000)
Issuance of shares - stock dividend	-	-	-	-
Issuance of penalty shares	60,000	300	(300)	-
Issuance of shares - initial public offering	-	-	-	-
Fees associated with initial public offering	-	-	-	-
Conversion of preferred stock to common stock	(3,351,219)	(16,756)	(5,291,385)	-
Conversion of notes payable to common stock	-	-	-	-
Issuance of options	-	-	-	-
Exercise of options	-	-	-	-
Issuance of warrants	-	-	-	-
Proceeds from sales of warrants	-	-	-	-
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	-	-	-	-
<b>Comprehensive loss</b>				
Balance at December 31, 2006	-	\$ -	\$ -	\$ -
Issuance of options	-	-	-	-
Issuance of Series B Preferred Shares	4,288,712	21,444	29,999,540	-
Fees associated with Series B Preferred offering	290,298	1,451	(1,154,308)	-
Issuance of restricted shares	-	-	-	-
Exercise of options	-	-	-	-
Exercise of warrants	-	-	-	-
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	-	-	-	-
<b>Comprehensive loss</b>				
Balance at September 30, 2007	4,579,010	\$ 22,895	\$ 28,845,232	\$ -

## CLEVELAND BIOLABS, INC.

STATEMENTS OF  
STOCKHOLDERS' EQUITY AND  
COMPREHENSIVE LOSS

Period From January 1, 2006 to  
December 31, 2006 and to  
September 30, 2007 (unaudited)

	Stockholders' Equity			Comprehensive
	Other Comprehensive Income/(Loss)	Accumulated Deficit	Total	Income (Loss)
Balance at January 1, 2006	(17,810)	(5,184,856)	3,556,604	
Issuance of shares - previously accrued penalty shares	-	-	-	
Issuance of shares - stock dividend	-	(368,410)	(43)	
Issuance of penalty shares	-	-	-	
Issuance of shares - initial public offering	-	-	10,200,000	
Fees associated with initial public offering	-	-	(1,890,444)	
Conversion of preferred stock to common stock	-	-	-	
Conversion of notes payable to common stock	-	-	313,003	
Issuance of options	-	-	506,078	
Exercise of options	-	-	2,813	
Issuance of warrants	-	-	114,032	
Proceeds from sales of warrants	-	-	110	
Net loss	-	(7,222,644)	(7,222,644)	(7,222,644)
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses)				

Edgar Filing: CLEVELAND BIOLABS INC - Form 10QSB

arising during period	6,678	-	6,678	\$	6,678
Less reclassification adjustment for (gains) losses included in net loss	6,967	-	6,967	\$	6,967
Comprehensive loss				\$	(7,208,999)
Balance at December 31, 2006	\$ (4,165)	\$ (12,775,910)	\$ 5,593,154		
Issuance of options	-	-	2,745,287		
Issuance of Series B Preferred Shares	-	-	30,020,984		
Fees associated with Series B Preferred offering	-	-	(1,152,857)		
Issuance of restricted shares	-	-	1,700,450		
Exercise of options	-	-	101,300		
Exercise of warrants	-	-	90,515		
Dividends on Series B Preferred Shares	-	(807,913)	(807,913)		
Net Loss	-	(17,709,413)	(17,709,413)		(17,709,413)
Other comprehensive income					
Unrealized gains (losses) on short term investments					
Changes in unrealized holding gains (losses)					
arising during period	-	-	-	\$	-
Less reclassification adjustment for (gains) losses included in net loss	4,165	-	4,165	\$	4,165
Comprehensive loss				\$	(17,705,248)
Balance at September 30, 2007	\$ -	\$ (31,293,236)	\$ 20,585,673		

## CLEVELAND BIOLABS, INC.

## STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2007 and 2006 (unaudited)

	September 30 2007 (unaudited)	September 30 2006 (unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (17,709,413)	\$ (4,117,684)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	110,979	68,204
Noncash interest expense	-	9,929
Noncash salaries and consulting expense	4,445,737	439,684
Deferred compensation	-	4,852
Loss on investments	305,479	-
Changes in operating assets and liabilities:		
Accounts receivable - trade	(484,789)	(76,644)
Accounts receivable - interest	(7,008)	(5,170)
Prepaid expenses	167,907	(132,729)
Deposits	(12,392)	(3,055)
Accounts payable	320,563	308,797
Deferred revenue	1,846,763	(100,293)
Accrued expenses	269,424	15,596
Milestone payments	(50,000)	50,000
Total adjustments	6,912,663	579,172
Net cash (used by) provided by operating activities	(10,796,750)	(3,538,512)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Sale/(purchase) of short-term investments	996,131	(500,000)
Issuance of notes receivable	(250,000)	-
Purchase of equipment	(831,430)	(143,693)
Costs of patents pending	(153,417)	(106,059)
Net cash (used in) provided by investing activities	(238,716)	(749,752)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Issuance of preferred stock	30,020,984	-
Financing costs	(1,152,857)	(1,679,456)
Dividends	(807,913)	(43)
Issuance of common stock	-	10,200,000
Exercise of stock options	101,300	2,813
Exercise of warrants	90,515	-
Issuance of warrants	-	100
Net cash (used in) provided by financing activities	28,252,029	8,523,413

INCREASE (DECREASE) IN CASH AND EQUIVALENTS	17,216,563	4,235,149
CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	3,061,993	1,206,462
CASH AND EQUIVALENTS AT END OF PERIOD	\$ 20,278,556	\$ 5,441,611

## Supplemental disclosures of cash flow information:

Cash paid during the period for interest	\$ 1,087	\$ 1,269
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	\$ 2,745,287	\$ 439,684
Issuance of shares to consultants	\$ 1,700,450	\$ -
Issuance of common stock dividend to preferred shareholders	\$ -	\$ 368,366
Conversion of notes payable and accrued interest to common stock	\$ -	\$ 313,003
Conversion of preferred stock to common stock	\$ -	\$ 5,308,142

**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 toxins. The Company was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York. The Company's initial technological development efforts are intended to be used as powerful antidotes with a broad spectrum of applications including protection from cancer treatment side effects, radiation and hypoxia. A 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 September 30, 2007 and September 30, 2006, and for the quarter and nine-month periods ended September 30, 2007 and September 30, 2006, 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, 2006, which were contained in the Company's Annual Report on Form 10-KSB filed with the U.S. Securities and Exchange Commission.
- B. **Cash and Equivalents** - The Company considers highly liquid investments with a maturity date of three months or less to be cash equivalents. In addition, the Company maintains cash and equivalents at financial institutions, which may exceed federally insured amounts at times and which may, at times, significantly exceed balance sheet amounts due to outstanding checks.
- C. **Marketable Securities and Short Term Investments** - The Company considers investments with a maturity date of more than three months to be short-term investments and has classified these securities as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as accumulated other comprehensive income (loss) in stockholders' equity. The cost of available-for-sale securities sold is determined based on the specific identification method.
- D. **Accounts Receivable** - The Company extends unsecured credit to customers under normal trade agreements, which generally require payment within 30 days. Management estimates an allowance for doubtful accounts which is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There is no allowance for doubtful accounts as of September 30, 2007 and December 31, 2006.
- E. **Notes Receivable** - On December 7, 2006, the Company entered into an agreement with the Orbit Brands Corporation (Borrower) and its subsidiaries whereby the Company would lend up to \$150,000 each on two promissory notes to the Borrower at a rate of 5% per annum with a maturity date of one year. The proceeds of the loans were to be used by the Borrower solely to cover expenses associated with converting the notes into common stock and preparing the lending motions for the bankruptcy case involving the Borrower. The loans were convertible into common stock of the Borrower and its subsidiaries. At September 30, 2007, the Company wrote off the balance outstanding of \$300,000 plus accrued interest of \$5,479 due to the fact that the Securities and Exchange Commission has initiated proceedings to permanently suspend trading in the shares of



Borrower and to revoke its registration under the Securities Exchange Act of 1934. In addition, Borrower does not appear to have sufficient funds to emerge from its bankruptcy proceedings.

- F. 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 \$49,298, and \$24,514 for the quarters ended September 30, 2007 and 2006, respectively. Depreciation expense was \$110,979 and \$68,206 for the nine months ended September 30, 2007 and 2006, respectively.
- G. 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.
- H. 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 (“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 \$366,918 and \$222,789 on behalf of CCF for 12 patent applications as of September 30, 2007 and December 31, 2006, 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 \$39,478 and \$30,189 on behalf of the Company for three patent applications as of September 30, 2007 and December 31, 2006, respectively. The patent applications are still pending approval.

- I. 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 September 30, 2007, there were no outstanding borrowings under this credit facility.
- J. Fair Value of Financial Instruments - Financial instruments, including cash and equivalents, accounts receivable, notes receivable, accounts payable and accrued liabilities, are carried at net realizable value. The 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.

- K. Use of Estimates - The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions that the Company believes to be reasonable under these circumstances. Actual results could differ from those estimates.
- L. Revenue Recognition - The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition." Revenue sources consist of government grants, government contracts and commercial development contracts.

Revenues from government grants and contracts are for research and development purposes and are recognized in accordance with the terms of the award and the government agency. Grant revenue is recognized in one of two different ways depending on the grant. Cost reimbursement grants require us to submit proof of costs incurred that are invoiced by us to the government agency, which then pays the invoice. In this case, grant revenue is recognized 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 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 has also begun recognizing revenue from a sponsored research agreement with Roswell Park Cancer Institute. This agreement was funded by the State of New York as part of the incentive for the Company to relocate its corporate headquarters and research facilities to Buffalo, New York. Commercial development revenues are recognized when the service or development is delivered.

- M. Deferred Revenue - Deferred revenue results when payment is received in advance of revenue being earned. When cash is received, 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 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. For the quarter ended September 30, 2007, the Company recognized \$153,238 of this revenue resulting in a balance of deferred revenue of \$1,846,763 at September 30, 2007. At September 30, 2006, the Company had no deferred revenue.

- N. Research and Development - Research and development expenses consist primarily of costs associated with salaries and related expenses for personnel, costs of materials used in 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.

12

---

- O. 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 quarter ended September 30, 2007, there were 18,000 options and 15,000 shares granted under the Plan, and as of September 30, 2007 there were 588,000 stock options and 190,000 shares granted under the Plan totaling 778,000 equity instruments awarded under the Plan.
- P. 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. The Company does not include the use of its own stock in the volatility calculation at this time because of the brief history of the stock as a publicly traded security on a listed exchange. The Company recognizes the fair value of share-based compensation in net income on a straight-line basis over the requisite service period.

During the quarter ended September 30, 2007, the Company granted 18,000 additional stock options pursuant to a stock award agreement. The Company recognized a total of \$395,129 in expense related to options for the three months ended September 30, 2007, and \$2,745,287 for the nine months ended September 30, 2007.

The weighted average, estimated grant date fair values of stock options granted during the quarter ended September 30, 2007 was \$4.95. The weighted average, estimated grant date fair values of stock options granted during the nine months ended September 30, 2007 was \$5.90.

The following tables summarize the stock option activity for the nine months ended September 30, 2007 and September 30, 2006, respectively.

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2006	483,490	\$ 2.17	
Granted	543,000	\$ 9.82	
Exercised	124,000	\$ 1.35	
Forfeited, Canceled	0	n/a	

Edgar Filing: CLEVELAND BIOLABS INC - Form 10QSB

Outstanding, September 30, 2007	902,490	\$	6.89	8.77
Exercisable, September 30, 2007	599,930	\$	6.58	8.78

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2005	324,240	\$ .82	
Granted	161,750	\$ 4.92	
Exercised	625	\$ 4.50	
Forfeited, Canceled	1,875	\$ 4.50	
Outstanding, September 30, 2006	483,490	\$ 2.17	9.02
Exercisable, September 30, 2006	239,433	\$ 2.27	9.03

In addition, the Company recognized \$1,700,450 in expense for shares issued under the Plan to various consultants during the nine months ended September 30, 2007. During the quarter ended September 30, 2007 the Company recognized \$159,150 in compensation expense for shares issued to a key consultant under the Plan. For the quarter and nine months ended September 30, 2006 there was no compensation expense recognized for share issuance.

- Q. Other Expense - The Company recognizes those expenses that cannot be traced directly to operations as Other Expense in accordance with FASB guidelines. The Company recognized Other Expense for the following items:

For the quarter ended September 30, 2007, the Company recognized \$901,964 in Other Expense due to the relocation of the corporate headquarters and research facilities to Buffalo, New York. For the nine months ended September 30, 2007 the Company recognized \$1,152,643 in Other Expense due to this relocation.

The Company recognized \$305,479 in Other Expense for the quarter and nine months ended September 30, 2007 for the loss on the investment in Notes Receivable from the Orbit Brands Corporation as described in Note E above.

For the quarters ended September 30, 2007 and 2006, the Company recognized \$0 and \$2,257 in Other Expense due to interest charges, respectively. For the nine months ended September 30, 2007 and 2006, the Company recognized \$1,087 and \$11,198 in Other Expense due to interest charges, respectively.

- R. 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 quarters and nine months ended September 30, 2007 and 2006:

	Quarter Ended Sept. 30, 2007	Quarter Ended Sept. 30, 2006	Nine-Months Ended Sept. 30, 2007	Nine-Months Ended Sept. 30, 2006
Net loss available to common shareholders	\$ (6,595,622)	\$ (1,609,565)	\$ (18,517,326)	\$ (4,333,617)
Net loss per share, basic and diluted	\$ (.54)	\$ (.15)	\$ (1.54)	\$ (.55)



Weighted-average shares used in computing	12,148,718	10,681,032	12,010,177	7,922,195
---	------------	------------	------------	-----------

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 764,424 for the quarters and nine months ended September 30, 2007 and 2006, 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 902,490 and 483,490 for the quarters and nine months ended September 30, 2007 and 2006, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

- S. Concentrations of Risk - Grant revenue was comprised wholly from grants and contracts issued by the federal government and accounted for 81.8% and 81.4% of total revenue for the quarter ended September 30, 2007 and 2006, respectively. Grant revenue accounted for 82.1% and 86.1% for the nine months ended September 30, 2007 and 2006, respectively. Although the Company anticipates ongoing federal grant 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.

- T. Foreign Currency Exchange Rate Risk - The Company has entered into a manufacturing agreement with a foreign third party to produce one of its drug compounds and is required to make payments in the foreign currency. As a result, the Company's financial results could be affected by changes in foreign currency exchange rates. Currently, the Company's exposure primarily exists with the Euro. As of September 30, 2007, the Company is obligated to make payments under the agreement of 537,017 Euros. The Company has established means to purchase forward contracts to hedge against this risk. As of September 30, 2007, the Company has commitments for 197,847 Euros of hedging transactions.

- U. 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. See Note 4 for further details on stock option agreements.

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, the Company ceased its 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 upcoming private placement offering.

On March 16, 2007, the Company entered into a Securities Purchase Agreement with various accredited investors (the "Buyers"), pursuant to which the Company agreed to sell to the Buyers Series B Convertible Preferred Stock ("Series B Preferred") convertible into an aggregate of 4,288,712 shares of common stock and Series B Warrants that are exercisable for an aggregate of 2,144,356 shares of common stock. The Series B Preferred have an initial conversion price of \$7.00 per share, and in the event of a conversion at such conversion price, one share of Series B Preferred would convert into one share of common stock. The Series B Warrants have an exercise price of \$10.36 per share, the closing bid price on the day prior to the private placement. To the extent, however, that the conversion price of the Series B Preferred or the exercise price of the Series B Warrants is reduced as a result of certain anti-dilution protections, the number of shares of common stock into which the Series B Preferred are convertible and for which the Series B Warrants are exercisable may increase.

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

In total, the securities issued in the private placement will be convertible into, or exercisable for, up to approximately 7,211,612 shares of common stock, which amount is subject to adjustment in the event of certain corporate events

such as stock splits or issuances of securities at a price below the conversion price of the Series B Preferred or exercise price of the warrants, as the case may be. On September 13, 2007, the Company paid \$807,913 to the Series B Preferred stockholders for the semiannual dividend.

On March 19, 2007, the Company issued 20,000 stock options to members of the Scientific Advisory Board of the Company under non-qualified stock option agreements. These options are immediately exercisable and allow for the purchase of 20,000 shares of common stock at a price of \$8.82. These options expire on March 19, 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 6, 2017.

On April 9, 2007, the Company issued 145,000 shares of common stock to various outside consultants under the Plan.

On June 12, 2007, the Company issued a total of 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 12, 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 matching or exceeding 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 15, 2017.

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 21, 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.

#### **Note 4. Commitments and Contingencies**

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

The Company is also party to three agreements that require it to make milestone payments, royalties on net sales of the Company's products and payments on sublicense income received by the Company. As of September 30, 2007, \$300,000 in milestone payments have been made under one of these agreements.

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

The Company currently has operating lease commitments in place for facilities in Buffalo, New York and Chicago, Illinois as well as office equipment. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. The operating lease expenses recognized were \$79,054, and \$42,715 for the quarters ended September 30, 2007 and 2006, respectively, and the operating lease expenses recognized were \$166,986 and \$117,824

for the nine months ended September 30, 2007 and 2006, respectively.

17

---

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

	<b>Operating Leases</b>
2007 (from October 1, 2007 through December 31, 2007)	\$ 83,120
2008	332,995
2009	347,214
2010	339,155
2011	307,300
2012	144,000
Total	\$ 1,636,904

The Company has entered into stock option agreements with key employees, board members and consultants with exercise prices ranging from \$0.00 to \$17.00. These awards were approved by the Company's Board of Directors. The options expire ten years from the date of grant, subject to the terms applicable in the agreement.

The following tables summarize the stock option activity for the nine months ended September 30, 2007 and 2006:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2006	483,490	\$ 2.17
Granted	543,000	\$ 9.82
Exercised	124,000	\$ 1.35
Forfeited	0	n/a
Outstanding at September 30, 2007	902,490	\$ 6.89

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2005	324,240	\$ .82
Granted	161,750	\$ 4.92
Exercised	625	\$ 4.50
Forfeited	1,875	\$ 4.50
Outstanding at September 31, 2006	483,490	\$ 2.17

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:

	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2006	814,424	\$ 3.36
Granted	2,687,602	\$ 10.40
Exercised	48,758	\$ 2.00
Forfeited	--	N/A
Outstanding at September 30, 2007	3,453,268	\$ 8.86





	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2005	594,424	\$ 1.61
Granted	170,000	\$ 8.70
Exercised	--	N/A
Forfeited	--	N/A
Outstanding at September 30, 2006	764,424	\$ 3.19

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

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

#### **Note 5. Subsequent Events**

No material subsequent events have occurred since the balance sheet date of September 30, 2007.

## **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 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-KSB for the year ended December 31, 2006.*

### **Overview**

#### ***General Overview***

We commenced business operations in June 2003. We are a drug discovery and development company leveraging our proprietary scientific research and discoveries relating to programmed cell death to treat cancer and protect normal tissues from exposure to radiation and other stresses.

#### ***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 nuclear 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 side effects of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe side effects 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.

#### ***Products In Development***

#### **Protectans**

Protectans are modified factors of microbes that protect cells from apoptosis, and have a broad spectrum of potential applications. These potential applications include 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 side effects.

### *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 acts as a natural activator of NF- $\kappa$ B. Protectan CBLB502 is administered through intramuscular injection.

### Biodefense Applications

In collaboration with the Cleveland Clinic, our scientists have demonstrated that injecting Protectan CBLB502 into mice 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.

Our research has also demonstrated that a single injection of less than 1% of the maximum tolerable dose of Protectan CBLB502 protected greater than 80% of NIH Swiss mice from exposure to as high as 13 Gy of total body irradiation. No other known compounds in development show this degree of protective effect from this level of radiation exposure.

Protectan CBLB502 also showed strong radioprotective efficacy as a single therapy in non-human primates, enabling the survival of 70% of the animals that received whole-body radiation, versus the control group, in which 75% of the animals died. Of the non-human primates in the control group that survived, none were without significant abnormalities. In contrast, the surviving non-human primates treated with CBLB502 possessed no significant structural abnormalities in their bone marrow, immune system organs, or small intestines after 40 days. This is consistent with data previously obtained from trials on mice. Irradiated mice treated with CBLB502 survived to their normal life span without developing any significant abnormalities and while preserving the normal formation of blood cells (hematopoiesis). This data suggests that CBLB502 may offer true protection from gamma-irradiation induced Acute Radiation Syndrome, including the lethal effects on both the GI and hematopoietic systems.

As in the protection regimen, a single-dose injection of Protectan CBLB502 given one hour after exposure (the mitigation regimen) to a lethal whole-body gamma irradiation increased the survival of rhesus monkeys from 20% in the control group to 70% in the treated group. Radiomitigation by Protectan CBLB502 was accompanied with less severe thrombocytopenia and neutropenia as well as reduced GI damage.

We have responded to the Request for Proposal (RFP) issued in March 2007, by The Department of Defense (DoD) for the Advanced Development of Medical Radiation Countermeasures (MRC) to treat gastrointestinal effects of acute radiation syndrome (ARS) using CBLB502. The objective of the RFP is to develop a post-exposure Medical Radiation Countermeasure through approval/licensure with the U.S. Food and Drug Administration (FDA) and procure quantities sufficient to achieve Initial Operational Capability (IOC). A range of 50,000 to 500,000 doses was specified. The RFP award would provide funding for development of the countermeasure through FDA approval, leading to purchase. We are anticipating the contract decision from the Department of Defense this year.

Also in March 2007, we received a \$1.3 million contract from the Defense Threat Reduction Agency (DTRA) of the Department of Defense (DoD) to fund "development leading to the acquisition" of Protectan CBLB502, in collaboration with the Armed Forces Radiobiology Research Institute (AFRRI), which has also received significant independent funding for work on Protectan CBLB502.

We have submitted responses to two Requests for Information (RFI) from the Department of Health and Human Services (HHS) and National Institute of Allergy and Infectious Diseases (NIAID) addressing medical countermeasures for neutropenia (low levels of neutrophils, a type of white blood cell) and thrombocytopenia (low platelet count) arising from Acute Radiation Syndrome (ARS).

The RFI from HHS noted the agency's intention to pursue initial acquisition of 100,000 treatment courses of a medical countermeasure for neutropenia arising as a consequence of ARS. The RFI further stated that there would be options for up to an additional 100,000 treatment courses to meet the HHS requirement of at least 200,000 treatment courses. We expect the RFP to be issued by HHS in the fourth quarter of 2007 with proposals due 60-90 days after the RFP is issued.

The RFI from NIAID requested the identification of therapeutics likely to be effective in preventing or reducing the development of thrombocytopenia, when administered after acute exposure to radiation. The NIAID RFI was distributed on behalf of the National Institutes of Health (NIH) and indicated that data obtained from this RFI would be used by the NIH in making recommendations and decisions regarding research and development of radiation countermeasures to meet the nation's biodefense needs. On September 27, 2007, NIAID announced a new grant initiative focused on the development of medical countermeasures to enhance platelet regeneration and thereby, increase survival after radiation exposure. The Company plans to submit the proposal in response to this solicitation by January 9, 2008.

#### Anticancer Applications

In addition to its military or other non-medical applications, we have found that Protectan CBLB502, on a preliminary research basis, 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. While protecting mice from lethal irradiation, Protectan CBLB502 had no effect on the radiosensitivity of tumor cells.

The use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs will be subject to the full FDA approval process.

#### Manufacturing

Together with our manufacturing partner, SynCo Bio Partners, we have completed the technology transfer and the production of the first cGMP batch of Protectan CBLB502 on schedule. The yields from the process and the purity of the final product exceeded our expectations. We currently have drug substance corresponding to over 100,000 projected human doses, or potentially many more, depending on the final therapeutic dose to be used, which will be determined in the coming months through our Phase I safety trial. The process we developed gives us the ability to manufacture up to five million estimated doses within a year without any additional scale-up; and, if necessary, scale-up could be implemented relatively easily.

#### *Protectan CBLB612*

Our Protectans 600 series are modified factors of Mycoplasmas. Much of our initial research in this area has been focused on radiation protection. Our lead candidate in this series, Protectan CBLB612, has been shown to provide protection in a mouse model from lethal hematopoietic-induced radiation sickness when administered between 48 hours prior or up to eight hours after radiation exposure. Protectan CBLB612 does not display any significant toxicity at its therapeutic doses in rodents and non-human primates.

Moreover, through our research in the area of radiation protection, we have discovered a unique property of the Protectans 600 series, which has led to a potential breakthrough in the rapidly emerging arena of stem cell research. A single administration of CBLB612 resulted in a three-fold increase in the number of progenitor stem cells in mouse bone marrow within 24 hours after administration. We also found that the number of these stem cells in peripheral blood was increased ten-fold within four days of administration. A study of the effects of Protectan CBLB612 on nonhuman primates regarding the proliferation and mobilization to peripheral blood of pluripotent hematopoietic stem cells in a primate model (Rhesus macaques) was recently completed. CBLB612 was found to be highly efficacious in stimulating proliferation and mobilization of hematopoietic stem cells into peripheral blood in these primates. A single

injection of CBLB612 in Rhesus macaques resulted in a 20- fold increase of hematopoietic progenitor cells in blood. Our research indicates that CBLB612 and the other compounds in the 600 series are not only potent stimulators of bone marrow stem cells, but also cause their mobilization and proliferation throughout the blood. This important discovery creates a new and innovative business opportunity for us to address a broad spectrum of human diseases, some of which currently lack effective treatment.



In a study of the efficacy of Protectan CBLB612, blood from healthy mice treated by Protectan CBLB612 was transplanted into mice that received a lethal dose of radiation that killed hematopoietic (bone marrow/blood production) stem cells. A small amount of blood from the CBLB612 treated mice successfully rescued the mice with radiation-induced bone marrow stem cell deficiency. 100% of the deficient mice transplanted with blood from CBLB612 treated mice survived past the 90 day mark, while 85% of the untreated deficient mice died within the first three weeks of the experiment. The 90 day mark is considered to be the critical point in defining the presence of long-term, adult bone marrow stem cells, which are capable of completely restoring lost or injured bone marrow function. The rescuing effect of the peripheral blood of the treated mice was equivalent to that of conventional bone marrow transplantation. This transplant study in particular, has advanced our research into clinical applications and suggests multiple potential uses within the field of regenerative medicine.

### **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 hormone refractory prostate cancer, renal cell carcinoma, or RCC, (a highly fatal form of kidney cancer), and soft-tissue sarcoma.

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

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

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

### *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 and continued at our research labs in Buffalo, NY which included testing in a variety of human tumor-derived cell lines representing cancers of different tissue origin (including RCC sarcomas, prostate, breast and colon carcinomas), we have observed that Curaxin CBLC102 behaves as a potent NF-kB suppressor and activator of p53 in these types of cancer cells. 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. The drug candidate is currently in Phase II clinical trials for treatment of hormone refractory prostate cancer. We also intend to conduct additional Phase II clinical trials with Curaxin CBLC102 for RCC and multiple myeloma.

We intend to seek orphan drug status with respect to Curaxin CBLC102. The orphan drug provisions of the Federal Food, Drug, and Cosmetic Act provide incentives to drug and biologic manufacturers to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S. We believe that Curaxin CBLC102 may qualify as an orphan drug for purposes of treatment of RCC and multiple myeloma. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first designated orphan drug approved by the FDA will be granted a seven-year period of marketing exclusivity for that drug. There is no assurance that we will receive orphan drug status for Curaxin CBLC102. Even if we do receive orphan drug status, while the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same indication and therefore may not provide sufficient protection against competitive products.

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. On May 26, 2006, we filed our IND application with the FDA to begin clinical trials in patients with hormone refractory prostate cancer. On June 26, 2006, the FDA advised us that we may initiate clinical Phase II studies after making additional minor modifications to the protocol. On June 5, 2007, we filed an amendment to the IND to include protocols for RCC Phase II clinical trials which are planned to start in November 2007.

Our Phase II efficacy study for Curaxin CBLC102 in advanced, hormone-refractory (androgen independent) prostate cancer has progressed to the next phase. The Phase II study will involve a total of 31 patients with advanced, hormone refractory prostate cancer. Primary endpoints for the study are reduction in PSA levels, reduction in tumor size, and disease-free survival. The duration of the study is two years; however certain preliminary data may be available earlier. The study is being conducted at the University of Chicago, the Cleveland Clinic, the University Hospitals of Cleveland, and the University of Pittsburgh.

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

#### *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. These molecules have a chemical structure different from 9-aminoacridine (Curaxin CBLC102) and are more active and appear to be more selective of tumor cells than the representatives of the first generation of curaxins (e.g., Curaxin CBLC102).

Following additional optimization, we are planning to embark upon the formal development of two to three additional second generation curaxins.

#### *Roswell Park Cancer Institute*

In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute (RPCI) to develop our cancer and radioprotectant drug candidates.

RPCI, founded in 1898, is a world-renowned cancer research hospital and the nation's first cancer research, treatment and education center. RPCI is a member of the prestigious National Comprehensive Cancer Network, an alliance of the nation's leading cancer centers, and is one of only ten free-standing cancer centers in the nation.

RPCI and various agencies of the state of New York will provide us with up to \$5 million of grant and other funding. We have established a major research/clinical facility at the RPCI campus in Buffalo, New York, which is the foundation for several of our advanced research and clinical trials. Dr. Andrei Gudkov, our Chief Scientific Officer, agreed to become Senior Vice President of Research Programming and Development for RPCI effective May 2007.

Our partnership with RPCI will enhance the speed and efficiency of our clinical research, and will provide us with access to state-of-the-art clinical development facilities in partnership with a globally recognized cancer research center. We believe that our proprietary technology, combined with the assistance of RPCI, and our continuing strong relationship with the Cleveland Clinic, will position us to become a leading oncology company. A key element of our long-term business strategy is to partner with world-class institutions to aid us in accelerating our drug development timeline. We believe that our firm alliances with both RPCI and the Cleveland Clinic provide us with a significant competitive advantage.

### ***Financial Overview***

We secured a \$6,000,000 investment via a private placement of Series A Preferred stock in March 2005. On July 20, 2006, we sold 1,700,000 shares of common stock in our initial public offering at \$6.00 per share. The net proceeds from this offering were approximately \$8,300,000. 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. In connection with the initial public offering, we issued warrants to purchase 170,000 shares of common stock to the underwriters and their designees. The warrants have an exercise price of \$8.70 per share.

On July 20, 2006, the effective date of our initial public offering, we issued 92,407 shares of common stock as accumulated dividends to the Series A Preferred stockholders. On the same date, all of our Series A Preferred shares automatically converted on a one-for-one basis into 3,351,219 shares of common stock, and notes of ours 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, we issued to each of our 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 ours 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. 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, unless exercised pursuant to the cashless exercise provisions. The registration statement was filed to satisfy registration rights that we had previously granted in connection with our Series A Preferred transaction.

On March 16, 2007, the Company entered into a Securities Purchase Agreement with various Buyers, pursuant to which the Company agreed to sell to the Buyers 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 aggregate purchase price paid by the Buyers for the Series B Preferred and Series B Warrants was approximately \$30,000,000. After related fees and expenses, the Company received net proceeds of approximately \$29,000,000. The Company is using 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 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.

The Company also issued to the 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 the Company's common stock, and Series C Warrants that are exercisable for 267,074 shares of the Company's common stock. The Series C Warrants have an exercise price of \$11.00 per share, and are also subject to anti-dilution protections that could increase the number of shares of common stock for which they are exercisable.

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

**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 expenses could be considered critical.

***Revenue Recognition***

We recognize revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition." Our revenue sources consist of government grants, government contracts and a commercial development contract.

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

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 September 30, 2007, \$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. 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, 2006, we have capitalized \$252,978 in expenditures associated with the preparation, filing and maintenance of certain of our patents, which were incurred through the year ended December 31, 2006. We capitalized an additional \$153,417 relating to these costs incurred for the nine months ended September 30, 2007, totaling \$406,395.



### ***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 compute an expected volatility based on similar high-growth, publicly-traded, biotechnology companies. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

During the quarter ended September 30, 2007, the Company granted 18,000 options pursuant to stock award agreements to a key consultant.

We recognized a total of \$395,129 and \$72,489 in expense for options for the quarter ended September 30, 2007, and 2006 respectively. The weighted average, estimated grant date fair values of stock options granted during the quarters ended September 30, 2007 and 2006 were \$4.95 and \$3.76, respectively.

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

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Correction - a Replacement of APB Opinion No. 20 and FASB Statement No. 3" ("SFAS 154"). SFAS 154 changes the requirements for the accounting for, and the reporting of, a change in accounting principle. SFAS 154 requires that a voluntary change in accounting principle be applied retroactively with all prior period financial statements presented under the new accounting principle. SFAS 154 is effective for accounting changes and corrections of errors in fiscal years beginning after December 15, 2005. We have determined that the adoption of the requirements required under SFAS 154 will not have a material impact on the financial statements of the company.

On July 15, 2006, the FASB issued FIN48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109*. We do not expect that the adoption of the recognition and measurement requirements required under FIN48 to have a material impact on the financial statements of the company.

In December 2004, SFAS No. 123(R), "Share-Based Payment," which addresses the accounting for employee stock options, was issued. SFAS 123(R) revises the disclosure provisions of SFAS 123 and supersedes APB Opinion No. 25. SFAS 123(R) requires that the cost of all employee stock options, as well as other equity-based compensation arrangements, be reflected in the financial statements based on the estimated fair value of the awards. This statement is effective for all public entities as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. We expect the adoption of SFAS 123R to increase our reported net loss per share.

In December 2004, the FASB issued SFAS 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29 (SFAS 153). The guidance in APB Opinion No. 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB Opinion No. 29, however, included certain exceptions to that principle. SFAS 153 amends APB Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We do not believe that the adoption of SFAS 153 will have a material impact on our results of operations or financial position.

## Results of Operations

Our operating results for the past three fiscal years have been nominal. The following table sets forth our statement of operations data for the quarter and nine months ended September 30, 2007 and September 30, 2006, and the year ended December 31, 2006 and December 31, 2005, 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-KSB for the year ended December 31, 2006.

	Quarter Ended September 30, 2007 (unaudited)	Quarter Ended September 30, 2006 (unaudited)	Nine Months Ended September 30, 2007 (unaudited)	Nine Months Ended September 30, 2006 (unaudited)	Year Ended December 31, 2006	Year Ended December 31, 2005
Revenues	\$ 660,544	\$ 323,368	\$ 1,617,996	\$ 1,476,787	\$ 1,708,214	\$ 1,138,831
Operating expenses	5,548,149	1,989,831	18,631,619	5,708,992	9,126,315	3,626,664
Other expense (income)	1,205,672	-	1,456,351	-	-	-
Net interest expense (income)	(305,568)	(78,933)	(760,561)	(114,521)	(195,457)	(101,378)
Net income (loss)	\$ (5,787,709)	\$ (1,587,530)	\$ (17,709,413)	\$ (4,117,684)	\$ (7,222,644)	\$ (2,386,455)

### Nine Months Ended September 30, 2007 Compared to Nine Months Ended September 30, 2006

#### Revenue

Revenue increased from \$1,476,787 for the nine months ended September 30, 2006 to \$1,617,996 for the nine months ended September 30, 2007 representing an increase of \$141,209 or 9.6% resulting primarily from an increase in revenue from various grants including the Collaborative Research Agreement with the Roswell Park Cancer Institute, 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 nine months ended September 30, 2007 as compared to \$1,100,293 for the nine months ended September 30, 2006.

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

Agency	Program	Amount	Period of Performance	Revenue 2007 (thru September 30) (unaudited)	Revenue 2006 (thru September 30) (unaudited)	Revenue 2006
NIH	BioShield program (NIAID)	\$ 1,500,000	07/2005-01/2007		\$ 1,100,293	\$ 1,100,293
NIH	Phase I NIH SBIR program	\$ 100,000	08/2005-01/2006		\$ 33,334	\$ 33,334
NASA	Phase I NASA STTR program	\$ 100,000	01/2006-01/2007	\$ 33,196	\$ 33,197	\$ 66,393
NIH	Phase II NIH SBIR program	\$ 750,000	07/2006-06/2008	\$ 280,461	\$ 88,320	\$ 212,713
NIH	NCI Contract	\$ 750,000	09/2006-08/2008	\$ 394,780	\$ 16,643	\$ 90,481
DoD	DTRA Contract	\$ 1,300,000	03/2007-02/2009	\$ 466,322		
NY State	RPCI Research Agreement	\$ 3,000,000	03/2007-02/2012	\$ 153,238		
Totals				\$ 1,327,997	\$ 1,271,787	\$ 1,503,214

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

### *Operating Expenses*

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

Operating expenses increased from \$5,708,992 for the nine months ended September 30, 2006 to \$18,631,619 for the nine months ended September 30, 2007, an increase of \$12,922,627 or 226.4%. The Company recognized a total of \$4,445,737 of noncash compensation for stock based compensation for the nine months ended September 30, 2007 compared to \$410,044 for the nine months ended September 30, 2006. If these noncash stock based compensation expenses were excluded, operating expenses would have increased from \$5,298,948 for the nine months ended September 30, 2006 to \$14,185,882 for the nine months ended September 30, 2007. This represents an increase in operating expenses of \$8,886,934 or 167.7%.

Research and development costs increased from \$4,341,535 for the nine months ended September 30, 2006 to \$11,663,054 for the nine months ended September 30, 2007. This represents an increase of \$7,321,519 or 168.6%. The higher research and development expenses were incurred as a result of increasing the number of research and

development personnel, commencing clinical trials for CBLC102 and completing the cGMP manufacturing of CBLB502. The Company recognized a total of \$199,609 of noncash compensation for R&D stock based compensation for the nine months ended September 30, 2006 compared to \$711,296 for the six months ended September 30, 2007 in R&D stock based compensation. Without the noncash stock based compensation, the R&D expenses increased from \$4,141,926 for the nine months ended September 30, 2006 to \$10,951,758 for the nine months ended September 30, 2007; an increase of \$6,809,832 or 164.4%.

Selling, general and administrative costs increased from \$1,367,457 for the nine months ended September 30, 2006 to \$6,968,565 for the nine months ended September 30, 2007. This represents an increase of \$5,601,108 or 409.6%. The company recognized a total of \$43,617 of noncash compensation for selling, general and administrative stock based compensation for the nine months ended September 30, 2006 compared to \$3,754,273 for the nine months ended September 30, 2007. Without the noncash stock based compensation, the selling, general and administrative expenses increased from \$1,323,840 for the nine months ended September 30, 2006 to \$3,214,292 for the nine months ended September 30, 2007; an increase of \$1,890,452 or 142.8%. The higher general and administrative expenses were incurred as a result of operating as a public company and improving 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, 2006 Compared to Year Ended December 31, 2005**

#### ***Revenue***

Revenue increased from \$1,138,831 for the year ended December 31, 2005 to \$1,708,214 for the year ended December 31, 2006, representing an increase of \$569,383 or 50%, resulting primarily from an increase in proceeds from the \$1,500,000 BioShield grant. The proceeds from the BioShield grant were \$1,100,293 for the year ended December 31, 2006 as compared to \$999,556 for all grant proceeds for the year ended December 31, 2005. Also, we realized \$205,000 for the year ended December 31, 2006 through a commercial contract with Peprotech Inc. to develop chemical compounds compared to \$139,275 for the year ended December 31, 2005.

#### ***Operating Expenses***

Operating expenses increased from \$3,626,664 for the year ended December 31, 2005 to \$9,126,315 for the year ended December 31, 2006. This represents an increase of \$5,499,651 or 152%. This increase resulted primarily from an increase in R&D expenses from \$2,640,240 for the year ended December 31, 2005 to \$6,989,804 for the year ended December 31, 2006, an increase of \$4,346,564 or 165%, as we increased the number of research scientists and related projects and started a number of clinical trials. In addition, general and administrative expenses increased from \$986,424 for the year ended December 31, 2005 to \$2,136,511, for the year ended December 31, 2006. This represents an increase of \$1,150,087 or 117%. 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.

#### **Liquidity and Capital Resources**

We have incurred annual operating losses since our inception, and, as of September 30, 2007, we had an accumulated deficit of \$31,293,236. 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 \$10,796,750 for the nine months ended September 30, 2007, compared to \$3,538,512 used in operating activities for the nine months ended September 30, 2006. Net cash used in operating activities totaled \$6,653,602 for the year ended December 31, 2006, compared to \$1,730,513 used in operating activities for the year ended December 31, 2005. For all periods, the increase in cash used was primarily attributable to increased R&D activities and creating, maintaining and improving the infrastructure necessary to support these R&D activities.

Net cash used in investing activities was \$238,716 for the nine months ended September 30, 2007, compared to net cash used in investing activities of \$749,752 for the nine months ended September 30, 2006. The decrease in cash used in investing activities resulted primarily from the liquidation of short term investments of \$996,131 as compared to a purchase of a short term investment of \$500,000 that was made during the nine months ended September 30, 2006. This was partially offset due to the increase in cash used for the issuance of the Notes Receivable, and increase in cash used to purchase equipment related to the company relocation. Net cash used in investing activities was \$14,281 for the year ended December 31, 2006 and \$2,805,113 used for the year ended December 31, 2005. The

decrease in cash used for investing activities resulted primarily from the maturing of short-term investments that converted to cash.

Net cash provided by financing activities totaled \$28,252,029 for the nine months ended September 30, 2007, compared to net cash provided by financing activities of \$8,523,413 for the nine months ended September 30, 2006. The increase in cash provided by financing activities was attributed to the proceeds from the issuance of preferred stock and warrants in the private placement offering. Net cash provided by financing activities totaled \$8,523,414 for the year ended December 31, 2006, compared to \$5,647,347 provided by financing activities for the year ended December 31, 2005. The increase in cash provided by financing activities was attributed to the proceeds from the issuance of common stock from the initial public 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	\$ 50,000
Complete Phase I studies for Protectan CBLB502	\$ 100,000
File NDA application for Protectan CBLB502	\$ 350,000
Receive regulatory approval to sell Protectan CBLB502	\$ 1,000,000
File IND application for Curaxin CBLC102 (completed May 2006)	\$ 50,000
Commence Phase II clinical trials for Curaxin CBLC102 (completed January 2007)	\$ 250,000
Commence Phase III clinical trials for Curaxin CBLC102	\$ 700,000
File NDA application for Curaxin CBLC102	\$ 1,500,000
Receive regulatory approval to sell Curaxin CBLC102	\$ 4,000,000

As of September 30, 2007, we have paid \$50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102 and paid \$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.

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.

Although we believe that existing cash resources will be sufficient to finance our currently planned operations for the near-term (9-21 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 changes in foreign currency exchange rates. We have entered into a manufacturing agreement with a foreign third party to produce one of our 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. As of September 30, 2007, we are obligated to make payments under the agreement of 539,017 Euros. We have established means to purchase forward contracts to hedge against this risk. As of September 30, 2007, hedging transactions totaling 197,847 Euros are in place

*Off-Balance Sheet Arrangements*

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

32

---

### **Item 3: Controls and Procedures**

#### **Effectiveness of Disclosure**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2007 as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2007, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective to assure that information required to be declared by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II Other Information**

**Item 1. Legal Proceedings**

As of September 30, 2007, we are 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 caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CLEVELAND BIOLABS, INC.

Dated: November 14, 2007

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

CLEVELAND BIOLABS, INC.

Dated: November 14, 2007

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