

CLEVELAND BIOLABS INC  
Form 10QSB  
November 13, 2006

**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, 2006

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.)**

**11000 Cedar Ave., Suite 290**  
**CLEVELAND, OHIO 44106**  
**(Address of principal executive offices and zip code)**

**(216) 229-2251**  
**(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, 2006 there were 11,826,389 shares of registrant's Common Stock, \$.005 par value

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

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CLEVELAND BIOLABS INC  
 10-Q  
 11/10/2006

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## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

September 30, 2006 (unaudited) and December 31, 2005

|                               | September 30<br>2006<br>(unaudited) | December 31<br>2005 |
|-------------------------------|-------------------------------------|---------------------|
| <b><u>ASSETS</u></b>          |                                     |                     |
| <b>CURRENT ASSETS</b>         |                                     |                     |
| Cash and equivalents          | \$ 5,441,611                        | \$ 1,206,462        |
| Short-term investments        | 2,892,447                           | 2,382,190           |
| Accounts receivable:          |                                     |                     |
| Trade                         | 76,644                              | -                   |
| Interest                      | 42,205                              | 37,035              |
| Prepaid expenses - IPO        | -                                   | 210,987             |
| Other prepaid expenses        | 144,978                             | 12,249              |
| Deferred compensation         | 846                                 | 5,134               |
| Total current assets          | 8,598,731                           | 3,854,057           |
| <b>EQUIPMENT</b>              |                                     |                     |
| Computer equipment            | 118,465                             | 91,788              |
| Lab equipment                 | 318,083                             | 225,997             |
| Furniture                     | 65,087                              | 40,158              |
|                               | 501,635                             | 357,943             |
| Less accumulated depreciation | 115,284                             | 47,080              |
|                               | 386,351                             | 310,863             |
| <b>OTHER ASSETS</b>           |                                     |                     |
| Deferred compensation         | 188                                 | 752                 |
| Intellectual Property         | 182,416                             | 76,357              |
| Deposits                      | 14,360                              | 11,304              |
|                               | 196,964                             | 88,413              |
| <b>TOTAL ASSETS</b>           | <b>\$ 9,182,046</b>                 | <b>\$ 4,253,333</b> |

## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

September 30, 2006 (unaudited) and December 31, 2005

|  | September 30<br>2006<br>(unaudited) | December 31<br>2005 |
|--|-------------------------------------|---------------------|
| <b><u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u></b>  |                                     |                     |
| <b>CURRENT LIABILITIES</b>   |                                     |                     |
| Accounts payable:  |                                     |                     |
| Trade  | \$ 573,581                          | \$ 264,783          |
| Deferred revenue   | -                                   | 100,293             |
| Accrued expenses   | 44,175                              | 28,579              |
| Total current liabilities  | 617,756                             | 393,655             |
| <b>LONG-TERM LIABILITIES</b>   |                                     |                     |
| Convertible notes payable  | -                                   | 303,074             |
| Milestone payables   | 50,000                              | -                   |
| Total long-term liabilities  | 50,000                              | 303,074             |
| <b>STOCKHOLDERS' EQUITY</b>  |                                     |                     |
| Series A convertible preferred stock, \$.005 par value   |                                     |                     |
| Authorized - 10,000,000 and 4,000,000 shares at September 30, 2006 and December 31, 2005, respectively           |                                     |                     |
| Issued and outstanding -0- and 3,051,219 shares at September 30, 2006 and December 31, 2005, respectively        | -                                   | 15,256              |
| Additional paid-in capital   | -                                   | 4,932,885           |
| Unissued shares - preferred stock  | -                                   | 360,000             |
| Common stock, \$.005 par value   |                                     |                     |
| Authorized - 40,000,000 and 12,000,000 shares at September 30, 2006 and December 31, 2005, respectively          |                                     |                     |
| Issued and outstanding 11,826,389 and 6,396,801 shares at September 30, 2006 and December 31, 2005, respectively | 59,132                              | 31,984              |
| Additional paid-in capital   | 18,133,661                          | 3,338,020           |
| Unissued shares - common stock   | -                                   | 81,125              |
| Accumulated other comprehensive income (loss)  | (7,553)                             | (17,810)            |
| Accumulated deficit  | (9,670,950)                         | (5,184,856)         |
| Total stockholders' equity   | 8,514,290                           | 3,556,604           |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>  | <b>\$ 9,182,046</b>                 | <b>\$ 4,253,333</b> |

## CLEVELAND BIOLABS, INC.

## STATEMENT OF OPERATIONS

Three Months and Nine Months Ending September 30, 2006 and 2005 (unaudited)

|  | Three Months Ended                  |                                     | Nine Months Ended                   |                                     |
|--|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
|  | September 30<br>2006<br>(unaudited) | September 30<br>2005<br>(unaudited) | September 30<br>2006<br>(unaudited) | September 30<br>2005<br>(unaudited) |
| <b>REVENUES</b>  |                                     |                                     |                                     |                                     |
| Grant  | \$ 263,368                          | \$ 446,194                          | \$ 1,271,787                        | \$ 624,850                          |
| Service  | 60,000                              | 120,000                             | 205,000                             | 139,275                             |
|  | 323,368                             | 566,194                             | 1,476,787                           | 764,125                             |
| <b>OPERATING EXPENSES</b>  |                                     |                                     |                                     |                                     |
| Research and Development   | 1,281,055                           | 846,454                             | 4,341,535                           | 1,507,040                           |
| Selling, general and administrative  | 708,776                             | 406,958                             | 1,367,457                           | 778,638                             |
| Total operating expenses   | 1,989,831                           | 1,253,412                           | 5,708,992                           | 2,285,678                           |
| <b>LOSS FROM OPERATIONS</b>  | <b>(1,666,463)</b>                  | <b>(687,218)</b>                    | <b>(4,232,205)</b>                  | <b>(1,521,553)</b>                  |
| <b>OTHER INCOME</b>  |                                     |                                     |                                     |                                     |
| Interest Income  | 81,189                              | 37,315                              | 125,719                             | 83,952                              |
| <b>OTHER EXPENSE</b>   |                                     |                                     |                                     |                                     |
| Interest Expense   | 2,257                               | 4,287                               | 11,198                              | 13,558                              |
| <b>NET LOSS</b>  | <b>\$ (1,587,530)</b>               | <b>\$ (654,190)</b>                 | <b>\$ (4,117,684)</b>               | <b>\$ (1,451,159)</b>               |
| <b>DIVIDENDS ON CONVERTIBLE<br/>PREFERRED STOCK</b>  | <b>(22,035)</b>                     | <b>(92,289)</b>                     | <b>(215,933)</b>                    | <b>(199,625)</b>                    |
| <b>NET LOSS AVAILABLE TO<br/>COMMON SHAREHOLDERS</b>   | <b>\$ (1,609,565)</b>               | <b>\$ (746,479)</b>                 | <b>\$ (4,333,617)</b>               | <b>\$ (1,650,784)</b>               |
| <b>NET LOSS AVAILABLE TO<br/>COMMON SHAREHOLDERS<br/>PER SHARE OF COMMON STOCK<br/>- BASIC AND<br/>DILUTED</b>     | <b>\$ (0.15)</b>                    | <b>\$ (0.12)</b>                    | <b>\$ (0.55)</b>                    | <b>\$ (0.27)</b>                    |
| <b>WEIGHTED AVERAGE NUMBER<br/>OF SHARES USED<br/>IN CALCULATING NET LOSS PER<br/>SHARE, BASIC AND<br/>DILUTED</b> | <b>10,681,032</b>                   | <b>6,314,531</b>                    | <b>7,922,195</b>                    | <b>6,201,126</b>                    |

## CLEVELAND BIOLABS, INC.

## STATEMENTS OF CASH FLOWS

Nine Months Ending September 30, 2006 and 2005 (unaudited)

|  | September 30<br>2006<br>(unaudited) | September 30<br>2005<br>(unaudited) |
|--|-------------------------------------|-------------------------------------|
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>                                    |                                     |                                     |
| Net loss   | \$ (4,117,684)                      | \$ (1,451,159)                      |
| Adjustments to reconcile net loss to net cash<br>used by operating activities: |                                     |                                     |
| Depreciation   | 68,204                              | 27,720                              |
| Noncash interest expense   | 9,929                               | 11,120                              |
| Noncash salaries and consulting expense  | 439,684                             | 225,944                             |
| Deferred compensation  | 4,852                               | (165,000)                           |
| Changes in operating assets and liabilities:                                   |                                     |                                     |
| Accounts receivable - trade  | (76,644)                            | 20,485                              |
| Accounts receivable - interest   | (5,170)                             | -                                   |
| Other prepaid expenses   | (132,729)                           | 6,616                               |
| Deposits   | (3,055)                             | (4,551)                             |
| Accounts payable   | 308,797                             | (60,821)                            |
| Deferred revenue   | (100,293)                           | -                                   |
| Accrued expenses   | 15,596                              | (33,011)                            |
| Milestone payments   | 50,000                              | -                                   |
| Total adjustments  | 579,172                             | 28,502                              |
| Net cash used in operating activities  | \$ (3,538,512)                      | \$ (1,422,657)                      |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                                    |                                     |                                     |
| Sale (purchase) of short-term investments                                      | (500,000)                           | (1,600,000)                         |
| Purchase of equipment  | (143,693)                           | (293,145)                           |
| Costs of patents pending   | (106,059)                           | -                                   |
| Net cash provided by (used in) investing activities                            | \$ (749,752)                        | \$ (1,893,145)                      |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>                                    |                                     |                                     |
| Issuance of preferred stock  | -                                   | 6,000,000                           |
| Financing costs  | (1,679,456)                         | (48,939)                            |
| Dividends  | (43)                                | (31)                                |
| Issuance of common stock - IPO   | 10,200,000                          | -                                   |
| Exercise of stock options  | 2,813                               | -                                   |
| Issuance of warrants   | 100                                 | -                                   |
| Proceeds from convertible notes payable  | -                                   | (50,000)                            |
| Net cash provided by (used in) financing activities                            | 8,523,413                           | 5,901,030                           |
| <b>NET INCREASE IN CASH AND EQUIVALENTS</b>                                    | <b>4,235,149</b>                    | <b>2,585,228</b>                    |
| <b>CASH AND EQUIVALENTS AT BEGINNING OF PERIOD</b>                             | <b>1,206,462</b>                    | <b>94,741</b>                       |
| <b>CASH AND EQUIVALENTS AT END OF PERIOD</b>                                   | <b>\$ 5,441,611</b>                 | <b>\$ 2,679,969</b>                 |

|   | September 30<br>2006<br>(unaudited) | September 30<br>2005<br>(unaudited) |
|---|-------------------------------------|-------------------------------------|
| Supplemental disclosures of cash flow information:                    |                                     |                                     |
| Cash paid during the period for interest                              | \$ 1,269                            | \$ -                                |
| Cash paid during the year for income taxes                            | \$ -                                | \$ -                                |
| Supplemental schedule of noncash financing activities:                |                                     |                                     |
| Issuance of stock options to employees and consultants                | \$ 439,684                          | \$ 345,144                          |
| Conversion of notes payable and accrued interest to common stock      | \$ 313,003                          | -                                   |
| Conversion of preferred stock to common stock                         | \$ 5,308,142                        | -                                   |
| Issuance of common stock dividend to preferred shareholders           | \$ 368,366                          | \$ 138,402                          |
| Common stock issued as financing fees on issuance of preferred shares | \$ -                                | \$ 589,662                          |
| Conversion of notes payable and accrued interest to preferred stock   | \$ -                                | \$ 102,438                          |
| Exercise of stock options into 59,600 common shares by consultant     | \$ -                                | \$ 119,200                          |



## CLEVELAND BIOLABS, INC

## STATEMENTS OF STOCKHOLDERS' EQUITY

Period From January 1, 2005 to December 31, 2005 and to September 30, 2006 (unaudited)

|  | Common Stock |           |                               |                |
|--|--------------|-----------|-------------------------------|----------------|
|  | Shares       | Amount    | Additional<br>Paid-in Capital | Penalty Shares |
| Balance at January 1, 2005   | 5,960,000    | 29,800    | 2,255,954                     | -              |
| Issuance of shares - Series A financing                            | 308,000      | 1,540     | 588,122                       | -              |
| Issuance of shares - stock dividend                                | 69,201       | 346       | 138,056                       | -              |
| Issuance of options (383,840 options issued, 324,240 outstanding)  |              |           | 318,111                       |                |
| Exercise of options (59,600 options exercised)                     | 59,600       | 298       | 118,902                       | -              |
| Unrealized loss on investments                                     |              |           | -                             | -              |
| Accrue unissued shares   | -            | -         | (81,125)                      | 81,125         |
| Net loss   | -            | -         | -                             | -              |
| Balance at December 31, 2005                                       | 6,396,801    | 31,984    | 3,338,020                     | 81,125         |
| Issuance of shares - previously accrued penalty shares (unaudited) | 54,060       | 270       | 80,855                        | (81,125)       |
| Issuance of shares - stock dividend (unaudited)                    | 184,183      | 922       | 367,445                       | -              |
| Issue penalty shares (unaudited)                                   | 15,295       | 76        | (76)                          | -              |
| Issuance of shares - initial public offering (unaudited)           | 1,700,000    | 8,500     | 10,191,500                    |                |
| Fees associated with initial public offering (unaudited)           |              |           | (1,890,444)                   |                |
| Conversion of preferred stock to common stock (unaudited)          | 3,351,219    | 16,756    | 5,291,385                     |                |
| Conversion of notes payable to common stock (unaudited)            | 124,206      | 621       | 312,382                       |                |
| Issuance of options (unaudited)                                    | -            | -         | 439,684                       | -              |
| Exercise of options (unaudited)                                    | 625          | 3         | 2,810                         |                |
| Issuance of warrants (unaudited)                                   |              |           | 100                           |                |
| Unrealized gain/(loss) on investments (unaudited)                  | -            | -         | -                             | -              |
| Net loss (unaudited)   | -            | -         | -                             | -              |
| Balance at September 30, 2006 (unaudited)                          | 11,826,389   | \$ 59,132 | \$ 18,133,661                 | \$ -           |

## CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY

Period From January 1, 2005 to December 31, 2005 and to September 30, 2006 (unaudited)

|   | Shares      | Preferred Stock<br>Amount | Additional<br>Paid-in<br>Capital | Penalty<br>Shares | Other<br>Comprehensive<br>Loss | Accumulated<br>Deficit | Total       |
|---|-------------|---------------------------|----------------------------------|-------------------|--------------------------------|------------------------|-------------|
| Balance at January 1,<br>2005   | -           | -                         | -                                | -                 | -                              | (2,659,968)            | (374,214)   |
| Issuance of shares -<br>Series A financing                                  | 3,051,219   | 15,256                    | 5,292,885                        | -                 | -                              | -                      | 5,897,803   |
| Issuance of shares -<br>stock dividend                                      | -           | -                         | -                                | -                 | -                              | (138,433)              | (31)        |
| Issuance of options<br>(383,840 options<br>issued,<br>324,240 outstanding)  | -           | -                         | -                                | -                 | -                              | -                      | 318,111     |
| Exercise of options<br>(59,600 options<br>exercised)                        | -           | -                         | -                                | -                 | -                              | -                      | 119,200     |
| Unrealized loss on<br>investments   | -           | -                         | -                                | -                 | (17,810)                       | -                      | (17,810)    |
| Accrue unissued<br>shares   | -           | -                         | (360,000)                        | 360,000           | -                              | -                      | -           |
| Net loss  | -           | -                         | -                                | -                 | -                              | (2,386,455)            | (2,386,455) |
| Balance at December<br>31, 2005   | 3,051,219   | 15,256                    | 4,932,885                        | 360,000           | (17,810)                       | (5,184,856)            | 3,556,604   |
| Issuance of shares -<br>previously accrued<br>penalty shares<br>(unaudited) | 240,000     | 1,200                     | 358,800                          | (360,000)         | -                              | -                      | -           |
| Issuance of shares -<br>stock dividend<br>(unaudited)                       | -           | -                         | -                                | -                 | -                              | (368,410)              | (43)        |
| Issue penalty shares<br>(unaudited)   | 60,000      | 300                       | (300)                            | -                 | -                              | -                      | -           |
| Issuance of shares -<br>initial public offering<br>(unaudited)              | -           | -                         | -                                | -                 | -                              | -                      | 10,200,000  |
| Fees associated with<br>initial public offering<br>(unaudited)              | -           | -                         | -                                | -                 | -                              | -                      | (1,890,444) |
| Conversion of<br>preferred stock to<br>common stock<br>(unaudited)          | (3,351,219) | (16,756)                  | (5,291,385)                      | -                 | -                              | -                      | -           |

|   |      |      |      |      |           |               |             |
|---|------|------|------|------|-----------|---------------|-------------|
| Conversion of notes payable to common stock (unaudited) |      |      |      |      |           |               | 313,003     |
| Compensation for stock options (unaudited)              | -    | -    | -    | -    | -         | -             | 439,684     |
| Exercise of stock options (unaudited)                   | -    | -    | -    | -    | -         | -             | 2,813       |
| Issuance of warrants (unaudited)                        | -    | -    | -    | -    | -         | -             | 100         |
| Unrealized gain/(loss) on investments (unaudited)       | -    | -    | -    | -    | 10,257    | -             | 10,257      |
| Net loss (unaudited)                                    | -    | -    | -    | -    | -         | (4,117,684)   | (4,117,684) |
| Balance at September 30, 2006 (unaudited)               | - \$ | - \$ | - \$ | - \$ | (7,553)\$ | (9,670,950)\$ | 8,514,290   |

**CLEVELAND BIOLABS, INC.**  
**NOTES TO UNAUDITED FINANCIAL STATEMENTS**

**Note 1. Summary of Significant Accounting Policies**

- A. Basis of Presentation - The information at September 30, 2006 and September 30, 2005, and for the three and nine-month periods ended September 30, 2006 and September 30, 2005, 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 Cleveland BioLabs, Inc.'s ("CBL" or the "Company") audited financial statements for the year ended December 31, 2005, which was contained in the Company's Form SB-2 registration statement filed with the United States Securities and Exchange Commission.
- B. Use of Estimates - The preparation of the unaudited financial statements in conformity with accounting principles generally accepted in the United States of America 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.
- C. 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 \$24,514 and \$16,055 for the quarters ended September 30, 2006 and 2005, respectively. Depreciation expense was \$68,206 and \$27,720 for the nine months ended September 30, 2006 and 2005, respectively.
- D. Intellectual Property - As a result of ongoing research and development efforts, there have been additional capitalized costs since December 31, 2005 associated with the preparation, filing, and maintenance of certain intellectual property rights. Gross capitalized patents pending costs are \$173,031 on behalf of the Cleveland Clinic Foundation ("CCF") for 12 patent applications as of September 30, 2006. All of the 12 CCF patent applications are still pending approval. The Company also has submitted two patent applications as a result of intellectual property exclusively developed and owned by the Company. Gross capitalized patents pending costs were \$9,385 for the two patent applications as of September 30, 2006. These patent applications are still pending approval. If these 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 applications are not approved, the costs associated with the preparation and filing of the patent application will be expensed as part of selling, general and administrative expenses at that time.
- E. Working Capital Line of Credit - To more effectively match short-term investment maturities with cash flow requirements, the Company has obtained a working capital line of credit which is fully-secured by the short-term investments. This fully-secured, working capital line of credit has a rate of Prime minus 1%, a borrowing limit of \$500,000, and an expiration date of July 1, 2007. At September 30, 2006, there were no outstanding borrowings under this credit facility.

F. Stock-Based Compensation - The FASB issued SFAS No. 123 (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 using the Black-Scholes option valuation model. 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 based on published rates from the St. Louis Federal Reserve at the time of the option grant; 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 as described in SEC Staff Accounting Bulletin No. 107; and computes 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.

On March 1, 2006, the Company granted 116,750 options pursuant to stock award agreements to certain employees and key consultants. On July 20, 2006 the Company granted 45,000 fully-vested, stock options to independent board members pursuant to stock award agreements. The assumptions used to value these option grants using the Black-Scholes option valuation model are as follows:

|                         | <b>March 1, 2006</b> | <b>July 20, 2006</b> |
|-------------------------|----------------------|----------------------|
| Risk-free interest rate | 4.66%                | 5.04%                |
| Expected dividend yield | 0%                   | 0%                   |
| Expected life           | 5 years              | 5 years              |
| Expected volatility     | 75.11%               | 71.43%               |

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes valuations model requires the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's options.

For the quarter ended September 30, 2006, the Company recognized \$72,489 in expense for stock based compensation under SFAS No. 123 (R). The Company recognized a total of \$439,684 and \$345,144 in expense for options for the nine-months ended September 30, 2006, and 2005, respectively.

The weighted average, estimated fair values of stock options granted during the nine-month period ended September 30, 2006 was \$3.14.

The following tables summarize the stock option activity for the nine-months ended September 30, 2006 and 2005.

|                                 | Shares  | Weighted<br>Average<br>Exercise<br>Price per<br>Share | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(in Years) |
|---------------------------------|---------|---|---|
| Outstanding, December 31, 2005  | 324,240 | \$ 0.82   |   |
| Granted, March 1, 2006          | 116,750 | 4.50  |   |
| Granted, July 20, 2006          | 45,000  | 6.00  |   |
| 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  |

|                                 | Options | Weighted<br>Average<br>Exercise<br>Price per<br>Share | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(in Years) |
|---------------------------------|---------|---|---|
| Outstanding, December 31, 2004  | -       | \$ -  |   |
| Granted, March 1, 2005          | 10,000  | 3.00  |   |
| Granted, July 1, 2005           | 294,240 | 0.66  |   |
| Exercised                       | -       | -   |   |
| Forfeited, Canceled             | -       | -   |   |
| Outstanding, September 30, 2005 | 304,240 | \$ 0.74   | 9.74  |
| Exercisable, September 30, 2005 | 83,560  | \$ 3.00   | 9.71  |

## Note 2. Stock Transactions

As a condition of the issuance of the Series A preferred stock in March 2005, a provision exists that all holders of Series A preferred stock will receive an additional 2% of all preferred stock, common stock and warrants that each Series A preferred stockholder owns for each 30 day period that a delay occurs in a required transaction. These penalty shares are not subject to compounding or prorating based on the number of days of delay. They are earned at the end of each 30-day penalty period. For the first quarter of 2006, one penalty period occurred in which 60,000 shares of Series A preferred stock were earned at \$120,000. In addition, 13,515 shares of common stock were earned at \$27,030. The penalty shares were issued in January 2006.

Pursuant to an Amendment to the Series A Rights Agreement, dated as of February 17, 2006, the Company's obligation to issue penalty shares was suspended for a period of 70 days, subject to a one-time 45-day extension, while the Company's registration statement was being reviewed by the SEC.

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 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 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. In connection with its initial public offering, the Company issued 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 Securities and Exchange Commission 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.

### Note 3. 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:

|  | Three Months Ended                  |                                     | Nine Months Ended                   |                                     |
|--|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
|  | September 30<br>2006<br>(unaudited) | September 30<br>2005<br>(unaudited) | September 30<br>2006<br>(unaudited) | September 30<br>2005<br>(unaudited) |
| NET LOSS AVAILABLE TO<br>COMMON SHAREHOLDERS   | \$ (1,609,565)                      | \$ (746,479)                        | \$ (4,333,617)                      | \$ (1,650,784)                      |
| NET LOSS AVAILABLE TO<br>COMMON SHAREHOLDERS PER<br>SHARE OF COMMON STOCK -<br>BASIC AND DILUTED     | \$ (0.15)                           | \$ (0.12)                           | \$ (0.55)                           | \$ (0.27)                           |
| WEIGHTED AVERAGE NUMBER<br>OF SHARES USED<br>IN CALCULATING NET LOSS PER<br>SHARE, BASIC AND DILUTED | 10,681,032                          | 6,314,531                           | 7,922,195                           | 6,201,126                           |



The Company has included \$22,035 and \$92,289 in the numerator for the quarter ended September 30, 2006 and 2005, respectively, to account for cumulative dividends for Series A preferred stock that were either paid or accrued throughout the period. The Company has included \$215,933 and \$199,625 in the numerator for the nine months ended September 30, 2006 and 2005, respectively, to account for cumulative dividends for Series A preferred stock that were either paid or accrued throughout the period.

The Company has excluded all outstanding warrants, options, and shares of Series A preferred stock 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 764,424 and 594,424 for the periods ended September 30, 2006 and 2005 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 483,490 and 304,240 for the periods ended September 30, 2006 and 2005, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

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

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company's fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an investigational new drug application to the U.S. Food and Drug Administration, or 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.

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 Cleveland, Ohio 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 \$112,967 and \$18,900 in 2005 and 2004, respectively. The Company recognized \$42,715 and \$35,196 in operating lease expenses for the quarter ended September 30, 2006 and 2005 and \$117,824 and \$51,296 for the nine months ended September 30, 2006 and 2005, respectively.

Annual future minimum lease payments under present lease commitments are as follows as of September 30, 2006. These future minimum payments have not been adjusted to reflect an inflation adjustment included into the lease for the Cleveland facilities based on the Gross Domestic Product Price Deflator.

|                      | <b>Operating<br/>Leases</b> |
|----------------------|-----------------------------|
| 2006 balance of year | \$ 43,745                   |
| 2007                 | 155,997                     |
| 2008                 | 53,137                      |
| 2009 and Beyond      | 1,935                       |
|                      | \$ 254,814                  |

The Company has entered into stock option agreements with key employees, board members and consultants with exercise prices ranging from \$0.00 to \$6.00. These awards were approved by the Board of Directors. Option grants beginning in 2005 vest ratably over periods ranging from zero to three years. The options expire ten years from the date of grant, subject to the terms applicable in the agreement. A list of the total stock options awarded and exercised appears below:

|                                   | <b>Number of<br/>Options</b> | <b>Weighted Average<br/>Exercise Price</b> |
|-----------------------------------|------------------------------|--|
| Outstanding at December 31, 2003  | —                            | N/A  |
| Granted                           | —                            | N/A  |
| Exercised                         | —                            | N/A  |
| Forfeited                         | —                            | N/A  |
| Outstanding at December 31, 2004  | —                            | N/A  |
| Granted                           | 383,840                      | \$ 0.69                                    |
| Exercised                         | 59,600                       | \$ —                                       |
| Forfeited                         | —                            | N/A  |
| Outstanding at December 31, 2005  | 324,240                      | \$ 0.82                                    |
| Granted                           | 161,750                      | \$ 4.92                                    |
| Exercised                         | 625                          | \$ 4.50                                    |
| Forfeited                         | 1,875                        | \$ 4.50                                    |
| Outstanding at September 30, 2006 | 483,490                      | \$ 2.17                                    |

The number of options and weighted average exercise price of options fully vested and exercisable for the years ending December 31, 2005 and 2004 were 83,560 and 0 options at \$0.88 and \$0 respectively. A table showing the number of options outstanding and exercisable (fully vested) appears below:

| Exercise Price | Outstanding          |  | Exercisable          |  |
|----------------|----------------------|--|----------------------|--|
|                | Number of<br>Options | Weighted Average<br>Years to<br>Expiration | Number of<br>Options |  |
| \$ 0.66        | 190,000              | 8.75                                       | 95,000               |  |
| 0.67           | 104,240              | 8.75                                       | 52,120               |  |
| 2.00           | 20,000               | 9.17                                       | 8,750                |  |
| 3.00           | 10,000               | 8.42                                       | 10,000               |  |
| 4.50           | 114,250              | 9.42                                       | 28,563               |  |
| 6.00           | 45,000               | 9.80                                       | 45,000               |  |
| Total          | 483,490              | 9.02                                       | 239,433              |  |

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

While no legal actions are currently pending, the Company may be party to certain claims brought against it arising from certain contractual matters. It is not possible to state the ultimate liability, if any, in these matters. In management's opinion, the ultimate resolution of any such claim will not have a material adverse effect on the financial position of the Company.

**Note 5. Subsequent Events**

On October 20, 2006, the Company finalized an agreement with SynCo Bio Partners B.V. to manufacture quantities of one of the Company's lead product candidates, Protectan CBLB502, for clinical trials and, if approved by governmental authorities, for commercial distribution. By virtue of this agreement, the Company has contractually committed 915,225 EUR (approximately \$1,120,000) for the process development activities and 995,000 EUR (approximately \$1,300,000) for manufacturing activities over the next fifteen months.

## 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.*

### Overview

We were formed in June 2003 as a development-stage company engaged in drug discovery. We have devoted substantially all of our resources to the identification, development and commercialization of new types of drugs for protection of normal tissue from exposure to radiation and other stresses, such as toxic chemicals and for cancer treatment. Our initial target is to develop a drug to protect humans from the effects of exposure to radiation, whether as a result of military or terrorist acts or as a result of a nuclear accident. Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have created a more immediate demand for further research and development in this area. Other potential applications of our drug candidates include reducing the side effects of cancer treatment as well as killing tumor cells.

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 or toxic chemicals or to internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack or acute renal failure. Conversely, apoptosis also is 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 attempt to 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 kill cancerous cells, we attempt to restore 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 be vital to the treatment of cancer patients.

Through our internal research and development efforts and our strategic partnerships, we have established a technological foundation for the development of new pharmaceuticals and their rapid preclinical evaluation. We have acquired rights to develop and commercialize the following prospective drugs:

- Protectans (CBLB500 and CBLB600 series) are modified proteins of microbes and tumors that protect cells from apoptosis, and, as a result, have a broad spectrum of potential applications. These potential applications include both

non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment side effects.

·Curaxins (CBLC100 series) are small molecules designed to kill tumor cells by simultaneously targeting two regulators of apoptosis. Initial test results indicate that curaxins can be effective against a number of malignancies, including renal cell carcinoma, or RCC (a highly fatal form of kidney cancer), soft-tissue sarcoma and hormone refractory prostate cancer.

Our R&D efforts are supported by agreements with our institutional founders, the Cleveland Clinic Foundation and ChemBridge Corporation. In September 2003, we commenced operations with funding from an R&D contract from the Cleveland Clinic employing two research scientists.

At the same time, our management team started our fund-raising efforts, which have resulted in significant grant and contract funding from NASA, NIH and DARPA. This funding, along with equity financing, allowed CBL to build a team consisting of 26 employees and several consultants and independent contractors as of September 30, 2006. As of September 30, 2006, we have received 12 grant and contract awards, totaling \$4,245,000.

An exclusive license from the Cleveland Clinic serves as a foundation for our intellectual property. As a result of this license, we have filed, on behalf of the Cleveland Clinic Foundation, a total of, 12 patent applications covering new classes of anticancer and radiation-protecting compounds, their utility and mode of action. Our relationship with ChemBridge has provided us with a 214,000 compound library to use in our high-throughput screening facility. Access to these compounds provides our scientists with a valuable resource to assist them in generating highly-promising hits against critically important cancer targets.

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

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. In connection with the initial public offering, we issued 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 Securities and Exchange Commission 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.

### **Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, 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.



The notes to our financial statements include disclosure of our significant accounting policies. While all decisions regarding accounting policies are important, we believe that the following policies 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 commercial development contracts.

Grant revenue is recognized in 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. To date, no milestone payments have been made, although \$50,000 has been accrued as of September 30, 2006 for milestone payments relating to the filing of an IND with the FDA for Curaxin CBL102. 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.

We have capitalized \$76,357 in expenditures associated with the preparation, filing and maintenance of certain of our patents, which we incurred during the year ended December 31, 2005. For the nine months ending September 30, 2006, we capitalized an additional \$106,059 relating to these costs, totaling \$182,416. These costs previously were expensed in selling, general and administrative expenses through December 31, 2004. For the periods ending December 31, 2004 and December 31, 2003, these costs were \$49,275 and \$21,690, respectively.



**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. We used the Black-Scholes valuation model to estimate the fair value of all options on the grant date.

**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 nine months ended September 30, 2006 and September 30, 2005, the quarter ended September 30, 2006 and September 30, 2005, and the year ended December 31, 2005, and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this filing.

|                               | <b>Quarter<br/>Ended Sept.<br/>30,<br/>2006<br/>(unaudited)</b> | <b>Quarter<br/>Ended Sept.<br/>30,<br/>2005<br/>(unaudited)</b> | <b>Nine Months<br/>Ended Sept.<br/>30,<br/>2006<br/>(unaudited)</b> | <b>Nine Months<br/>Ended Sept.<br/>30,<br/>2005<br/>(unaudited)</b> | <b>Year Ended<br/>December 31,<br/>2005</b> |
|-------------------------------|---|---|---|---|---|
| Revenues                      | \$ 323,368  | \$ 566,194  | \$ 1,476,787  | \$ 764,125  | \$ 1,138,831                                |
| Operating expenses            | 1,989,831   | 1,253,412   | 5,708,992   | 2,285,678   | 3,626,664                                   |
| Net interest expense (income) | (78,933)  | (33,028)  | (114,521)   | (70,394)  | (101,378)                                   |
| Net income (loss)             | \$ (1,587,530)  | \$ (654,190)  | \$ (4,117,684)  | \$ (1,451,159)  | \$ (2,386,455)                              |

**Nine Months Ended September 30, 2006 Compared to Nine Months Ended September 30, 2005****Revenue**

Revenue increased from \$764,125 for the nine months ended September 30, 2005 to \$1,476,787 for the nine months ended September 30, 2006 representing an increase of \$712,663 or 93% 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 nine months ended September 30, 2006 as compared to \$624,849 for all grant proceeds for the nine months ended September 30, 2005. Also, we realized \$205,000 for the nine months ended September 30, 2006 through a commercial contract with Peptotech Inc. to develop chemical compounds compared to \$130,525 for the same commercial contract for the nine months ended September 30, 2005.

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

| Agency | Program                            | Amount     | Period of<br>Performance | Revenue<br>2006<br>(thru<br>Sept. 30)<br>(unaudited) | Revenue<br>2005<br>(thru<br>Sept. 30)<br>(unaudited) | Revenue<br>2005 |
|--------|------------------------------------|------------|--------------------------|--|--|-----------------|
| NIH    | Phase I NIH<br>SBIR program        | \$ 100,000 | 08/2004-04/2005          |  | \$ 49,999  | \$ 49,998       |
| NIH    | NIH SBIR<br>Contract, Topic<br>186 | \$ 100,000 | 09/2004-03/2005          | —  | —  | —               |
| NIH    | Phase I NIH<br>STTR program        | \$ 100,000 | 08/2004-04/2005          |  | —  | —               |

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|              |                                 |              |                 |              |                       |
|--------------|---------------------------------|--------------|-----------------|--------------|-----------------------|
| <b>DARPA</b> | DARPA,<br>program<br>BAA04-12   | \$ 475,000   | 11/2004-08/2005 | -\$ 283,185  | \$ 283,185            |
| <b>NIH</b>   | Phase I NIH<br>SBIR program     | \$ 100,000   | 06/2005-01/2006 | -\$ 100,000  | \$ 100,000            |
| <b>NIH</b>   | BioShield<br>program<br>(NIAID) | \$ 1,500,000 | 07/2005-01/2007 | \$ 1,100,293 | \$ 150,000 \$ 399,707 |
| <b>NIH</b>   | Phase I NIH<br>SBIR program     | \$ 100,000   | 08/2005-01/2006 | \$ 33,334    | \$ 16,666 \$ 66,666   |
| <b>NIH</b>   | Phase I NIH<br>SBIR program     | \$ 100,000   | 09/2005-02/2006 | -\$ 25,000   | \$ 100,000            |
| <b>NASA</b>  | Phase I NASA<br>STTR program    | \$ 100,000   | 01/2006-01/2007 | \$ 33,197    | \$ —                  |
| <b>NIH</b>   | Phase II NIH<br>SBIR program    | \$ 750,000   | 07/2006-06/2008 | \$ 88,320    | \$ —                  |
| <b>NIH</b>   | NCI Contract                    | \$ 750,000   | 09/2006-08/2008 | \$ 16,643    | —                     |
| Totals       |                                 |              |                 | \$ 1,271,787 | \$ 624,850 \$ 999,556 |

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 will receive additional revenue from licensing fees.

### ***Operating Expenses***

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

Operating expenses increased from \$2,285,678 for the nine months ended September 30, 2005 to \$5,708,922 for the nine months ended September 30, 2006. This represents an increase of \$3,423,314 or 150%. This increase resulted primarily from an increase in R&D expenses from \$1,507,040 for the nine months ended September 30, 2005 to \$4,341,535 for the nine months ended September 30, 2006 as we increased the number of research scientists and related projects. In addition, higher general and administrative expenses were incurred as a result of creating and improving the infrastructure of the company.

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

### **Year Ended December 31, 2005 Compared to Year Ended December 31, 2004**

#### ***Revenue***

Revenue increased from \$636,341 for the year ended December 31, 2004 to \$1,138,831 for the year ended December 31, 2005 representing an increase of \$502,490 or 79.0%. This increase is primarily due to the increase from grants and contracts received through various government agencies including DARPA (Army) and NIH during 2005. Grant and contract revenue increased from \$531,341 for the year ended December 31, 2004 to \$999,556 for the year ended December 31, 2005 representing an increase of \$468,216 or 88.1%.

Revenue from other sources for the years ended December 31, 2005 and 2004 was \$139,275 and \$105,000 respectively. Other revenue in 2005 was earned solely through our commercial agreement with Peprotech, Inc. Other revenue in 2004 was earned from high throughput screening services for the Cleveland Clinic.

### ***Operating Expenses***

Operating expenses increased from \$3,155,784 for the year ended December 31, 2004 to \$3,626,664 for the year ended December 31, 2005. This represents an increase of \$470,880 or 14.9%. Of the \$3,155,784 in operating expenses for the year ended December 31, 2004, \$2,250,000 represents a non-cash expense regarding the valuation of 2,250 pre-stock split shares issued to the Cleveland Clinic in exchange for use of their licenses and technologies. Excluding this one-time, non-cash transaction, operating expenses increased from \$905,784 for the year ended December 31, 2004 to \$3,626,664 for the year ended December 31, 2005. This represents an increase of \$2,720,880 or 300.4%. This increase resulted primarily from an increase in R&D expenses from \$642,967 for the year ended December 31, 2004 (excluding the \$2,250,000 one-time, non cash transaction) to \$2,640,240 for the year ended December 31, 2005 incurred to service the above referenced operating revenue as well as for R&D expenses for internal projects. Research expenditures increased over time in 2004 reflecting our growth from two scientists at the beginning of the year to six scientists by year-end as compared to 2005 when there were 16 scientists at year-end. Research costs totaled \$1,782,155 for 2005 and \$471,195 in 2004 excluding the one-time, non-cash transaction with the Cleveland Clinic. Development activities did not begin until July 2005 and totaled \$546,252 in 2005. In addition, selling, general and administrative expenses of \$851,319 were incurred in 2005 versus \$434,450 in 2004 as a result of creating and improving our infrastructure as we moved into larger lab facilities in May 2005. Accounting and auditing fees also increased to \$70,667 in 2005 from \$2,246 in 2004 as we raised equity capital in March 2005 and began plans for our initial public offering.

### **Liquidity and Capital Resources**

We have incurred annual operating losses since our inception, and, as of September 30, 2006, we had an accumulated deficit of \$9,670,950. Our principal sources of liquidity have been cash provided by government grants and sales of our securities. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government grants, 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. We anticipate that the proceeds from our initial public offering should be sufficient to fully develop Protectan CBLB502 for non-medical applications; however, to complete the development of Curaxin CBLC102 and Protectan CBLB502 for medical applications, additional investment or revenue sources will be needed.

Net cash used in operating activities totaled \$3,538,512 for the nine months ended September 30, 2006, compared to \$1,422,657 used in operating activities for the same period in 2005. Net cash used in operating activities totaled \$1,730,512 for the year ended December 31, 2005, compared to \$207,911 used in operating activities for the same period in 2004. For all periods, the increase in cash used was primarily attributable to increased R&D activities and creating and maintaining the infrastructure necessary to support these R&D activities.

Net cash used in investing activities was \$749,752 for the nine months ended September 30, 2006 and \$1,893,145 used for the same period in 2005. The decrease in cash used for investing activities resulted primarily from the maturing of short-term investments that converted to cash. Net cash used in investing activities was \$2,805,113 for the year ended December 31, 2005 and \$27,991 for the same period in 2004. The increase resulted from investments in long-term certificates of deposit and by purchases of property and equipment.

Net cash provided by financing activities totaled \$8,523,413 for the nine months ended September 30, 2006, compared to \$5,901,030 provided by financing activities for the same period in 2005. The increase in cash provided by financing activities was attributed to the proceeds from the issuance of common stock as a consequence of the initial public offering. Net cash provided by financing activities totaled \$5,647,347 for the year ended December 31, 2005, compared to \$320,517 for the same period in 2004. The funds provided in the same period in 2005 and for the year ended December 31, 2005 were attributable primarily to the net proceeds from our private placement of Series A Preferred Stock in March 2005.



Although we believe that existing cash resources will be sufficient to fund our currently planned operations for the near-term, such amounts may 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 to 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. If we are unable to obtain additional funding in the required amounts, the development timeline for our products would slow or possibly be suspended. Delay or suspension of any of our R&D efforts could have an adverse impact on our ability to raise funds in the future, enter into collaborations with corporate partners or obtain additional federal funding from contracts or grants. 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 status 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 regulatory submissions, the amount of cash generated by our operations, the amount of competition we face and how successful we are with obtaining any required licenses and entering into collaboration arrangements.

Under our exclusive license agreement with the Cleveland Clinic, we may be responsible for making milestone payments to the Cleveland Clinic 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         | \$ 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 |

We have accrued \$50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102.

Our agreement with the Cleveland Clinic Foundation (CCF) also provides for payment by us to CCF of royalty payments calculated as a percentage of the net sales of the drug candidates ranging from 1-2%, and sublicense royalty payments calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%. However, any royalty payments and sublicense royalty payments assume that we will be able to commercialize our drug candidates, which are subject to numerous risks and uncertainties, including those associated with the regulatory approval process, our R&D process and other factors. Each of the above milestone payments, royalty payments and sublicense royalty payments will be accrued until CCF owns less than five percent of our common stock on a fully-diluted basis or we receive more than \$30,000,000 in funding and/or revenues from sources other than CCF, neither of which have occurred.

To more effectively match short-term investment maturities with cash flow requirements, we have obtained a working capital line of credit, which is fully secured by our short-term investments. This fully-secured, working capital line of credit has an interest rate of Prime minus 1%, a borrowing limit of \$500,000 and expires on July 1, 2007. At September 30, 2006, there were no outstanding borrowings under this credit facility.





***Impact of Inflation***

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

***Off-Balance Sheet Arrangements***

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

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### **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, 2006 as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2006, 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, 2006 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, 2006, we are not a party to any litigation or other legal proceeding.

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

The Securities and Exchange Commission declared our Registration Statement on Form SB-2 (File No. 333-131918) effective on July 20, 2006. Our initial public offering was consummated on July 26, 2006. In the initial public offering, we sold 1,700,000 shares of our common stock at an offering price of \$6.00 per share. Our underwriters were Sunrise Securities Corp. and Roth Capital Partners LLC. The sale of our common stock generated gross proceeds to us, after underwriting discounts and expenses, but before other expenses, of \$9,180,000 and net proceeds after expenses of approximately \$8,300,000. Net proceeds have been used to further the development of Protectan CBLB502 and Curaxin CBLC102, for working capital and general corporate purposes, including payment of bonuses to members of our executive management upon completion of our initial public offering in the aggregate amount of \$105,000 as reported in our filing on Form 8-K dated September 6, 2006. We intend to use the remaining proceeds to continue the development of Protectan CBLB502 and Curaxin CBLC102, to continue research and development related to new generations of drugs and for working capital and general corporate purposes.

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

None

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

None

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

Rule 14-8 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires that a stockholder intending to submit a proposal to be included in a company's proxy statement to be considered at a company's annual meeting notify the company of such proposal not less than 120 calendar days before the date of the proxy statement that the company released to shareholders the previous year or, if the company did not hold an annual meeting the previous year, a reasonable time before the company begins to print and mail the proxy statement for the current year's annual meeting. We did not have an annual meeting in 2006. Accordingly, to be included in the Company's Proxy Statement for the 2007 Annual Meeting, stockholder proposals should be received by the Company on or before January 8, 2007, which is approximately 90 calendar days before the anticipated date of the Company's proxy statement for the next annual meeting. In addition, the advance notice provisions in our bylaws require that a stockholder intending to submit a nomination to be considered at the Company's annual meeting must notify the Company's Secretary of such proposal within ten days following the day on which notice of the date of the annual meeting is mailed or public disclosure of the date of the annual meeting is made, whichever is first to occur.

### **Item 6. Exhibits**

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

| <b>Exhibit<br/>Number</b> | <b>Description of Document</b> |
|---------------------------|--------------------------------|
|---------------------------|--------------------------------|

- 31.1 Certification of Michael Fonstein, Chief Executive Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
- 31.2 Certification of John A. Marhofer, Jr., Chief Financial Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
- 32.1 Certification Pursuant To 18 U.S.C. Section 1350

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**Signatures**

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

CLEVELAND BIOLABS, INC.

Dated: November 13, 2006

By: /s/ JOHN A. MARHOFER, JR.

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

CLEVELAND BIOLABS, INC.

Dated: November 13, 2006

By: /s/ MICHAEL FONSTEIN.

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Michael Fonstein  
Chief Executive Officer  
(Principal Executive Officer)