CLEVELAND BIOLABS INC
Form 10-Q
May 07, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

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

For the transition period from ____ to ____

Commission file number 001-32954

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

| DELAWARE | 20-0077155 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 73 High Street, Buffalo, New York | 14203 |
| (Address of principal executive offices) | (Zip Code) |

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

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

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

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

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

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer x |
| Non-accelerated filer ¨ | Smaller reporting company ¨ |

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

As of April 30, 2012, there were 35,696,793 shares outstanding of registrant's common stock, par value $0.005 per share.

CLEVELAND BIOLABS INC. AND SUBSIDIARY
10-Q
5/7/2012

TABLE OF CONTENTS PAGE

In this report, except as otherwise stated or the context otherwise requires, the terms “Cleveland BioLabs” and “CBLI” refer to Cleveland BioLabs, Inc., but not its consolidated subsidiaries and the “Company,” “we,” “us” and “our” refer to Cleveland BioLabs, Inc. together with its consolidated subsidiaries. Our common stock, par value $0.005 per share, is referred to as “common stock.”

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

| | March 31, 2012 (unaudited) | December 31, 2011 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $18,111,487 | $22,872,589 |
| Short-term investments | 5,520,000 | 5,520,000 |
| Accounts receivable | 806,438 | 1,740,629 |
| Other current assets | 781,684 | 876,889 |
| Total current assets | 25,219,609 | 31,010,107 |
| | | |
| Equipment, net | 1,260,865 | 1,084,204 |
| Other long-term assets | 38,191 | 32,490 |
| | | |
| Total assets | $26,518,665 | $32,126,801 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| | | |
| Current liabilities: | | |
| Accounts payable | $1,068,568 | $909,144 |
| Accrued expenses | 2,224,774 | 1,686,202 |
| Accrued warrant liability | 5,566,203 | 7,285,959 |
| Current portion of capital lease obligation | 64,418 | - |
| Total current liabilities | 8,923,963 | 9,881,305 |
| | | |
| Noncurrent portion of capital lease obligation | 152,306 | - |
| | | |
| Commitments and contingencies | - | - |
| | | |
| Total liabilities | 9,076,269 | 9,881,305 |
| | | |
| Stockholders' equity: | | |
| Preferred stock, $.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of March 31, 2012 and December 31, 2011, respectively | - | - |
| Common stock, $.005 par value; 80,000,000 shares authorized, 35,692,593 and 35,612,192 shares issued and outstanding as of March 31, 2012 and December 31, 2011, respectively | 178,463 | 178,061 |
| Additional paid-in capital | 109,726,399 | 108,865,645 |
| Accumulated other comprehensive income | 500,163 | 84,613 |
| Accumulated deficit | (105,454,793) | (100,067,647) |
| Total Cleveland BioLabs, Inc. stockholders' equity | 4,950,232 | 9,060,672 |
| Noncontrolling interest in stockholders' equity | 12,492,164 | 13,184,824 |
| Total stockholders' equity | 17,442,396 | 22,245,496 |
| | | |
| Total liabilities and stockholders' equity | $26,518,665 | $32,126,801 |

See Notes to Consolidated Financial Statements

1

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

| | For the Three Months Ended March 31, | |
|---|---|---|
| | 2012 | 2011 |
| Revenues: | | |
| Grants and contracts | $ 931,397 | $ 2,473,982 |
| | | |
| Operating expenses: | | |
| Research and development | 5,985,801 | 5,708,933 |
| General and administrative | 2,427,471 | 1,877,202 |
| Total operating expenses | 8,413,272 | 7,586,135 |
| | | |
| Loss from operations | (7,481,875) | (5,112,153) |
| | | |
| Other income (expense): | | |
| Interest and other income | 55,641 | 49,023 |
| Foreign exchange gain (loss) | (692,416) | 32,715 |
| Change in value of warrant liability | 1,719,756 | (714,951) |
| Total other income (expense) | 1,082,981 | (633,213) |
| | | |
| Net loss | (6,398,894) | (5,745,366) |
| | | |
| | | |
| Net loss attributable to noncontrolling interests | 1,011,748 | 246,307 |
| | | |
| Net loss attributable to Cleveland BioLabs, Inc. | $ (5,387,146) | $ (5,499,059) |
| | | |
| Net loss available to common stockholders per share of common stock, basic and diluted | $ (0.15) | $ (0.19) |
| | | |
| Weighted average number of shares used in calculating net loss per share, basic and diluted | 35,657,563 | 29,110,979 |

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

| | For the Three Months Ended March 31, | |
|---|---|---|
| | 2012 | 2011 |
| Net loss including noncontrolling interests | $ (6,398,894) | $ (5,745,366) |
| Other comprehensive income | | |
| Foreign currency translation adjustment | 734,638 | 204,099 |
| | | |
| Comprehensive loss including noncontrolling interests | (5,664,256) | (5,541,267) |
| Comprehensive loss attributable to noncontrolling interests | 692,660 | 200,604 |
| | | |
| Comprehensive loss attributable to Cleveland BioLabs, Inc. | $ (4,971,596) | $ (5,340,663) |

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

| | For the Three Months Ended March 31, | |
|---|---|---|
| | 2012 | 2011 |
| Cash flows from operating activities: | | |
| Net loss | $ (6,398,894) | $ (5,745,366) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 127,411 | 103,501 |
| Amortization | - | 6,892 |
| Unrealized loss on short-term investments | 539,781 | - |
| Noncash compensation | 565,981 | 923,035 |
| Change in value of warrant liability | (1,719,756) | 714,951 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 1,001,603 | 3,129,152 |
| Other current assets | 115,161 | 364,824 |
| Other long-term assets | (4,671) | (15,628) |
| Accounts payable | 153,535 | 11,202 |
| Deferred revenue | - | (4,213) |
| Accrued expenses | 825,477 | (330,574) |
| Net cash used in operating activities | (4,794,372) | (842,224) |
| | | |
| Cash flows from investing activities: | | |
| Purchase of short-term investments | - | (1,442,189) |
| Purchase of equipment | (81,560) | (167,966) |
| Investment in patents | - | (120,215) |
| Net cash used in investing activities | (81,560) | (1,730,370) |
| | | |
| Cash flows from financing activities: | | |
| Noncontrolling interest capital contribution to Incuron, LLC | - | 2,340,374 |
| Exercise of options | 1,425 | 307,345 |
| Repayment of capital lease obligation | (4,966) | - |
| Warrant exercise fees | - | (31,207) |
| Exercise of warrants | - | 891,635 |
| | | |
| Net cash provided by (used in) financing activities | (3,541) | 3,508,147 |
| | | |
| Effect of exchange rate change on cash and equivalents | 118,371 | 164,716 |
| | | |
| Increase (decrease) in cash and cash equivalents | (4,761,102) | 1,100,269 |
| | | |
| Cash and cash equivalents at beginning of period | 22,872,589 | 10,918,537 |
| | | |
| Cash and cash equivalents at end of period | $ 18,111,487 | $ 12,018,806 |
| | | |
| Supplemental disclosure of cash flow information: | | |
| Cash paid during the period for interest | $ 2,646 | $ - |

| | | |
|---|---|---|
| Supplemental schedule of noncash financing activities: | | |
| Conversion of warrant liability to equity upon warrant exercise | $ - | $ 947,538 |
| Equipment acquired through lease financing | $ 221,690 | $ - |

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(UNAUDITED)

| | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Noncontrolling Interests | Total |
|---|---|---|---|---|---|---|---|
| Balance at January 1, 2012 | 35,612,192 | $178,061 | $108,865,645 | $84,613 | $(100,067,647) | $13,184,824 | $22,245,496 |
| Stock based compensation | 79,651 | 398 | 859,333 | - | - | - | 859,731 |
| Exercise of options | 750 | 4 | 1,421 | - | - | - | 1,425 |
| Net loss | - | - | - | - | (5,387,146 ) | (1,011,748 ) | (6,398,894 |
| Foreign currency translation | - | - | - | 415,550 | - | 319,088 | 734,638 |
| Balance at March 31, 2012 | 35,692,593 | $178,463 | $109,726,399 | $500,163 | $(105,454,793) | $12,492,164 | $17,442,396 |

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Description of Business

Cleveland BioLabs, Inc. (“CBLI”) is a clinical-stage biotechnology company with a focus on oncology indications. Since inception, CBLI has pursued the research, development and commercialization of products that have the potential to evidence direct anti-cancer activity, prevent and treat acute radiation syndrome and counteract the toxic effects of radio and chemotherapies for oncology patients.

CBLI was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York. CBLI has two majority-owned subsidiaries, Incuron, LLC (“Incuron”) and Panacela Labs Inc. (“Panacela”), which were formed in 2010 and 2011, respectively. Additionally, Panacela has a wholly-owned subsidiary, OOO “Panacela Labs.”

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited consolidated financial statements include the accounts of CBLI and its majority-owned subsidiaries, Incuron and Panacela, collectively referred to herein as the “Company.” All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the SEC.

In the opinion of the Company’s management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of March 31, 2012, along with its results of operations and cash flows for the three month periods ended March 31, 2012 and 2011. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, 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. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. As of March 31, 2012, CBLI, Panacela and Incuron held cash and cash equivalent balances of $12,977,441, $4,667,091 and $466,955, respectively. The cash and cash equivalents of each of our subsidiaries are restricted for their use only.

Short-Term Investments

The Company’s short-term investments are classified as held to maturity given the intent and ability to hold the investments to maturity. Accordingly, these investments are carried at amortized cost. Short-term investments classified as held-to-maturity consisted of certificates of deposit with maturity dates beyond three months and less than one year. As of March 31, 2012, $5,520,000 of short-term investments were restricted to the use of Panacela.

Significant Customers and Accounts Receivable

Grant and contract revenue from the United States government accounted for 100.0% and 99.8% of total revenue for the three months ended March 31, 2012 and 2011, respectively. Although the Company anticipates ongoing federal government contract and grant revenue, there is no guarantee that this revenue stream will continue in the future.

Accounts receivable consist of amounts due under reimbursement contracts with certain government and foreign entities. 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 that is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There were no allowances for doubtful accounts as of March 31, 2012 and December 31, 2011, as the collection history from the Company’s customers indicated that collection was probable.

Intellectual Property

Costs related to filing and pursuing patent applications are recognized as general and administrative expenses as incurred, since the recoverability of such expenditures is uncertain. Upon marketability approval by the U.S. Food and Drug Administration (“FDA”) or the respective foreign governing body, such costs will be capitalized and depreciated over the expected life of the related patent.

Line of Credit

CBLI has a working capital line of credit that is fully secured by cash equivalents and short-term investments. The working capital line of credit carries an interest rate equal to the prime rate, has a borrowing limit of $600,000, and expires on May 31, 2012. At March 31, 2012 and December 31, 2011, there were no outstanding borrowings under this credit facility.

Accounting for Stock-Based Compensation

The 2006 Equity Incentive Plan, as amended (the “Plan”), authorizes CBLI to grant (i) options to purchase common stock, (ii) restricted or unrestricted stock units, and (iii) stock appreciation rights, so long as the exercise or grant price of each are at least equal to the fair market value of the stock on the date of grant. As of March 31, 2012, an aggregate of 7.0 million shares of common stock were authorized for issuance under the Plan, of which a total of approximately 1.0 million shares of common stock remained available for future awards. A single participant cannot be awarded more than 400,000 shares annually. Awards granted under the Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Plan are specified in an award document, and approved by the Company’s compensation committee.

The Company estimates the fair value of all grants using the closing market price of CBLI’s common stock on the day of the grant. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below are the assumptions used in valuing the stock options granted and a discussion of the Company’s methodology for developing each of the assumptions used:

| | For the three months ended March 31, | |
|---|---|---|
| | 2012 | 2011 |
| Risk-free interest rate | .91 - 1.49 % | 1.96- 2.55% |

| | | | | |
|---|---|---|---|---|
| Expected dividend yield | 0 | % | 0 | % |
| Expected life | 5 - 6 Years | | 5 - 6 Years | |
| Expected volatility | 86.58 - 90.05 | % | 84.44 - 88.69 | % |

“Risk-free interest rate” means the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date the option is granted.

“Expected dividend yield” of zero is based on the fact that the Company has not historically paid regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

“Expected life” means the period of time that options granted are expected to remain outstanding, based solely on the use of the simplified (safe harbor) method. The simplified method is used because the Company does not yet have adequate historical exercise information to estimate the expected life the options granted.

“Expected volatility” is a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. Effective January 1, 2012, expected volatility is based on the historical volatility of the Company's common stock. Prior to that date, expected volatility was based on both the historical volatility of the Company's common stock and the volatility of the common stock of comparable companies when the expected life of the option exceeded the Company’s trading history.

Income Taxes

No income tax expense was recorded for the three months ended March 31, 2012 and 2011, as the Company does not expect to have taxable income for 2012 and did not have taxable income in 2011. A full valuation allowance has been recorded against the Company's deferred tax asset.

Earnings (Loss) per Share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted net loss per share is identical to basic net loss per share as potentially dilutive securities have been excluded from the calculation of diluted net loss per common share because the inclusion of such securities would be antidilutive.

The Company has excluded the following outstanding dilutive securities from the calculation of diluted net loss per share because all such securities were antidilutive for the periods presented:

| Common Equivalent Securities | As of March 31, 2012 | 2011 |
|---|---|---|
| Warrants | 7,533,620 | 9,103,596 |
| Options | 4,353,512 | 3,876,957 |
| Total | 11,887,132 | 12,980,553 |

Reclassifications

Certain amounts presented in the prior year financial statements have been reclassified to conform to the current year presentation.

Recently Issued Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04, Fair Value Measurement (Topic 820) ("ASU 2011-04"), which contains amendments to achieve common fair value measurement and disclosures in U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 explains how to measure fair value for financial reporting. The guidance does not require fair value measurements in addition to those already required or permitted by other Topics. This ASU was effective for the Company beginning January 1, 2012. The adoption of ASU 2011-04 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity, but did require expanded disclosures as set forth in Note 3, Fair Value of Financial Instruments.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income ("ASU 2011-05"). This guidance is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single statement or two-statement approach. This ASU was effective for the Company beginning January 1, 2012. The adoption of ASU 2011-05 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity. The Company elected to present comprehensive income (loss) in two separate but consecutive statements as part of the consolidated financial statements included in this Quarterly Report on Form 10-Q.

Contingencies

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.

3. Fair Value of Financial Instruments

The Company measures and records cash equivalents and warrant liabilities at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value, include:

Level 1 - Observable inputs for identical assets or liabilities such as quoted prices in active markets;
Level 2 - Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
Level 3 - Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The following tables represent the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2012 and December 31, 2011:

| | As of March 31, 2012 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $12,225,166 | $- | $- | $12,225,166 |
| Total assets | $12,225,166 | $- | $- | $12,225,166 |
| Liabilities: | | | | |
| Compensatory stock options not yet issued (2) | $- | $- | $85,000 | $85,000 |
| Accrued warrant liability | - | - | 5,566,203 | 5,566,203 |
| Total liabilities | $- | $- | $5,651,203 | $5,651,203 |

| | As of December 31, 2011 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $16,326,888 | $- | $- | $16,326,888 |
| Total assets | $16,326,888 | $- | $- | $16,326,888 |
| Liabilities: | | | | |
| Compensatory stock options not yet issued (2) | $- | $- | $378,750 | $378,750 |
| Accrued warrant liability | - | - | 7,285,959 | 7,285,959 |
| Total liabilities | $- | $- | $7,664,709 | $7,664,709 |

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.
(2) Included in accrued expenses in the accompanying consolidated balance sheets.

The Company uses the Black-Scholes model to measure the accrued warrant liability and its accrual for compensatory stock options not yet issued. The following are the assumptions used to measure the accrued warrant liability at March 31, 2012 and December 31, 2011, which were determined in a manner consistent with that described for grants of options to purchase common stock as set forth in Note 2:

| | March 31, 2012 | | December 31, 2011 | |
|---|---|---|---|---|
| Stock Price | $ 2.46 | | $ 2.86 | |
| Exercise Price | $ 1.60 - 5.00 | | $ 1.60 - 5.00 | |
| Term in years | 1.46 - 2.11 | | 1.58- 2.23 | |
| Volatility | 67.85 - 73.25 | % | 66.68 - 71.55 | % |
| Annual rate of quarterly dividends | 0 | % | 0 | % |
| Discount rate- bond equivalent yield | 0.25 - 0.35 | % | 0.20 - 0.28 | % |

The following are the assumptions used to measure the compensatory stock options not yet issued at March 31, 2012 and December 31, 2011:

| | March 31, 2012 | December 31, 2011 |
|---|---|---|
| Stock price | $ 2.46 | $ 2.86 |
| Term in years | 5 | 5 |
| Volatility | 89.39 % | 92.75 % |
| Expected dividend yield | 0.0 % | 0.0 % |
| Risk-free interest rate | 1.04 % | 0.83 % |

The following table sets forth a summary of changes in the fair value of the Company's Level 3 fair value measurements for the three months ended March 31, 2012 and 2011:

| | Accrued Warrant Liability | Compensatory Stock Options Not Yet Issued |
|---|---|---|
| Balance, December 31, 2011 | $7,285,959 | $ 378,750 |
| Total (gains) or losses, realized and unrealized, included in earnings (1)(2) | (1,719,756 ) | 51,823 |
| Issuances | - | 85,000 |
| Settlements | - | (430,573 ) |
| | | |
| Balance, March 31, 2012 | $5,566,203 | $ 85,000 |
| | | |
| Balance, December 31, 2010 | $25,350,733 | $ 2,992,180 |
| Total (gains) or losses, realized and unrealized, included in earnings (1)(2) | 714,951 | (17,953 ) |
| Issuances | - | - |
| Settlements | (947,538 ) | (2,974,227 ) |
| | | |
| Balance, March 31, 2011 | $25,118,146 | $ - |
| | | |
| Amount of total gains or losses for the period included in earnings as change in value of warrant liability attributable to the change in unrealized gains or losses relating to liabilities recorded at the reporting date: | | |
| March 31, 2012 | $(1,719,756 ) | $ - |
| March 31, 2011 | $742,677 | $ - |

(1) Realized & unrealized gains or losses related to the accrued warrant liability were included as change in value of accrued warrant liability.
(2) Realized gains or losses related to compensatory stock options were included in research & development expense and general & administrative expense.

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of March 31, 2012 and December 31, 2011, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability and compensatory stock options not yet issued to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. Both the accrued

warrant liability and compensatory stock options not yet issued use management’s estimate for the expected term, which is based on the safe harbor method as historical exercise information over the term of each security is not readily available. Additionally, the number of compensatory options awarded involves an estimate of management’s performance in relation to the targets set forth in the Company's Executive Compensation Plan. The following table summarizes the unobservable inputs into the fair value measurements:

| | March 31, 2012 | | | |
|---|---|---|---|---|
| Description | Fair Value | Valuation Technique | Unobservable Input | Range |
| Compensatory stock options not yet issued | $85,000 | Black-scholes pricing model | Expected term | 5 years |
| | | | Quantity of options | 200,000 |
| Accrued warrant liability | 5,566,203 | Black-scholes pricing model | Expected term | 1.46 - 2.11 years |
| | $5,651,203 | | | |

Management believes the value of both the accrued warrant liability and compensatory stock options is more sensitive to a change in the Company's stock price at the end of the respective reporting period as opposed to a change in one of the unobservable inputs described above.

The carrying amounts of the Company's short-term financial instruments, which include cash, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

4. Stockholders' Equity

The Company has granted options to purchase shares of common stock and has granted restricted stock units under the Plan.

The following is a summary of option award activity under the Plan during the three months ended March 31, 2012:

| | Stock Options | Weighted Average Exercise Price per Share | Weighted Average Remaining Contractual Term (in Years) | Intrinsic Value |
|---|---|---|---|---|
| Outstanding, December 31, 2011 | 4,117,979 | $ 5.21 | 7.77 | $ 303,825 |
| Exercisable, December 31, 2011 | 3,761,879 | 5.26 | 7.65 | 231,517 |
| Granted | 274,500 | 3.25 | | |
| Exercised | (750) | 1.90 | | |
| Forfeited, Canceled | (38,217) | 6.30 | | |
| Outstanding, March 31, 2012 | 4,353,512 | 5.08 | 7.67 | 100,528 |
| Exercisable, March 31, 2012 | 3,841,537 | 5.22 | 7.46 | 79,740 |

During the three months ended March 31, 2012 and 2011, the Company granted 274,500 and 760,673 stock options under the Plan, respectively. The Company recognized a total of $309,787 and $283,933 in net expense related to stock options for the three months ended March 31, 2012 and 2011, respectively. The Company granted 79,651 and 45,361 shares of stock under the Plan and recognized a total of $256,194 and $283,933 in expense during the three months ended March 31, 2012 and 2011, respectively.

5. Warrants

The Company has issued warrants to strategic partners, consultants and investors with exercise prices ranging from $1.60 to $5.00. The warrants expire between one and seven years from the date of grant, subject to the terms applicable in the agreement. The following is a summary of warrant activity for the three months ended March 31, 2012:

| | Number of Warrants | Weighted Average Exercise Price | Number of Common Shares Exerciseable Into |
|---|---|---|---|
| Outstanding at December 31, 2011 | 10,121,219 | $ 3.76 | 12,564,193 |
| Forfeited, Canceled | (2,587,599 ) | 5.39 | (5,030,573 ) |
| Outstanding at March 31, 2012 | 7,533,620 | $ 3.21 | 7,533,620 |

6. Noncontrolling Interests

On January 20, 2011 and March 14, 2011, Bioprocess Capital Ventures, the noncontrolling interest in Incuron, contributed 68.0 million Russian Rubles (approximately $2.3 million) and 1.73 million Russian Rubles (approximately $0.1 million), respectively, to Incuron, which increased their ownership percentage from 16.1% to 24.2% and decreased CBLI's ownership percentage from 83.9% to 75.8%. There were no changes to CBLI's ownership percentages in its subsidiaries during the three months ended March 31, 2012.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

This management's discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our research and development efforts and clinical trials, product demand, market acceptance and other factors discussed below and in our other SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2011. See also the Risk Factors discussed under Item 1A of such Annual Report. This management's discussion and analysis of financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this filing and in our Annual Report on Form 10-K for the year ended December 31, 2011.

OVERVIEW

We are a clinical-stage biotechnology company with a focus on oncology indications. Our lead drug candidate, CBLB502, is being developed for dual indications as a radiation countermeasure under an FDA regulation commonly referred to as the “Animal Rule”, and as an anti-cancer agent and an oncologic supportive care therapy under the FDA’s traditional drug approval pathway. We anticipate that CBLB502, upon licensure as a radiation countermeasure, will be sold to the U.S. government for the national stockpile and other defense-related purposes, allied foreign governments and the nuclear energy industry, and upon licensure as an anti-cancer agent, will be sold to the public through traditional channels.

Since our inception, we have pursued the research, development and commercialization of products that have the potential to evidence direct anti-cancer activity, prevent and treat acute radiation syndrome and counteract the toxic effects of radio and chemotherapies for oncology patients. Presently, we have nine product candidates in our pipeline that are being developed directly by us and our majority-owned subsidiaries, Incuron, LLC (“Incuron”) and Panacela Labs, Inc. (“Panacela”).

In addition to CBLB502, our product pipeline includes: CBLB612, an inducer and mobilizer of hematopoietic stem cells; the Curaxin line of anti-cancer product candidates being developed by Incuron, which specifically include CBLC102, a nonproprietary molecule originally used to combat the effects of malaria, which we have identified as having direct anti-cancer properties and CBLC137, a new, proprietary molecule that leverages similar mechanisms of action in combating cancer, and five preclinical product candidates being developed by Panacela (Revercom, Mobilan, Arkil, and Antimycon for anti-cancer applications and Xenomycins for anti-infective applications).

See “Item 1. Business” in our Annual Report on Form 10-K for the year ended December 31, 2011 for more information on our product candidates.

Critical Accounting Policies and Significant Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, income taxes, stock-based compensation, investments and in-process research and development. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2011. Other than as set forth below, our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

Fair Value of Financial Instruments

We use the Black-Scholes model to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants in Level 3. The Black-Scholes model utilizes inputs consisting of: (i) the closing price of our common stock; (ii) the expected remaining life of the warrants; (iii) the expected volatility using a weighted average of historical volatilities of CBLI and a group of comparable companies; and (iv) the risk-free market rate.

As of March 31, 2012, we held approximately $12.2 million in money market funds, classified as a Level 1 security, and held approximately $5.6 million in accrued expenses classified as a Level 3 security, primarily related to warrants to purchase common stock.

Recently Issued Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04, Fair Value Measurement (Topic 820) ("ASU 2011-04"), which contains amendments to achieve common fair value measurement and disclosures in U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 explains how to measure fair value for financial reporting. The guidance does not require fair value measurements in addition to those already required or permitted by other Topics. This ASU was effective for the Company beginning January 1, 2012. The adoption of ASU 2011-04 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity, but did require expanded disclosures as set forth in Note 3, Fair Value of Financial Instruments in the financial statements included elsewhere in this Quarterly Report on Form 10-Q.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income ("ASU 2011-05"). This guidance is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single statement or two-statement approach. This ASU was effective for the Company beginning January 1, 2012. The adoption of ASU 2011-05 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity. The Company elected to present comprehensive income in two separate but consecutive statements as part of the consolidated financial statements included in this Quarterly Report on Form 10-Q.

Three Months Ended March 31, 2012 Compared to Three Months Ended March 31, 2011

Revenue

Revenue decreased from approximately $2.5 million for the three months ended March 31, 2011 to approximately $0.9 million for the three months ended March 31 2012, representing a decrease of approximately $1.5 million, or 62%. This decrease was due to decreases in research sponsored by the U.S. Department of Defense ("DoD"), the Defense Threat Reduction Agency ("DTRA"), and the U.S. Department of Health and Human Services ("HHS"), as set forth in the following table:

| Funding Source | Program | Three Months Ended March 31, 2012 | 2011 | Variance |
|---|---|---|---|---|
| DoD | CBMS-MITS Contract | $ 879,834 | $ 1,875,134 | $ (995,300) |
| DTRA | DTRA Contract | 51,563 | 356,887 | (305,324) |
| HHS | BARDA Contract | - | 237,748 | (237,748) |
| NY State/RPCI | Sponsored Research Agreement | - | 4,213 | (4,213) |
| | | $ 931,397 | $ 2,473,982 | $ (1,542,585) |

Research and Development Expenses

Research and development expenses increased from approximately $5.7 million for the three months ended March 31, 2011 to approximately $6.0 million for the three months ended March 31, 2012, representing an increase of approximately $0.3 million, or 5%. This increase was primarily due to programs relating to Panacela Compounds and CBLB612 that were not active for the three month period ended March 31, 2011. These programs, in the aggregate, accounted for approximately $1.0 million of the growth in research and development expenses. We also experienced an increase in research and development expenses for CBLB502 – Oncology, as we began our Advanced Cancer Trial at Roswell Park Cancer Institute ("RPCI"). These increases were partially offset by a decline in spending related to CBLB502-ARS, as we complete development work and commence pivotal studies.

14

| | Three Months Ended March 31, | | |
|---|---|---|---|
| | 2012 | 2011 | Variance |
| CBLB502 - ARS | $ 3,806,968 | $ 4,504,932 | $(697,964) |
| Curaxins | 1,030,303 | 1,121,628 | (91,325) |
| General | - | 59,603 | (59,603) |
| Panacela Compounds | 665,579 | - | 665,579 |
| CBLB612 | 286,749 | - | 286,749 |
| CBLB502 - Oncology | 196,202 | 22,770 | 173,432 |
| | | | |
| Total research & development expenses | $ 5,985,801 | $ 5,708,933 | $276,868 |

General and Administrative Expenses

General and administrative costs increased from approximately $1.9 million for the three months ended March 31, 2011 to approximately $2.4 million for the three months ended March 31, 2012. This represents an increase of approximately $0.5 million or 29%. Approximately $0.3 million, or 55%, of this increase was related to the general and administrative expenses of our new subsidiary Panacela, which commenced operations in the fourth quarter of 2011. The remaining increase of approximately $0.2 million, or 45% of the increase, was related to a variety of cost increases between the periods, none of which were individually significant, including: increases in personnel costs, travel and professional fees related to business development and investor relation activities, and an increase in outside finance and legal fees in part related to improved financial reporting systems, controls and general corporate governance.

Other Income and Expenses

Other income increased from a net expense of approximately $0.6 million for the three months ended March 31, 2011 to net income of approximately $1.1 million for the three months ended March 31, 2012, representing an increase of approximately $1.7 million, or 271%. This increase was primarily attributable to the periodic fair valuation of the Company's warrant liability which generated non-cash income of approximately $1.7 million for the three months ended March 31, 2012 as compared to non-cash expense of approximately $0.7 million for the three months ended March 31, 2011, for a total increase of approximately $2.4 million between the periods. This increase was partially offset by an increase in foreign currency exchange losses between the periods of approximately $0.7 million.

Liquidity and Capital Resources

At March 31, 2012, we had approximately $18.1 million in cash and cash equivalents and $5.5 million in short-term investments, along with accounts receivable of approximately $0.8 million, and approximately $1.8 million in funded backlog from the federal government. On April 30, 2012, we announced that the Russian Federation opened an IND for CBLC137 which is a funding milestone for our Incuron subsidiary, and we expect Incuron will receive 194 million Russian Rubbles during the second quarter of 2012, or approximately $6.6 million at current exchange rates. Additionally, Incuron has approximately $4.0 million (based on current exchange rates) of unfunded backlog available to it under its development grant from Skolkovo.

We are also in active discussions with BARDA and DoD for continued funding of our research and development of CBLB502 as a medical countermeasure for acute radiation syndrome. In addition, we are actively responding to all other contract and grant award possibilities we believe appropriate. However, there can be no assurance that any of these contract and grant award applications will result in funding.

Operating Activities

Net cash used in operations increased from approximately $0.8 million for the three months ended March 31, 2011 to approximately $4.8 million for the three months ended March 31, 2012, representing an increase of approximately $3.9 million, or 469%. After adjusting for non-cash items, the net loss increased by approximately $2.9 million between the periods and the changes in working capital items netted an additional cash usage of approximately $1.0 million.

Investing Activities

Net cash used in investing activities decreased from approximately $1.7 million during the three months ended March 31, 2011 to approximately $82,000 during the three months ended March 31, 2012, representing a decrease of approximately $1.6 million, or 95%. For the three months ended March 31, 2012, the net cash used in investing activities was limited to the purchase of equipment of approximately $82,000. For the three months ended March 31, 2011, the net cash used in investing activities included the purchase of short-term investments of approximately $1.4 million, equipment of approximately $168,000, and patents of approximately $120,000. As discussed in Note 2 to the audited financial statements included in our Annual Report on Form 10-K, we adopted a more restrictive standard of capitalization of intellectual property costs during the quarter ended September 30, 2011.

Financing Activities

For the three months ended March 31, 2012, cash flows from financing activities were negligible. For the three months ended March 31, 2011, cash provided by financing activities included an investment in Incuron of approximately $2.3 million by the non-controlling interest holder in such subsidiary and the exercise of options and warrants for approximately $1.2 million, for a total of cash provided by financing operations of approximately $3.5 million.

Other

We have incurred cumulative net losses and expect to incur additional losses to perform further research and development activities. We do not have commercial products and have limited capital resources. We will need additional funds to complete the development of our products. Our plans with regard to these matters may include seeking additional capital through a combination of government contracts, collaborative agreements, strategic alliances, research grants, and future equity and debt financing. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining future financing on commercially reasonable terms or that we will be able to secure funding from anticipated government contracts and grants.

We believe that our existing funds combined with cash flows from existing government grants and contracts will be sufficient to support our operations into 2013. The success of our company is dependent upon commercializing our research and development programs and our ability to obtain adequate future financing. If we are unable to raise adequate capital and/or achieve profitable operations, future operations might need to be scaled back or discontinued. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

Impact of Inflation

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

Impact of Exchange Rate Fluctuations

From time-to-time, our operations are somewhat dependent upon changes in foreign currency exchange rates, however at March 31, 2012, we were not obligated to make payments in foreign currencies.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no significant change in our exposure to market risk during the first three months of 2012. For a discussion of our exposure to market risk, refer to Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” contained in our Annual Report on Form 10-K for the year ended December 31, 2011.

Item 4. Controls and Procedures

Effectiveness of Disclosure

Our management, with the participation of our interim Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the

Securities Exchange Act of 1934, as amended, or the Exchange Act as of March 31, 2012. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2012, our interim 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 interim Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during the fiscal quarter ended March 31, 2012, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - Other Information

Item 1. Legal Proceedings

As of March 31, 2012, we were not a party to any litigation or other legal proceeding.

Item 1A. Risk Factors

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2011. For a further discussion of our Risk Factors, refer to the “Risk Factors” discussion contained in our Annual Report on Form 10-K for the period ended December 31, 2011.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

| Exhibit Number | Description of Document |
|---|---|
| 31.1 | Certification of Yakov Kogan, Interim Chief Executive Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002. |
| 31.2 | Certification of C. Neil Lyons, 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. |

| | |
|---|---|
| 101.1 | The following information from CBLI's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 formatted in XBRL: (i) Unaudited Consolidated Statements of Operations for the three months ended March 31, 2012 and 2011; (ii) Consolidated Balance Sheets as of March 31, 2012 (Unaudited) and December 31, 2011; (iii) Unaudited Consolidated Statements of Stockholders' Equity as of March 31, 2012; (iv) Unaudited Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2012; (v) Unaudited Consolidated Statements of Cash Flows for the three months ended March 31, 2012 and 2011; and (vi) Notes to Unaudited Consolidated Financial Statements tagged as blocks of text.* |

* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

Signatures

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

CLEVELAND BIOLABS, INC.

| | | |
|---|---|---|
| Dated: May 7, 2012 | By: | /s/ YAKOV KOGAN<br>Yakov Kogan<br>Interim Chief Executive Officer<br>(Principal Executive Officer) |
| Dated: May 7, 2012 | By: | /s/ C. NEIL LYONS<br>C. Neil Lyons<br>Chief Financial Officer<br>(Principal Financial Officer) |