

CHEMBIO DIAGNOSTICS, INC.  
Form 10QSB  
August 11, 2006

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

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**FORM 10 - QSB**

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**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934.**

**For the quarterly period ended June 30, 2006.**

**000-30379**

*(Commission File Number)*

**Chembio Diagnostics, Inc.**

*(Exact name of registrant as specified in its charter)*

**Nevada      88-0425691**

*(State or other  
jurisdiction of  
incorporation)*      *(IRS  
Employer  
Identification  
Number)*

**3661 Horseblock Road**

**Medford, New York 11763**

*(Address of principal executive offices including zip code)*

**(631) 924-1135**

*(Registrant's telephone number, including area code)*

*(Former Name or Former Address, 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 Exchange Act 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

Transitional Small Business Disclosure Format (check one): Yes  No

As of August 9, 2006, the Registrant had 11,015,095 shares outstanding of its \$.01 par value common stock.

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June 30, 2006  
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**PART I****Item 1. FINANCIAL STATEMENTS****CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS****- ASSETS -**

|  | <b>June 30, 2006</b> | December 31,        |
|--|----------------------|---------------------|
|  | <b>(Unaudited)</b>   | 2005                |
| <b>CURRENT ASSETS:</b>   |                      |                     |
| Cash   | \$ 1,289,298         | \$ 232,148          |
| Accounts receivable, net of allowance for doubtful accounts of \$27,366 and \$20,488 for 2006 and 2005, respectively | 918,239              | 1,255,073           |
| Inventories  | 918,657              | 687,983             |
| Deferred financing cost  | 328,341              | -                   |
| Prepaid expenses and other current assets  | 210,934              | 292,989             |
| <b>TOTAL CURRENT ASSETS</b>  | <b>3,665,469</b>     | <b>2,468,193</b>    |
| <b>FIXED ASSETS, net of accumulated depreciation of \$543,330 and \$559,228 for 2006 and 2005, respectively</b>      |                      |                     |
|  | <b>621,395</b>       | <b>438,632</b>      |
| <b>OTHER ASSETS:</b>   |                      |                     |
| Deposits and other assets  | 376,319              | 109,581             |
|  | <b>\$ 4,663,183</b>  | <b>\$ 3,016,406</b> |

**- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)-**

|   |                  |                  |
|---|------------------|------------------|
| <b>CURRENT LIABILITIES:</b>                               |                  |                  |
| Accounts payable and accrued liabilities                  | \$ 2,637,009     | \$ 1,477,925     |
| Accrued interest payable                                  | 120,000          | 120,000          |
| Loan payable  | 1,300,000        | -                |
| Current portion of obligations under capital leases       | 40,532           | 38,368           |
| Payable to related party                                  | 182,181          | 182,181          |
| <b>TOTAL CURRENT LIABILITIES</b>                          | <b>4,279,722</b> | <b>1,818,474</b> |
| <b>OTHER LIABILITIES:</b>                                 |                  |                  |
| Obligations under capital leases - net of current portion | 23,594           | 44,417           |
| Liabilities in respect to warrants                        | 328,341          | -                |
| Accrued interest, net of current portion                  | 33,160           | 100,812          |
| <b>TOTAL LIABILITIES</b>                                  | <b>4,664,817</b> | <b>1,963,703</b> |

**COMMITMENTS AND  
CONTINGENCIES**

**STOCKHOLDERS' EQUITY  
(DEFICIENCY)**

|   |                     |                     |
|---|---------------------|---------------------|
| Preferred Stock - 10,000,000<br>shares authorized:  |                     |                     |
| Series A 8% Convertible - \$.01<br>par value: 149.92119 and<br>158.68099 shares issued and<br>outstanding as of 2006 and 2005 ,<br>respectively. Liquidation<br>preference of \$4,553,204 | <b>2,499,913</b>    | 2,628,879           |
| Series B 9% Convertible - \$.01<br>par value: 113.93591 and<br>102.19760 shares issued and<br>outstanding as of 2006 and 2005,<br>respectively. Liquidation<br>preference of \$5,937,289  | <b>3,529,493</b>    | 3,173,239           |
| Common stock - \$.01 par value;<br>100,000,000 shares authorized<br>10,669,185 and 8,491,429 shares<br>issued and outstanding as of 2006<br>and 2005, respectively                        | <b>106,692</b>      | 84,914              |
| Additional paid-in capital  | <b>16,006,080</b>   | 14,034,099          |
| Accumulated deficit   | <b>(22,143,812)</b> | (18,868,428)        |
| <b>TOTAL STOCKHOLDERS'<br/>EQUITY (DEFICIENCY)</b>  | <b>(1,634)</b>      | 1,052,703           |
|   | <b>\$ 4,663,183</b> | <b>\$ 3,016,406</b> |

*See notes accompanying the financial statements.*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(UNAUDITED)

|   | <b><u>Three months ended</u></b>             |  | <b><u>Six months ended</u></b>               |  |
|---|--|--|--|--|
|   | <b><u>June 30,</u></b><br><b><u>2006</u></b> | <b><u>June 30,</u></b><br><b><u>2005</u></b> | <b><u>June 30,</u></b><br><b><u>2006</u></b> | <b><u>June 30,</u></b><br><b><u>2005</u></b> |
| <b>REVENUES:</b>  |  |  |  |  |
| Net sales   | \$ 1,572,442                                 | \$ 814,307                                   | \$ 2,741,511                                 | \$ 1,160,432                                 |
| License revenue   | -  | -  | -  | 250,000                                      |
| Research grants and development income  | 64,794                                       | 91,382                                       | 133,392                                      | 227,142                                      |
| <b>TOTAL REVENUES</b>   | <b>1,637,236</b>                             | <b>905,689</b>                               | <b>2,874,903</b>                             | <b>1,637,574</b>                             |
| Cost of sales   | 1,072,802                                    | 636,380                                      | 1,874,930                                    | 1,100,930                                    |
| <b>GROSS PROFIT</b>   | <b>564,434</b>                               | <b>269,309</b>                               | <b>999,973</b>                               | <b>536,644</b>                               |
| <b>OVERHEAD COSTS:</b>  |  |  |  |  |
| Research and development expenses   | 351,465                                      | 426,782                                      | 744,271                                      | 761,532                                      |
| Selling, general and administrative expenses  | 1,333,321                                    | 729,435                                      | 2,630,968                                    | 1,285,495                                    |
|   | <b>1,684,786</b>                             | <b>1,156,217</b>                             | <b>3,375,239</b>                             | <b>2,047,027</b>                             |
| <b>LOSS FROM OPERATIONS</b>   | <b>(1,120,352)</b>                           | <b>(886,908)</b>                             | <b>(2,375,266)</b>                           | <b>(1,510,383)</b>                           |
| <b>OTHER INCOME (EXPENSES):</b>   |  |  |  |  |
| Sale of fixed asset   | 5,000  | 400  | 5,000  | 400  |
| Interest income   | 289  | 15,613                                       | 886  | 25,081                                       |
| Interest (expense)  | (12,312)                                     | (4,247)                                      | (21,710)                                     | (10,225)                                     |
| <b>LOSS BEFORE INCOME TAXES</b>   | <b>(1,127,375)</b>                           | <b>(875,142)</b>                             | <b>(2,391,090)</b>                           | <b>(1,495,127)</b>                           |
| Income taxes  | -  | -  | -  | -  |
| <b>NET LOSS</b>   | <b>(1,127,375)</b>                           | <b>(875,142)</b>                             | <b>(2,391,090)</b>                           | <b>(1,495,127)</b>                           |
| Dividends payable in stock to preferred stockholders  | 207,937                                      | 212,061                                      | 420,860                                      | 394,239                                      |
| Dividend accreted to preferred stock for associated costs and a beneficial conversion feature | -  | -  | 463,434                                      | 2,698,701                                    |

|                               |                       |                       |                       |                       |
|-------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <b>NET LOSS</b>               |                       |                       |                       |                       |
| <b>ATTRIBUTABLE</b>           |                       |                       |                       |                       |
| <b>TO COMMON</b>              |                       |                       |                       |                       |
| <b>STOCKHOLDERS</b>           | <b>\$ (1,335,312)</b> | <b>\$ (1,087,203)</b> | <b>\$ (3,275,384)</b> | <b>\$ (4,588,067)</b> |
| <b>Basic and diluted loss</b> |                       |                       |                       |                       |
| <b>per share</b>              | <b>\$ (.13)</b>       | <b>\$ (.15)</b>       | <b>\$ (.34)</b>       | <b>\$ (.64)</b>       |
| <i>Weighted number of</i>     |                       |                       |                       |                       |
| <i>shares outstanding,</i>    |                       |                       |                       |                       |
| <i>basic and diluted</i>      | <b>10,024,545</b>     | 7,413,129             | <b>9,517,323</b>      | 7,180,780             |

*See notes accompanying the financial statements.*



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

|   | Six months ended |                    |
|---|------------------|--------------------|
|   | June 30, 2006    | June 30, 2005      |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>  |                  |                    |
| Net loss  | \$ (2,391,090)   | \$ (1,495,127)     |
| Adjustments to reconcile net loss to net cash used in operating activities:   |                  |                    |
| Depreciation and amortization   | 84,790           | 38,865             |
| Provision for doubtful accounts   | 6,878            | (2,321)            |
| Common stock, options and warrants issued as compensation   | 281,470          | -                  |
| Changes in:   |                  |                    |
| Accounts receivable   | 329,956          | (117,650)          |
| Restricted cash   | -                | 250,000            |
| Inventories   | (230,674)        | (25,536)           |
| Prepaid expenses and other current assets   | 82,055           | 16,532             |
| Other assets and deposits   | -                | (84,543)           |
| Accounts payable and accrued expenses   | 1,004,284        | (336,572)          |
| <b>Net cash used in operating activities</b>  | <b>(832,331)</b> | <b>(1,756,352)</b> |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>  |                  |                    |
| Acquisition of fixed assets   | (267,553)        | (239,648)          |
| <b>Net cash used in investing activities</b>  | <b>(267,553)</b> | <b>(239,648)</b>   |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>  |                  |                    |
| Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing for the periods ended in 2006 and 2005 of \$2,750 and \$321,639, respectively | 997,250          | 4,725,861          |
| Proceeds from bridge loan   | 1,300,000        | -                  |
|   | <b>86,321</b>    | <b>25,196</b>      |

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|   |                     |                     |
|---|---------------------|---------------------|
| Proceeds from exercise of warrants  |                     |                     |
| Payment of capital lease obligation   | (18,659)            | (28,097)            |
| Proceeds from working capital loan  | -                   | 161,917             |
| Payment of working capital loan   | -                   | (206,917)           |
| Payment of accrued interest   | (67,652)            | (59,790)            |
| Payment of dividends  | (140,226)           | -                   |
| <b>Net cash provided by financing activities</b>                                      | <b>2,157,034</b>    | <b>4,618,170</b>    |
| <b>NET INCREASE IN CASH</b>   | <b>1,057,150</b>    | <b>2,622,170</b>    |
| Cash - beginning of the period  | 232,148             | 34,837              |
| <b>CASH - end of the period</b>   | <b>\$ 1,289,298</b> | <b>\$ 2,657,007</b> |
| <b>Supplemental disclosure of cash flow information:</b>                              |                     |                     |
| Cash paid during the period for interest  | \$ 12,312           | \$ 68,465           |
| <b>Supplemental disclosures for non-cash investing and financing activities:</b>      |                     |                     |
| Stock issued as payment for financing fees  | \$ -                | \$ 15,000           |
| Warrants issued as payment for financing fees   | -                   | 364,268             |
| Preferred B issued as payment for financing fees                                      | 100,000             | 249,000             |
| Preferred A and associated warrants exchanged for Preferred B and associated warrants | -                   | 20,000              |
| Warrants issued with bridge loan  | 328,341             | -                   |
| Cost of royalty rate reduction accrued and included in other assets                   | 200,000             | -                   |
| Value of warrants issued allocated to additional paid in capital                      | 481,470             | 2,349,893           |
| Accreted beneficial conversion to preferred stock                                     | 463,434             | 2,698,701           |
| Accreted dividend to preferred stock  | 420,860             | 394,239             |
| Common stock issued as payment of dividend  | 189,218             | 187,679             |
|   | <b>89,899</b>       | <b>-</b>            |

|  |                |         |
|--|----------------|---------|
| Preferred B issued as<br>payment of dividend |                |         |
| Preferred A converted to<br>common stock     | <b>122,006</b> | 42,088  |
| Preferred B converted to<br>common stock     | <b>360,651</b> | 197,566 |

*See notes accompanying the financial statements.*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2006**  
**(UNAUDITED)**

|             |          |   |                                 |
|-------------|----------|---|---------------------------------|
| <b>NOTE</b> | <b>1</b> | — | <b>Description of Business:</b> |
|-------------|----------|---|---------------------------------|

Chembio Diagnostics, Inc. and its subsidiaries (the Company) develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases and other conditions in humans and animals. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV 1/2, HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although the Company's revenues and gross margins increased significantly in recent periods, it has sustained significant operating losses in the six months of 2006 and the years 2005 and 2004. At June 30, 2006, the Company had a Stockholders' Deficiency of \$1,634 and a working capital deficiency of \$614,253. The Company believes its resources are sufficient to fund its needs through late third quarter of 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will be successful in raising sufficient capital.

**RECENT DEVELOPMENTS:**

On May 30, 2006, the Company received approval of its Pre-Market Applications (PMAs) from the U. S. Food Drug Administration (FDA) for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The approved PMAs allow Chembio to market its rapid HIV tests to clinical laboratories and hospitals in the United States. FDA approval also allows Chembio to further expand its international marketing efforts into countries that require regulatory approval in the manufacturer's country of domicile.

On June 29, 2006, the Company entered into Agreements for the private placement of up to \$1,800,000 of secured debentures, of which \$1,300,000 was then borrowed. The principal and accrued interest under this obligation is due on September 29, 2006 and is secured by a lien on all assets of the Company. The Company also issued warrants for the purchase of its Common Stock in connection with this transaction; each \$1,000 of debenture entitles the lender to a warrant to purchase 400 shares of common stock at an exercise price of \$0.75 per share with a term of exercise of five years.

The lenders also have a right to participate in future equity financings on the same terms and conditions as the offer, up to the lesser of \$2,000,000 or 40% of the offering amount. The lenders may also convert the outstanding secured debentures and accrued interest into securities being offered in the future by the Company on the same terms and conditions as the other participants, at a discounted rate of 12.5%.

The related Agreements require the Company to register and maintain the registration of the shares underlying the aforementioned warrants. The Company will incur cash penalties if it fails to do so.

Pursuant to the provisions of Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" and EITF 00-19: "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19"), the Company has recorded the value of the warrants, \$328,341, as deferred financing costs with a corresponding credit to a long term derivative liability on the Consolidated Balance Sheet as of June 30, 2006. The debt discount will be amortized on a straight-line basis over the life of the underlying debt.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2006**  
**(UNAUDITED)**

The liability for the value of the warrants will be “marked to market” in future accounting periods until such time as the warrants are exercised or they meet the criteria for equity classification.

**NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

**(a) Basis of Presentation:**

The consolidated interim financial information as of June 30, 2006 and for the three and six-month periods ended June 30, 2006 and 2005 has been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations, although we believe that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the Financial Statements and the notes thereto, included in the Company’s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of consolidated financial position as of June 30, 2006, and consolidated results of operations and cash flows for the three and six-month periods ended June 30, 2006 and 2005, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

**(b) Inventories:**

Inventory consists of the following at:

|                        | <b>JUNE 30,</b>   | December   |
|------------------------|-------------------|------------|
|                        | <b>2006</b>       | 31, 2005   |
| <b>Raw Materials</b>   | <b>\$ 561,281</b> | \$ 425,758 |
| <b>Work in Process</b> | <b>143,183</b>    | 86,001     |
| <b>Finished Goods</b>  | <b>214,193</b>    | 176,224    |
|                        | <b>\$ 918,657</b> | \$ 687,983 |

**(c) Fixed Assets**

In June 2006, the Company retired fully depreciated fixed assets with an original cost of \$100,687.

**(d) Earnings Per Share**

The following weighted average number of shares were used for the computation of basic and diluted earnings per share:

|                | <u>For the three months ended</u> |                      | <u>For the six months ended</u> |                      |
|----------------|-----------------------------------|----------------------|---------------------------------|----------------------|
|                | <u>June 30, 2006</u>              | <u>June 30, 2005</u> | <u>June 30, 2006</u>            | <u>June 30, 2005</u> |
| <b>Basic</b>   | <b>10,024,545</b>                 | <b>7,413,129</b>     | <b>9,517,323</b>                | <b>7,180,780</b>     |
| <b>Diluted</b> | <b>10,024,545</b>                 | <b>7,413,129</b>     | <b>9,517,323</b>                | <b>7,180,780</b>     |

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of other securities into Common Stock, but only if dilutive. Diluted loss per share for the three and six months ended June 30, 2006 and 2005 is the same as basic loss per share, since the effect of including such potential Common Stock equivalents was anti-dilutive as the Company incurred losses for all periods presented. Such securities, shown below, presented on a common share equivalent basis, have been excluded from the per share computations:

|                                    | <u>For the three months ended</u> |                      | <u>For the six months ended</u> |                      |
|------------------------------------|-----------------------------------|----------------------|---------------------------------|----------------------|
|                                    | <u>June 30, 2006</u>              | <u>June 30, 2005</u> | <u>June 30, 2006</u>            | <u>June 30, 2005</u> |
| <b>1999 Plan Stock Options</b>     | <b>1,619,500</b>                  | <b>1,256,500</b>     | <b>1,461,500</b>                | <b>1,256,500</b>     |
| <b>Other Stock Options</b>         | <b>144,625</b>                    | <b>144,625</b>       | <b>144,625</b>                  | <b>144,625</b>       |
| <b>Warrants</b>                    | <b>23,351,159</b>                 | <b>21,363,966</b>    | <b>22,457,650</b>               | <b>21,363,966</b>    |
| <b>Convertible Preferred Stock</b> | <b>17,204,644</b>                 | <b>16,100,290</b>    | <b>16,572,985</b>               | <b>16,100,290</b>    |

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE 30, 2006**  
**(UNAUDITED)**

**(e) Employee Stock Option Plan:**

Effective January 1, 2006, the Company's Plan is accounted for in accordance with the recognition and measurement provisions of Statement of Financial Accounting Standards ("FAS") No. 123 (revised 2004), Share-Based Payment ("FAS 123(R)"), which replaces FAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion ("APB") No. 25, Accounting for Stock Issued to Employees, and related interpretations. FAS 123(R) requires compensation costs related to share-based payment transactions, including employee stock options, to be recognized in the financial statements. In addition, the Company adheres to the guidance set forth within Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 107 ("SAB 107"), which provides the Staff's views regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides interpretations with respect to the valuation of share-based payments for public companies.

Prior to January 1, 2006, the Company accounted for similar transactions in accordance with APB No. 25 which employed the intrinsic value method of measuring compensation cost. Accordingly, compensation expense was not recognized for fixed stock options if the exercise price of the option equaled or exceeded the fair value of the underlying stock at the grant date.

While FAS No. 123 encouraged recognition of the fair value of all stock-based awards on the date of grant as expense over the vesting period, companies were permitted to continue to apply the intrinsic value-based method of accounting prescribed by APB No. 25 and disclose certain pro-forma amounts as if the fair value approach of SFAS No. 123 had been applied. In December 2002, FAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of SFAS No. 123, was issued, which, in addition to providing alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation, required more prominent pro-forma disclosures in both the annual and interim financial statements. The Company complied with these disclosure requirements for all applicable periods prior to January 1, 2006.

In adopting FAS 123(R), the Company applied the modified prospective approach to transition. Under the modified prospective approach, the provisions of FAS 123(R) are to be applied to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date shall be recognized as the requisite service is rendered on or after the required effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated for either recognition or pro-forma disclosures under FAS 123.

As a result of the adoption of FAS 123(R), the Company's results for the three and six month period ended June 30, 2006 include share-based compensation expense totaling approximately \$89,000 and \$214,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold (\$11,000 and \$22,000), research and development (\$18,000 and \$56,000) and selling, general and administrative expenses (\$60,000 and \$136,000). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to history of operating losses.



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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Stock option compensation expense in the first and second quarters of 2006 represent the estimated fair value of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value of stock options granted in the three and six months ended June 30, 2006 and 2005 was \$.54 and \$.53 and \$.51 and \$.53 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. During 2006, the Company took into consideration guidance under SFAS 123(R) and SAB 107 when reviewing and updating assumptions. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has no history of employee exercise of options to-date.

The assumptions made in calculating the fair values of options are as follows:

|                          | June 30,<br>2006 | June<br>30,<br>2005 |
|--------------------------|------------------|---------------------|
| Expected term (in years) | 4                | 5                   |
| Expected volatility      | 116.20%          | 95.56%              |
| Expected dividend yield  | 0%               | 0%                  |
| Risk-free interest rate  | 4.92%            | 3.72%               |

The following table addresses the additional disclosure requirements of 123(R) in the period of adoption. The table illustrates the effect on net income and earnings per share as if the fair value recognition provisions of FAS No. 123 had been applied to all outstanding and unvested awards in the prior year comparable period.

|  | <b>For the three<br/>months ended</b> | <b>For the six<br/>months ended</b> |
|--|---------------------------------------|-------------------------------------|
|  | June 30,<br>2005                      | June 30,<br>2005                    |
| Net loss attributable to common stockholders, as reported  | \$ (1,087,203)                        | \$ (4,588,607)                      |
| Add: Stock-based compensation included in reported net loss  | -                                     | -                                   |
| Deduct: Total stock based compensation expense determined under the fair value based method for all awards (no tax effect) | (53,008)                              | (86,549)                            |

|  |                |                |
|--|----------------|----------------|
| Pro forma net loss attributable to common stockholders | \$ (1,140,211) | \$ (4,675,156) |
| Net loss per share:                                    |                |                |
| Basic and diluted loss per share - as reported         | \$ (0.15)      | \$ (0.64)      |
| Basic and diluted loss per share - pro forma           | \$ (0.15)      | \$ (0.65)      |

The Company granted 36,000 new options under the Plan during the three months ended June 30, 2006 at an exercise price of \$0.75 per share. The Company granted 316,000 new options under the Plan during the three months ended March 31, 2006 at exercise prices ranging from \$0.55 per share to \$0.62 per share.

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| Stock Options                  | Number of Shares | Weighted Average Exercise Price per Share | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|--------------------------------|------------------|---|---|---------------------------|
| Outstanding at January 1, 2006 | 1,285,750        | \$ 1.20                                   |   |                           |
| Granted                        | 1,147,250        | \$ 0.71                                   |   |                           |
| Cancelled                      | (795,250)        | \$ 1.56                                   |   |                           |
| Exercised                      | -                | -   |   |                           |
| Forfeited/expired              | (500)            | \$ 0.75                                   |   |                           |
| Outstanding at June 30, 2006   | 1,637,250        | \$ 0.69                                   | 4.15 years                                  | \$ 117,824                |
| Exercisable at June 30, 2006   | 1,164,250        | \$ 0.68                                   | 4.00 years                                  | \$ 90,499                 |

As of June 30, 2006, there was \$84,475 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately .67 years. The total fair value of shares vested during the three and six months ended June 30, 2006 and 2005, was \$283,613 and \$397,734 and \$137,655 and \$153,415, respectively.

On April 17, 2006 the Compensation Committee of the Company's Board of Directors approved the cancellation of all employee options where the exercise price was greater than \$.75 per share (an aggregate of 795,250 options) and issued new options at an exercise price of \$.75 per share with the same vesting schedule and expiration dates (except for 122,500 new options that were issued with a vesting date of January 1, 2007 which is later than the vesting date of the options they replaced). The expense related to this modification in the second quarter of 2006 was \$58,000.

No options were exercised during the six months ended June 30, 2006 or June 30, 2005. Options for 500 shares expired in the three months ended June 30, 2006.

*(f)* **Geographic Information:**

SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information" establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as "rapid medical tests". As per the provisions of SFAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

|  | <b>For the three months ended</b> | <b>For the six months ended</b> |
|--|-----------------------------------|---------------------------------|
|  |                                   |                                 |

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|                  | <b>June 30,<br/>2006</b> | June 30,<br>2005 | <b>June 30,<br/>2006</b> | June 30,<br>2005 |
|------------------|--------------------------|------------------|--------------------------|------------------|
| Africa           | \$ <b>524,697</b>        | \$ 176,641       | \$ <b>735,161</b>        | \$ 217,711       |
| Asia             | <b>108,478</b>           | 48,688           | <b>151,289</b>           | 76,088           |
| Australia        | -                        | 1,455            | -                        | 13,078           |
| Europe           | <b>7,630</b>             | 20,385           | <b>46,328</b>            | 54,843           |
| Middle<br>East   | <b>7,065</b>             | 12,510           | <b>7,740</b>             | 97,316           |
| North<br>America | <b>89,310</b>            | 160,467          | <b>149,271</b>           | 235,680          |
| South<br>America | <b>835,262</b>           | 394,161          | <b>1,651,722</b>         | 465,716          |
|                  | <b>\$ 1,572,442</b>      | \$ 814,307       | <b>\$ 2,741,511</b>      | \$ 1,160,432     |

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(g) **Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities consists of:

|                                 | <b>June 30,<br/>2006</b> | December<br>31, 2005 |
|---------------------------------|--------------------------|----------------------|
| Accounts payable - suppliers    | <b>\$ 1,221,377</b>      | \$ 550,247           |
| Accrued commissions             | <b>186,046</b>           | 171,587              |
| Accrued royalties / licenses    | <b>499,389</b>           | 381,510              |
| Accrued payroll and other taxes | <b>95,326</b>            | 63,146               |
| Accrued vacation                | <b>171,309</b>           | 145,566              |
| Accrued legal and accounting    | <b>101,205</b>           | 50,024               |
| Accrued expenses - other        | <b>362,357</b>           | 115,845              |
| <b>TOTAL</b>                    | <b>\$ 2,637,009</b>      | <b>\$ 1,477,925</b>  |

**NOTE****3**

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**LONG-TERM DEBT:**

In connection with the Series B offering, interest payable on certain debt was agreed to be paid over 33 months in installments of \$10,000 per month and a final payment of \$3,160 in the 34<sup>th</sup> month. These payments are subordinate to the redemption rights of the Series B preferred stockholders. No interest accrues on this payable.

**NOTE 4—STOCKHOLDERS' EQUITY:**

(a)

**Common Stock**

During the three and six months ended June 30, 2006 the Company issued 113,749 and 122,082 shares, respectively of its Common Stock to a consultant as compensation. The shares were valued from \$0.55 to \$.91 per share and the related compensation expense for the three and six months ended June 30, 2006 was \$90,278 and \$94,861 respectively.

In the three and six months ended June 30, 2006 Series A Preferred shareholders converted 6.00784 and 8.75980 shares into 300,391 and 437,989 shares of Common Stock, respectively. Series B Preferred shareholders converted 5.35286 and 12.05966 shares into 438,757 and 988,494 shares of Common Stock, respectively.

During the three months ended June 30, 2006 the Company issued 140,691 shares of its Common Stock upon the exercise of warrants and received cash of \$86,321.

In the six months ended June 30, 2006 the Company issued 399,121 shares of its Common Stock as payment of dividends on its Series A Preferred Stock and 89,379 shares of its Common Stock as payment of dividends on its Series B Preferred Stock.

*(b)*

**Warrants**

The warrants to purchase 1,713,114 shares of Common Stock issued in connection with the March 2006 Series B offering were assigned a value of \$481,470.

Warrants to purchase 520,000 shares of Common Stock were issued in connection with the bridge loan and were assigned a value of \$328,341.

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During the three and six months ended June 30, 2006, the Company issued warrants to purchase 84,695 and 158,599 shares, respectively of Common Stock at exercise prices from \$0.55 to \$0.883 per share to a distributor as payment for commissions (value \$34,100) and commissions accrued at year end 2005 (value \$24,000) and to consultants as compensation for 2006 (value for the three and six months ended June 30, 2006 was \$16,000 and \$22,824, respectively).

**(c) Series A 8% Convertible Preferred Stock:**

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series A Preferred Stock. The Series A Preferred Stock is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$30,000 per share plus accrued and unpaid dividends, presently \$370.65 per share, an aggregate for all such shares of \$4,553,204. Accrued but unpaid dividends of \$55,568 are included in the preferred stock carrying value as at June 30, 2006.

Dividends: The 8% per annum dividend is payable semi-annually, in cash or, at the Company's option, in Common Stock. In June 2006, the Series A Preferred Stock was amended to provide, among other matters, that dividends in Preferred or Common Stock would be based on a 10 day volume weighted average market price at the time of the dividend. To date all dividends have been paid in Common Stock.

**(d) Series B 9% Convertible Preferred Stock:**

On March 30, 2006, the Company sold \$1 million of additional Series B Preferred Stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. Approximately \$140,000 of these proceeds was used to pay cash dividends which were accrued as of December 31, 2005.

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series B Preferred Stock. The Series B Preferred is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$2,110.77 per share, an aggregate for all such shares of \$5,937,289. Accrued but unpaid dividends of \$240,493 are included in the preferred stock carrying value as at June 30, 2006. The accrued but unpaid dividend was paid on January 2, 2006 by the issuance of 4.60249 shares Series B Preferred Stock. Subsequent to this issuance a Series B shareholder asserted its right, which is exclusive to such shareholder, to receive its dividend in cash; the certificate for 2.80452 shares of Series B was surrendered and the equivalent amount of \$140,226 was paid in April 2006.

As per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments", the Company evaluated the Series B Preferred Stock transaction that occurred in January 2005 and found that there was an associated beneficial conversion feature totaling \$2,437,035; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately. The Company also evaluated the Series B Preferred Stock transaction that occurred on March 30, 2006, see above, and found that there was an associated beneficial conversion feature totaling \$463,434; the preferred stock was further discounted by this amount. The beneficial conversion amount was then

accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately.

Dividends: The 9% Series B Preferred Stock accrues dividends at 9% per annum, payable semi-annually. Dividends are payable in Series B Preferred Stock, Common Stock or in cash. In June 2006, the Series B Preferred Stock was amended to provide, among other matters, that the dividend could be paid in Common Stock (in addition to Preferred Stock or cash) and that dividends in Preferred or Common Stock would be based on a 10 day volume weighted average market price at the time of the dividend. The majority investor in the Series B financing has the option as it pertains to its dividend payment to choose cash or Preferred or Common shares. The Company has the option to choose cash or Preferred or Common shares as to the balance of the dividends. To date all dividends have been paid in Preferred or Common Shares, except \$140,226 which was paid in cash at the option of the majority investor.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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**NOTE 5 — COMMITMENTS AND CONTINGENCIES:**

**(a) Economic Dependency:**

The Company had sales to three customers in excess of 10% of total sales in the three months ended June 30, 2006. Sales to these customers approximated \$477,000, \$347,310 and \$270,000, respectively.

The Company had sales to one customer in excess of 10% of total sales in the three months ended June 30, 2005. Sales to this customers approximated \$352,500.

The Company had sales to two customers in excess of 10% of total sales in the six months ended June 30, 2006. Sales to these customers approximated \$965,448 and \$685,670, respectively.

The Company had sales to two customers in excess of 10% of total sales in the six months ended June 30, 2005. Sales to these customers approximated \$352,500 and \$118,294, respectively.

The Company had no purchases from any vendor in excess of 10% of total purchases for the three months ended June 30, 2006.

The Company had purchases from one vendor in excess of 10% of total purchases for the six months ended June 30, 2006. Purchases from this vendor approximated \$132,300.

The Company had no purchases from any vendor in excess of 10% of total purchases for the three and six months ended June 30, 2005.

**(b) Governmental Regulation:**

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

**(c) Litigation:**

The Company is involved in a patent litigation with Statsture Diagnostics Systems, Inc., formerly Saliva Diagnostic Systems, Inc. ("SDS"), the assignee of a patent related to a method for collecting samples. The Company has requested relief from the court that its Sure Check HIV test does not infringe SDS's patent, that such patent is invalid, and that it is unenforceable due to inequitable procurement. SDS has answered and counterclaimed, alleging that the Company has infringed the patent, which the Company has denied. In the years 2001 through 2003, the Company paid royalties to SDS and took several other actions based upon SDS's representations regarding its alleged patent.

In response to the Company's aforementioned request for relief, the Court has decided that it is not yet prepared to rule on the significant issues in the case. The Company does not believe that the Court's decision adversely affects the strength of its position. Accordingly, we are not presently appealing this decision, although we believe we have a

meritorious basis for future appeal. The discovery phase of the litigation is proceeding pursuant to a scheduling order and trial is presently expected to convene in late 2006.

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## **ITEM 2. MANAGEMENT's Discussion and Analysis and Plan of Operation**

This discussion and analysis should be read in conjunction with the accompanying Consolidated Financial Statements and related notes. Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. We review our estimates and assumptions on an on-going basis. Our estimates are based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly.

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance, or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

### **OVERVIEW**

The following management discussion and analysis relates to the business of Chembio Diagnostics, Inc. and its subsidiaries (the Company), which develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases and other conditions in humans and animals. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of Chembio Diagnostic Systems Inc. (CDS) or the private labels of its distributors or their customers. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV 1/2, HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and Chagas STAT PAK(TM), a rapid test for Chagas Disease. In 2005, the Company sold substantially all of the business related to its private label pregnancy test and is focusing on the products mentioned above together with certain products and technologies under development.

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although the Company's revenues and gross margins increased significantly in recent periods, it has sustained significant operating losses in the six months of 2006 and the years 2005 and 2004. At June 30, 2006, the Company had Stockholders' Deficiency of \$1,634 and a working capital deficiency of \$614,253. The Company believes its resources are sufficient to fund its needs through late third quarter of 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no

assurances that the Company will be successful in raising sufficient capital.

On March 30, 2006, the Company sold \$1 million of additional Series B preferred stock to a Series B preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder

On May 30, 2006, the Company received approval of its Pre-Market Applications (PMAs) from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid tests. The approved PMAs allow Chembio to market its rapid HIV tests to clinical laboratories and hospitals in the United States. FDA approval also allows Chembio to further expand its international marketing efforts into countries that require regulatory approval in the manufacturer's country of domicile.

On June 29, 2006, the Company borrowed \$1,300,000. The loan is repayable on September 27, 2006 and is secured by a lien on the assets of the Company. See Note 1 of the financial statements for further details.

## **Critical Accounting Policies and Estimates**

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2005, (except for the implementation of FAS 123(R) for accounting of share based payments, for which see note 2-e ) see our annual report on Form 10-KSB for the period ended December 31, 2005 which was filed on March 30, 2006.

## **RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2006 AS COMPARED WITH THE THREE MONTHS ENDED JUNE 30, 2005**

### **Revenues:**

Revenues are comprised of \$1,572,000 in net product sales and \$65,000 in grants and development income for the three months ended June 30, 2006 as compared with \$814,000 in net product sales and \$91,000 in grant and development income for the three months ended June 30, 2005. The increase in net product sales is attributable to increased sales of our HIV tests of \$391,000 and increased sales of our Chagas tests of \$447,000 from \$11,000 to \$458,000, partially offset by decreased sales of our pregnancy test kit (a deemphasized product) of \$48,000 and decreases in other product sales aggregating \$32,000. The decrease in grant and development income of \$26,000 was due to certain grants received in 2005 that weren't continued or awarded in 2006.

Net product sales for the three month period ended June 30, 2006 increased 93% compared to the same period in 2005. HIV net product sales increased 79% in this period compared to the same period in 2005. The Company believes that sales of its HIV products will continue to increase in 2006 as compared to 2005 both as a result of the international marketing strategies that were implemented in 2005 and from the sales to the United States market due to the approval from the U.S. Food and Drug Administration (FDA). The Chagas net product sales increase was a result of the Company obtaining its first significant order for this product, in the amount of \$1.2 million of which it shipped \$480,000 in the first quarter of 2006 and \$450,000 in the second quarter of 2006. The Company expects to ship the balance of this order in the third quarter of 2006.

### **Gross Margin:**

Gross margin on net product sales for the three months ended June 30, 2006 was 31.8%, as compared to 21.8% for the three months ended June 30, 2005. The increase in gross margin percentage is attributable to the increased sales of HIV products, which were at a higher margin than other product lines, and because sales volume in 2005 was significantly lower, fixed overhead expenses per dollar of sales were disproportionately high.

### **Research and Development:**

Research and development expenses for the three months ended June 30, 2006 were \$351,000 compared with \$427,000 for the three months ended June 30, 2005.

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs totaled \$101,000 for the three months ended June 30, 2006, a decrease of \$70,000 compared to the three months ended June 30, 2005. Most of this decrease is due to reductions in costs for clinical studies of \$65,000. The costs related to the clinical trials and consulting in 2005 were related to the evaluation of the Company's HIV tests in relation of its FDA Pre-Marketing Approval ("PMA") application which was submitted in February of 2005.

Expenses other than Clinical & Regulatory Affairs decreased \$6,000 and were related to a reduction in the cost of materials of \$6,000, reduction in grant funding of \$30,000 and a reduction in travel and entertainment costs of

\$13,000 offset by increased salaries and wage-related costs of \$23,000 for new hires in the R&D group and the cost related to employee stock options vesting in the period of \$18,000.

The Company presently plans to increase its spending on research and development because it believes such spending will result in the development of new and innovative products. The Company will continue to focus its development efforts on its tuberculosis related products and new lateral flow technologies, some of which have patents pending.

The Company currently has several R&D projects underway. Some highlights include:

**Rapid Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples**

The Company has filed an application with the United States Department of Agriculture (USDA) to license its rapid assay, PrimaTB STAT-PAK(TM). A final set of clinical reproducibility trials is scheduled to start during the third quarter of 2006, that, if successful, would lead to a conditional license (the ability to sell the product commercially worldwide with USDA approval on an order by order basis) by late fourth quarter of 2006. The Company anticipates that additional commercialization will begin in the first quarter of 2007, although there are no assurances that it will be successful.

**Rapid Test for the detection of antibodies to active pulmonary tuberculosis in multiple host species**

Chembio has completed development and is in final validation stage on a series of rapid lateral-flow assays for the detection of veterinary TB in multiple host species including; cattle, cervids, badgers, camels, elephants, and exotic wildlife species. The name for the technology is VetTB STAT-PAK(TM). Application to the USDA is targeted for the fourth quarter of 2006 for the Elephant TB assay with the other to follow in early 2007. The Company anticipates commercialization of these products to start in the first and second quarters of 2007, although there are no assurances that it will be successful.

**Dual Path Platform (DPP(TM))**

During the second quarter of 2006 significant progress was made in developing prototypes of this new patent-pending platform, including the testing of our current HIV test strip (as well as our human TB and Leptospirosis assays) that was recently approved in this new platform. Studies were conducted internally and externally on stored serum samples, negative whole blood, and serum-oral fluid pairs, as well as against early seroconversion panels that certain other rapid tests that are on the market have been tested against as well. These studies provide a high level of confidence that the DPP does produce improved sensitivity as compared with conventional single path immunochromatographic assays, and that our existing HIV test strip know-how and regulatory experience will permit us to accelerate regulatory submission for a next generation rapid HIV test incorporating oral fluids. Similar increases in both clinical and analytical sensitivity were observed for our human TB and Leptospirosis assays. We believe we can extend this technology to many other applications within the infectious disease field, as well as other medical fields.

**Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$604,000 to \$1,333,000 in the three months ended June 30, 2006 compared with \$729,000 for the same period in 2005. This increase was attributable to increased staff costs in the accounting, administration and sales and marketing departments of \$113,000 and the cost related to employee stock options vesting in the period of \$50,000. Increased sales resulted in an increase in royalties and commissions of \$115,000. In addition there was an increase of \$94,000 in costs regarding investor relations, \$31,000 which resulted from an increase in the number of members of the Company's Board of Directors, \$29,000 from increased travel and entertainment costs, \$19,000 from increased trade show costs, \$14,000 in increased license fees, increased legal expenses of \$98,000 related to patent litigation and \$35,000 related to general patent and other legal services.

As the Company's sales of its HIV rapid test products increase, it expects selling, general and administrative expense to also increase. This will be in large measure due to increased costs for commissions and royalties on intellectual property licenses. At the end of 2005, the Company renegotiated one of its license agreements to provide for a

decrease of 50% in the royalty rate, from 10% to 5% of sales of HIV products, in exchange for \$350,000 in cash payments (of which \$100,000 was paid in 2005, \$50,000 paid in June 2006 and the balance accrued as of June 30, 2006). Such payment is being amortized over the life of the royalty agreement as licensing fees.

**Other Income and Expense:**

Interest expense increased by \$8,000 for the three months ended June 30, 2006 compared with the three months ended June 30, 2005 resulting from accrued interest payable on license fees offset by reductions in interest expense of leases. Interest income for the three months ended June 30, 2006 decreased \$15,000 due to less availability of funds to invest. In addition the Company sold a piece of equipment which was fully depreciated for \$5,000.



## **RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2006 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2005**

### **Revenues:**

Revenues are comprised of \$2,742,000 in net product sales and \$133,000 in grants and development income for the six months ended June 30, 2006 as compared with \$1,160,000 in net product sales, \$250,000 license revenue and \$227,000 in grant and development income for the six months ended June 30, 2005. The increase in net product sales is attributable to increased sales of our HIV tests of \$839,000 and increased sales of our Chagas tests of \$906,000 from \$36,000 to \$942,000, partially offset by decreased sales of our pregnancy test kit (a deemphasized product) of \$110,000 and decreases in other product sales aggregating \$53,000. The decrease in license revenue of \$250,000 is due to a technology transfer agreement which took place in 2005. The Company does not expect that this particular license revenue will continue in the future. The decrease in grant and development income of \$94,000 was due to certain grants received in 2005 that weren't continued or awarded in 2006.

Net product sales for the six month period ended June 30, 2006 increased 136% compared to the same period in 2005. HIV net product sales increased 144% in this period compared to the same period in 2005. The Company believes that sales of its HIV products will continue to increase in 2006 as compared to 2005 both as a result of the international marketing strategies that were implemented in 2005 and from the sales to the United States market due to the approval from the U.S. Food and Drug Administration (FDA). The Chagas net product sales increase was a result of the Company obtaining its first significant order for this product, in the amount of \$1.2 million, of which it shipped \$930,000 in the six months of 2006 and expects to ship the balance in the third quarter of 2006.

### **Gross Margin:**

Gross margin on net product sales for the six months ended June 30, 2006 was 31.6%, as compared to 5.1% for the six months ended June 30, 2005. The increase in gross margin percentage is attributable to the increased sales of HIV products, which were at a higher margin than other product lines, and because sales volume in 2005 was significantly lower, fixed overhead expenses per dollar of sales were disproportionately high.

### **Research and Development:**

Research and development expenses for the six months ended June 30, 2006 were \$744,000 compared with \$762,000 for the six months ended June 30, 2005.

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$179,000 for the six months ended June 30, 2006, a decrease of \$130,000 compared to the six months ended June 30, 2005. Most of this decrease is due to reductions in costs for clinical studies of \$95,000, salary and related expenses of \$10,000 and outside regulatory consultants of \$27,000. The costs related to the clinical trials and consulting in 2005 were related to the evaluation of the Company's HIV tests in relation of its FDA Pre-Marketing Approval ("PMA") application which was submitted in February of 2005.

Expenses other than Clinical & Regulatory Affairs increased \$113,000 and were related to increased salaries and wage-related costs of \$73,000 for new hires in the R&D group, the cost related to employee stock options vesting in the period of \$48,000, increased cost of materials of \$50,000, net of a reduction in travel and entertainment costs of \$21,000 and a reduction in grant funding of \$35,000.

The Company presently plans to increase its spending on research and development because it believes such spending will result in the development of new and innovative products. The Company will continue to focus its development efforts on its tuberculosis related products and new lateral flow technologies, some of which have patents pending.

### **Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$1,346,000 to \$2,631,000 in the six months ended June 30, 2006 compared with \$1,285,000 for the same period in 2005. This increase was attributable to increased staff costs in the accounting, administration and sales and marketing departments of \$260,000 and the cost related to employee stock options vesting in the period of \$103,000. Increased sales resulted in an increase in royalties and commissions of \$309,000. In addition there was an increase of \$190,000 in costs regarding investor relations, \$73,000 which resulted from an increase in the number of members of the Company's Board of Directors, \$52,000 from increased travel and entertainment costs, \$33,000 related to marketing consultants, \$21,000 from increased trade show costs, \$35,000 in increased license fees, increased legal expenses of \$164,000 related to patent litigation and \$84,000 related to general patent and other legal services.

**Other Income and Expense:**

Interest expense increased by \$11,000 for the six months ended June 30, 2006 compared with the six months ended June 30, 2005 resulting from accrued interest payable on license fees offset by reductions in interest expense of leases. Interest income for the six months ended June 30, 2006 decreased \$24,000 due to less availability of funds to invest. In addition the Company sold a piece of equipment which was fully depreciated for \$5,000.

**LIQUIDITY AND CAPITAL RESOURCES**

The Company had a working capital deficiency of \$614,000 at June 30, 2006 and a working capital surplus of \$650,000 at December 31, 2005. On June 29, 2006, the Company borrowed \$1,300,000 as described in the Overview section above and more fully in Note 1 of the financial statements. On March 30, 2006, the Company completed a transaction related to the Series B Offering which raised \$1,000,000 before costs in the form of 9% Convertible Series B Preferred Stock and associated warrants ("Series B Offering"). The proceeds from the bridge loan and the Series B Offering have been and are being used primarily for general corporate purposes including for sales and marketing, research and development, and intellectual property, and also for working capital, investor relations, and capital expenditures.

The Company believes its resources are sufficient to fund its needs through late third quarter of 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. Its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that it will be successful in raising sufficient capital.

The following table lists the future payments required on the Company's debt and any other contractual obligations as of June 30, 2006:

| <b>OBLIGATIONS</b>                | <b>Total</b>        | <b>Less than<br/>1 Year</b> | <b>1-3 Years</b>  | <b>4-5 Years</b> | <b>Greater<br/>than<br/>5 Years</b> |
|-----------------------------------|---------------------|-----------------------------|-------------------|------------------|-------------------------------------|
| Long Term Debt(1)                 | \$ 1,453,160        | \$ 1,420,000                | \$ 33,160         | \$ -             | \$ -                                |
| Capital Leases (2)                | \$ 64,126           | \$ 40,532                   | \$ 23,594         | \$ -             | \$ -                                |
| Operating Leases                  | \$ 75,337           | \$ 75,337                   | \$ -              | \$ -             | \$ -                                |
| Other Long Term<br>Obligations(3) | \$ 1,185,717        | \$ 838,442                  | \$ 259,775        | \$ 25,000        | \$ 62,500                           |
| <b>Total Obligations</b>          | <b>\$ 2,778,340</b> | <b>\$ 2,374,311</b>         | <b>\$ 316,529</b> | <b>\$ 25,000</b> | <b>\$ 62,500</b>                    |

(1) This includes the \$1,300,000 borrowed on June 29, 2006 (see Note 1) and accrued interest (see Note 3).

(2) This represents capital leases used to purchase capital equipment.

(3) This represents contractual obligations for fixed cost licenses and employment contracts.

**RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS**

Please see section entitled Overview above.

During the third quarter of 2006, the Company expects to start marketing its SURE CHECK HIV 1/2 and HIV 1/2 STAT-PAK in the U.S. These are the products for which it has received FDA approval.

Based upon the expected CLIA waivers referred to in the Overview section above, the Company is developing plans for marketing its HIV products in the U.S. and is considering entering into marketing arrangements with major companies who market diagnostic products in the U.S.

Recently, the United States Centers for Disease Control issued draft recommendations for HIV testing for all Americans between the ages of 13 and 64, a White House 2007 budget request for \$90 million to test an additional three million Americans using rapid HIV tests is being negotiated by Senate and House conference committees, and the FDA adopted guidelines recommended by its Blood Products Advisory Committee that set forth the conditions under which rapid HIV tests could be approved for direct over-the-counter sales to U.S. consumers. All of these developments bode well for the expansion of the U.S. rapid HIV test market; however there are still many obstacles and uncertainties to be overcome before these items become a reality that can result in realizable opportunities for the Company, and there is no assurance that they will be realized.

During 2005, the Company established offices in Nigeria and Tanzania which it believes will be significant in its continuing efforts to become part of the national testing protocols in many countries in Africa. The Company's STAT-PAK is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda and in February of 2006 was designated in four of the eight parallel testing algorithms (two tests used on each patient) adopted by the Nigerian Ministry of Health in its Interim National Testing Algorithm. The Company is making good progress towards having its HIV products designated in other countries where it has focused its efforts. The Company has registered its products and has arrangements with distribution partners in certain of these countries and is in negotiations for similar arrangements in other countries. The Company believes that its strategy of establishing offices in these challenging markets is a very effective way to obtain sustainable and supportable business.

In 2006, Chembio was one of four companies selected by the Clinton Foundation HIV/AIDS Initiative ("CHAI") to make available low-cost rapid HIV tests in order to more quickly and cost effectively achieve treatment objectives. Under the CHAI agreement, the Company has agreed to offer its HIV STAT-PAK Dipstick, Chembio's lowest cost HIV rapid test product, at a reduced price in the expectation that the Company will receive significant order volume not otherwise obtainable; this should result in efficiencies of scale that will more than justify the reduced sales price. If these order volumes are not realized, the Company has the right to terminate the agreement or renegotiate pricing. Chembio is the only U.S.-based manufacturer of the four companies in this agreement. The CHAI Procurement Consortium is currently comprised of more than 50 countries in Africa, Asia, Eastern Europe, Latin America and the Caribbean that have Memoranda of Understanding (MOUs) with CHAI. Consequently, the Company is now actively engaged with CHAI in developing sales opportunities in many of these countries. Although in some of these countries the Company has already made substantive sales efforts, there are many more where this is not the case. There is no commitment or assurance that either the Company's direct efforts to establish additional distributors and/or local assembly, or its activities through CHAI will materialize into meaningful sales.

The Company's technology transfer and supply agreement in Brazil is moving forward. The Company shipped 335,000 HIV rapid tests in the six months ended June 30, 2006, a 123% increase over the quantity sold in the same period in 2005. The Company expects to deliver components for an additional 465,000 tests during the rest of 2006, although there is no assurance that this will occur.

The Company also received, in January of 2006, an order for \$1.2 million to supply its Chagas Disease rapid test. The Company shipped approximately \$930,000 in the six months ended June 30, 2006, with the balance expected to be delivered in the third quarter of 2006. This procurement is being made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement will be used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. The Company is actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

In September 2005, the Company hired a senior diagnostics marketing executive to focus on its Tuberculosis products, both for veterinary and human TB. The Company's Non-human primate Tuberculosis product is currently under review by the United States Department of Agriculture (USDA) and it expects USDA approval toward the end of 2006 provided its tests meet certain performance and other criteria; the Company plans to submit additional veterinary TB products to the USDA this year, including a cattle TB test, subject to having the necessary performance data.

During the second quarter of 2006 the Company made significant progress in developing prototypes of the Dual Path Platform (DPP(TM)). In addition to our internal product development efforts in the infectious disease area, we believe we can also extend this technology to other medical fields, based on significant interest for a number of different applications of this technology from various potential users.

### **ITEM 3. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

As of the end of the period covered by this report, the Company conducted an evaluation under the supervision and with the participation of the principal executive officer and principal financial officer, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, to allow timely decisions regarding required disclosures.

*Changes In Internal Controls Over Financial Reporting*

There have been no changes in internal controls over financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**PART II.**

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

On April 15, 2006, as part of its regular compensation plan for non-employee directors, the Company issued an option to acquire 36,000 shares of Common Stock to one of the Company's non-employee directors, Alan Carus. The exercise price of the option is \$.75 per share, and the option vests in three equal annual installments beginning on April 15, 2006. The option expires on April 15, 2011. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

On April 17, 2006, the Compensation Committee of Chembio Diagnostics, Inc. (the "Company") approved the cancellation of each employee stock option award issued under the 1999 Equity Incentive Plan where the exercise price was greater than \$.75 per share of the Company's Common Stock, and the issuance of a new stock option award under the 1999 Equity Incentive Plan, for the same number of shares of the Company's Common Stock, with an exercise price of \$.75 per share of the Company's Common Stock for each cancelled stock option award. The market price of the Common Stock of the Company on April 17, 2006 was \$0.72 per share. In total, stock option awards to acquire 795,000 shares of Company Common Stock were cancelled, and stock option awards to acquire 795,000 shares of Company Common Stock were issued. Other than the change in the exercise price, all of the terms and conditions in each newly issued stock option award are identical to the cancelled stock option award it replaces, with the following exceptions: (i) Lawrence A. Siebert's stock option award for 50,000 shares of the Company's Common Stock, exercisable on May 28, 2006 and terminating on May 28, 2011 was replaced with a stock option award for 50,000 shares of the Company's Common Stock, exercisable on January 1, 2007 and terminating on May 28, 2011; (ii) Avi Pelosof's stock option awards for an aggregate 72,500 shares of the Company's Common Stock, 50,000 exercisable on May 28, 2005 and 22,500 on May 28, 2006 and both terminating on May 28, 2011 was replaced with a stock option award for 72,500 shares of the Company's Common Stock, exercisable on January 1, 2007 and terminating on May 28, 2011. The Company relied on Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated thereunder as the basis for its exemption from registration of this issuance. Executive officers of the Company are considered to be "accredited investors" when purchasing securities issued by the Company.

On April 30, 2006, May 31, 2006 and on June 30, 2006, the Company issued to Investor Relations Group, Inc., in payment for consulting services, warrants to purchase an aggregate of 24,999 shares, of the Company's Common Stock having an exercise price of \$.70 per share and an aggregate of 24,999 shares of the Company's Common Stock. The warrants are exercisable immediately and expire five years from the date of issue. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The sole investor in the issuance was an accredited investor.

On May 10, 2006 and on July 10, 2006, the Company issued to Bio-Business Science & Development LTDA, in payment of a liability for commissions, warrants to purchase 29,858 and 29,838 shares, respectively of the Company's Common Stock, with warrants to purchase 29,858 shares having an exercise price of \$0.883 per share and warrants to purchase 29,838 shares having an exercise price of \$0.753 per share. These warrants are exercisable immediately and expire five years from the date of issue. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The sole investor in the issuance was an accredited investor.

On May 15, 2006, the Company issued 315,364 shares of Common Stock as payment of dividends on the Company's Series A Preferred Stock. No cash was exchanged in this issuance. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investors in the issuance were accredited investors of the Company.

On June 9, 2006, the Company issued to Investor Relations Group, Inc., in payment of a liability for consulting services, 88,750 shares of the Company's Common Stock. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The sole investor in the issuance was an

accredited investor.

On June 14, 2006, the Company issued 83,757 shares of Common Stock as payment of dividends on the Company's Series A Preferred Stock. No cash was exchanged in this issuance. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investors in the issuance were accredited investors of the Company.

On June 14, 2006, the Company issued 89,379 shares of Common Stock as payment of dividends on the Company's Series B Preferred Stock. No cash was exchanged in this issuance. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investors in the issuance were accredited investors of the Company.

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**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

On June 15, 2006, the Company held its annual stockholder meeting for the purpose of 1) election of directors of the Corporation, 2) to ratify the selection of Lazar, Levine & Felix as the Corporation's certified independent accountants, 3) to vote upon adjournment or postponement of the meeting and 4) to vote upon such other business as may properly come before the meeting (there being none). A summary of the voting is tabulated below:

| #1 proposal -<br>Directors | Alan<br>Carus | Gerald<br>A.<br>Eppner | Dr. Gary<br>Meller | Lawrence<br>A.<br>Siebert |
|----------------------------|---------------|------------------------|--------------------|---------------------------|
| <b>For</b>                 | 6,440,584     | 6,440,184              | 6,440,584          | 6,440,184                 |
| <b>Against</b>             | -             | -                      | -                  | -                         |
| <b>withheld</b>            | 83,950        | 84,350                 | 83,950             | 84,350                    |
| <b>Abstain/no-vote</b>     | 3,045,329     | 3,045,329              | 3,045,329          | 3,045,329                 |

| Proposal               | #2 -<br>accounting<br>firm | #3 -<br>adjournment | #4 -<br>other<br>business |
|------------------------|----------------------------|---------------------|---------------------------|
| <b>For</b>             | 6,522,084                  | 4,641,401           | 4,563,825                 |
| <b>Against</b>         | 500                        | 218,391             | 164,240                   |
| <b>withheld</b>        | 950                        | 38,450              | 84,501                    |
| <b>Abstain/no-vote</b> | 3,046,329                  | 4,671,621           | 4,757,297                 |

**ITEM 6. EXHIBITS.**

3.1 Articles of Incorporation, as amended. (3)

3.2 Bylaws. (1)

3.3 Amendment No. 1 to Bylaws dated May 3, 2004. (2)

4.13 Form of Warrant, dated June 29, 2006. (4)

10.2 Employment Agreement dated June 15, 2006 w/ Lawrence A. Siebert. (5)

10.14 Securities Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)

10.15 Registration Rights Agreement, dated June 29, 2006. (4)

10.16 Form of Secured Debenture, dated June 29, 2006. (4)

10.17 Security Agreement, dated June 29, 2006, among the Company, Chembio Diagnostic Systems, Inc., and purchasers of the Company's Secured Debentures. (4)

10.18 Subsidiary Guarantee, dated June 29, 2006, made by Chembio Diagnostic Systems, Inc., in favor of Purchasers of the Company's Secured Debentures. (4)

31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on August 23, 1999.

(2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on May 14, 2004.

**(3) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.**

**(4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.**

**(5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Chembio Diagnostics, Inc.

Date: August 11, 2006 By: /s/ Lawrence A. Siebert  
Lawrence  
A. Siebert  
C h i e f  
Executive  
Officer  
(Principal  
Executive  
Officer)

Date: August 11, 2006 By: /s/ Richard J. Larkin  
Richard J.  
Larkin  
C h i e f  
Financial  
Officer  
(Principal  
Financial  
and  
Accounting  
Officer)