

CHEMBIO DIAGNOSTICS, INC.  
Form 10QSB  
November 13, 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 September 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 November 10, 2006, the Registrant had 11,044,580 shares outstanding of its \$.01 par value common stock.

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**Quarterly Report on FORM 10-QSB For The Periods Ended**

**September 30, 2006**

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(unaudited)

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**PART I****Item 1. FINANCIAL STATEMENTS**

**CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**

| - ASSETS -   | September 30,<br>2006<br>(Unaudited) | December 31,<br>2005 |
|--|--------------------------------------|----------------------|
| <b>CURRENT ASSETS:</b>   |                                      |                      |
| Cash   | \$ 3,474,030                         | \$ 232,148           |
| Accounts receivable, net of allowance for doubtful accounts of \$35,312 and \$20,488 for 2006 and 2005, respectively | 870,435                              | 1,255,073            |
| Inventories  | 1,091,024                            | 687,983              |
| Prepaid expenses and other current assets  | 177,451                              | 292,989              |
| <b>TOTAL CURRENT ASSETS</b>  | <b>5,612,940</b>                     | <b>2,468,193</b>     |
| <b>FIXED ASSETS</b> , net of accumulated depreciation of \$604,887 and \$559,228 for 2006 and 2005, respectively     |                                      |                      |
|  | 613,036                              | 438,632              |
| <b>OTHER ASSETS:</b>   |                                      |                      |
| Deposits and other assets  | 361,125                              | 109,581              |
|  | \$ 6,587,101                         | \$ 3,016,406         |
| <b>- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)-</b>  |                                      |                      |
| <b>CURRENT LIABILITIES:</b>  |                                      |                      |
| Accounts payable and accrued liabilities   | \$ 2,632,830                         | \$ 1,477,925         |
| Accrued interest payable   | 120,000                              | 120,000              |
| Loan payable   | 800,000                              | -                    |
| Current portion of obligations under capital leases  | 41,293                               | 38,368               |
| Payable to related party   | 182,181                              | 182,181              |
| <b>TOTAL CURRENT LIABILITIES</b>   | <b>3,776,304</b>                     | <b>1,818,474</b>     |
| <b>OTHER LIABILITIES:</b>  |                                      |                      |
| Obligations under capital leases - net of current portion  | 13,113                               | 44,417               |
| Liabilities in respect to warrants   | 331,114                              | -                    |
| Derivative liability   | 218,025                              | -                    |
| Accrued interest, net of current portion   | 3,160                                | 100,812              |
| <b>TOTAL LIABILITIES</b>   | <b>4,341,716</b>                     | <b>1,963,703</b>     |

**COMMITMENTS AND  
CONTINGENCIES**
**PREFERRED STOCK - Series C**

7% Convertible - \$.01 par value: 80 and none shares issued and outstanding as of 2006 and 2005, respectively - net of derivative liability of \$218,025. Liquidation preference of \$4,000,000

**3,143,415** -

**STOCKHOLDERS' EQUITY  
(DEFICIENCY)**

Preferred Stock - 10,000,000 shares authorized:

Series A 8% Convertible - \$.01 par value: 149.92119 and 158.68099 shares issued and outstanding as of 2006 and 2005, respectively.

Liquidation preference of \$4,644,882

**2,591,591** 2,628,879

Series B 9% Convertible - \$.01 par value: 113.93591 and 102.19760 shares issued and outstanding as of 2006 and 2005, respectively.

Liquidation preference of \$5,822,663

**3,414,868** 3,173,239

Common stock - \$.01 par value; 100,000,000 shares authorized 11,036,246 and 8,491,429 shares issued and outstanding as of 2006 and 2005, respectively

**110,363** 84,914

Additional paid-in capital

**17,462,415** 14,034,099

Accumulated deficit

**(24,477,267)** (18,868,428)

**TOTAL STOCKHOLDERS'  
EQUITY (DEFICIENCY)**

**(898,030)** 1,052,703

**\$ 6,587,101** \$ 3,016,406

*See notes accompanying the financial statements.*

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

(UNAUDITED)

|  | <u>Three months ended</u>           |                                     | <u>Nine months ended</u>            |                                     |
|--|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
|  | <u>September</u><br><u>30, 2006</u> | <u>September</u><br><u>30, 2005</u> | <u>September</u><br><u>30, 2006</u> | <u>September</u><br><u>30, 2005</u> |
| <b>REVENUES:</b>                                     |                                     |                                     |                                     |                                     |
| Net sales  | \$ 942,088                          | \$ 843,435                          | \$ 3,683,599                        | \$ 2,003,868                        |
| License revenue                                      | -                                   | -                                   | -                                   | 250,000                             |
| Research grants and development income               | 76,102                              | 101,277                             | 209,494                             | 328,419                             |
| <b>TOTAL REVENUES</b>                                | <b>1,018,190</b>                    | 944,712                             | <b>3,893,093</b>                    | 2,582,287                           |
| Cost of sales  | 830,819                             | 669,817                             | 2,705,749                           | 1,770,747                           |
| <b>GROSS PROFIT</b>                                  | <b>187,371</b>                      | 274,895                             | <b>1,187,344</b>                    | 811,540                             |
| <b>OVERHEAD COSTS:</b>                               |                                     |                                     |                                     |                                     |
| Research and development expenses                    | 318,048                             | 292,198                             | 1,062,319                           | 1,053,731                           |
| Selling, general and administrative expenses         | 1,109,797                           | 822,010                             | 3,740,765                           | 2,109,030                           |
|  | <b>1,427,845</b>                    | 1,114,208                           | <b>4,803,084</b>                    | 3,162,761                           |
| <b>LOSS FROM OPERATIONS</b>                          | <b>(1,240,474)</b>                  | (839,313)                           | <b>(3,615,740)</b>                  | (2,351,221)                         |
| <b>OTHER INCOME (EXPENSES):</b>                      |                                     |                                     |                                     |                                     |
| Other income   | 25,000                              | -                                   | 25,000                              | -                                   |
| Sale of fixed asset                                  | -                                   | -                                   | 5,000                               | 400                                 |
| Interest income                                      | 2,094                               | 10,135                              | 2,980                               | 33,456                              |
| Interest (expense)                                   | (360,606)                           | (2,804)                             | (382,316)                           | (11,269)                            |
| <b>LOSS BEFORE INCOME TAXES</b>                      | <b>(1,573,986)</b>                  | (831,982)                           | <b>(3,965,076)</b>                  | (2,328,634)                         |
| Income taxes   | -                                   | -                                   | -                                   | -                                   |
| <b>NET LOSS</b>                                      | <b>(1,573,986)</b>                  | (831,982)                           | <b>(3,965,076)</b>                  | (2,328,634)                         |
| Dividends payable in stock to preferred stockholders | 220,909                             | 206,256                             | 641,769                             | 600,495                             |
| Dividend accreted to preferred stock for             | 538,560                             | -                                   | 1,001,994                           | 2,698,701                           |

associated costs and  
a beneficial  
conversion feature

**NET LOSS  
ATTRIBUTABLE  
TO COMMON**

**STOCKHOLDERS**    \$    (2,333,455)    \$    (1,038,238)    \$    (5,608,839)    \$    (5,627,830)

**Basic and diluted  
loss per share**

                          \$            (0.21)    \$            (0.13)    \$            (0.56)    \$            (0.75)

*Weighted number of  
shares outstanding,  
basic and diluted*

**10,961,662**            8,137,727            **10,014,207**            7,500,167

*See notes accompanying the financial statements.*



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

|   | Nine months ended     |                       |
|---|-----------------------|-----------------------|
|   | September 30,<br>2006 | September 30,<br>2005 |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>  |                       |                       |
| Net loss  | \$ (3,965,076)        | \$ (2,328,634)        |
| Adjustments to reconcile net loss to net cash used in operating activities:   |                       |                       |
| Depreciation and amortization   | 146,346               | 79,429                |
| Provision for doubtful accounts   | 7,945                 | (4,278 )              |
| Non-cash interest expense   | 331,114               | -                     |
| Common stock, options and warrants issued as compensation   | 458,412               | 26,240                |
| Changes in:   |                       |                       |
| Accounts receivable   | 376,693               | (559,878)             |
| Restricted cash   | -                     | 250,000               |
| Inventories   | (403,041)             | (32,215)              |
| Prepaid expenses and other current assets   | 115,538               | 90,189                |
| Other assets and deposits   | (251,544)             | (100,212)             |
| Payment of accrued interest   | (97,652)              | (89,790)              |
| Accounts payable and accrued expenses   | 1,178,931             | (365,326)             |
| <b>Net cash used in operating activities</b>  | <b>(2,102,334)</b>    | <b>(3,034,475)</b>    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>  |                       |                       |
| Acquisition of fixed assets   | (320,750)             | (324,642)             |
| <b>Net cash used in investing activities</b>  | <b>(320,750)</b>      | <b>(324,642)</b>      |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>  |                       |                       |
| Sale of Series C Preferred Stock and associated warrants, net of cash cost of financing of \$50,000   | 3,950,000             | -                     |
| 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             | -                     |
| Payment on bridge loan  | (500,000)             |                       |
| Proceeds from exercise of warrants  | 86,321                | 25,196                |
| Payment of capital lease obligation   | (28,379)              | (28,402)              |

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|   |                     |                     |
|---|---------------------|---------------------|
| Proceeds from working capital loan  | -                   | 161,917             |
| Payment of working capital loan   | -                   | (206,917)           |
| Payment of dividends  | (140,226)           | -                   |
| <b>Net cash provided by financing activities</b>                                      | <b>5,664,966</b>    | <b>4,677,655</b>    |
| <b>NET INCREASE IN CASH</b>   | <b>3,241,882</b>    | <b>1,318,538</b>    |
| Cash - beginning of the period  | 232,148             | 34,837              |
| <b>CASH - end of the period</b>   | <b>\$ 3,474,030</b> | <b>\$ 1,353,375</b> |
| <b>Supplemental disclosure of cash flow information:</b>                              |                     |                     |
| Cash paid during the period for interest  | \$ 112,302          | \$ 118,531          |
| <b>Supplemental disclosures for non-cash investing and financing activities:</b>      |                     |                     |
| Warrants issued as payment for fees   | \$ -                | \$ 366,559          |
| 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              |
| Value of warrants issued allocated to additional paid in capital                      | 1,120,030           | 2,349,893           |
| Accreted beneficial conversion to preferred stock                                     | 1,001,994           | 2,698,701           |
| Accreted dividend to preferred stock  | 641,769             | 600,495             |
| Common stock issued as payment of dividend  | 522,794             | 187,679             |
| Preferred B issued as payment of dividend   | 89,899              | 203,493             |
| Preferred A converted to common stock   | 122,006             | 52,631              |
| Preferred B converted to common stock   | 360,651             | 228,877             |

*See notes accompanying the financial statements.*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 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® HIV 1/2, HIV 1/2 STAT-PAK™ and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease (Chagas STAT-PAK™).

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. The Company has sustained significant operating losses in the nine months of 2006 and the years 2005 and 2004. At September 30, 2006, the Company had a Stockholders' Deficiency of \$898,030 and a working capital surplus of \$1,836,636. On September 29, 2006 and October 5, 2006, the Company completed a private offering which raised \$8,150,000 (please see Recent Developments below for a more complete discussion of this financing). The Company believes its resources are sufficient to fund its needs through the end of 2007. 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. If the Company's resources are not sufficient to fund its needs through 2007 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 and Drug Administration (FDA) for its SURE CHECK® HIV 1/2 and HIV 1/2 STAT-PAK™ 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.

*Bridge Loan payable*

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 was due on September 29, 2006 and was 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. See footnote 4(b) for further information on the valuation and terms of the warrants.

The lenders also had 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 could 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%. Subsequent to September 30, 2006, \$600,245, plus

interest, of the secured debentures were converted into the Series C Offering (see below) at a discount of 12.5% and the balance amount of \$199,755 was repaid from the proceeds of the Series C Offering.

The Agreements related to the June 2006 financing 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.

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

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 (calculated on a Black-Scholes option pricing model) of the warrants in connection to the June 29, 2006 private placement, \$328,341, as deferred financing costs with a corresponding credit to a long term derivative liability on the Consolidated Balance Sheet as of September 30, 2006. The deferred financing cost was amortized on a straight-line basis over the life of the underlying debt. Accordingly, as at September 30, 2006, the deferred financing cost was fully amortized.

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.

*CLIA Waiver*

In July 2006 the Company submitted to the FDA CLIA ("Clinical Laboratory Improvement Act" waiver applications for its HIV 1/2 STAT-PAK™ and SURE CHECK® HIV 1/2 products. These waivers are essential in order to market FDA approved products to the POL (physician office laboratory) and public health segments of the United States market. These applications are pending at the FDA.

*Series C Preferred Stock Offering*

On September 29, 2006, the Company sold 80 shares of its 7% series C convertible preferred stock, together with warrants to purchase 1,250,000 shares of common stock, exercisable at \$1.00 per share. This issuance was made in connection with the Company's private placement for \$8,150,000, consisting of 165 shares of 7% series C convertible preferred stock (at a stated value of \$50,000 per share), together with warrants to purchase 2,578,125 shares of its common stock (the "Series C Offering"). \$500,000 of the proceeds were used during September 2006, to repay part of the bridge loan borrowed on June 29, 2006. The balance was either repaid (\$199,755) or converted into Series C in October of 2006 (\$600,245). The Company believes this Series C Offering will be enough to supply the Company's cash needs through the end of 2007. Refer to footnote 4(e) for a description of selected terms and the accounting of the Series C Offering.

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

***(a) Basis of Presentation:***

The consolidated interim financial information as of September 30, 2006 and for the three and nine-month periods ended September 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 September 30, 2006, and consolidated results of operations for the three and nine-month periods, and cash flows for the nine month periods ended September 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.

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

**(b) Inventories:**

Inventory consists of the following at:

|                  | <b>September</b>    | <b>December</b>   |
|------------------|---------------------|-------------------|
|                  | <b>30, 2006</b>     | <b>31, 2005</b>   |
| <b>Raw</b>       |                     |                   |
| <b>Materials</b> | <b>\$ 475,077</b>   | <b>\$ 425,758</b> |
| <b>Work in</b>   |                     |                   |
| <b>Process</b>   | <b>93,422</b>       | <b>86,001</b>     |
| <b>Finished</b>  |                     |                   |
| <b>Goods</b>     | <b>522,525</b>      | <b>176,224</b>    |
|                  | <b>\$ 1,091,024</b> | <b>\$ 687,983</b> |

**(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 loss per share:

|                | <b><u>For the three</u></b> |                         | <b><u>For the nine months ended</u></b> |                             |
|----------------|-----------------------------|-------------------------|---|-----------------------------|
|                | <b><u>months ended</u></b>  |                         | <b><u>September</u></b>                 |                             |
|                | <b><u>September</u></b>     | <b><u>September</u></b> | <b><u>September</u></b>                 | <b><u>September 30,</u></b> |
|                | <b><u>30, 2006</u></b>      | <b><u>30, 2005</u></b>  | <b><u>30, 2006</u></b>                  | <b><u>2005</u></b>          |
| <b>Basic</b>   | <b>10,961,662</b>           | <b>8,137,727</b>        | <b>10,014,207</b>                       | <b>7,500,167</b>            |
| <b>Diluted</b> | <b>10,961,662</b>           | <b>8,137,727</b>        | <b>10,014,207</b>                       | <b>7,500,167</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 nine months ended September 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 and outstanding as at September 30, 2006 and 2005, have been excluded from the per share computations:

|                  | <b><u>September</u></b> | <b><u>September</u></b> |
|------------------|-------------------------|-------------------------|
|                  | <b><u>30, 2006</u></b>  | <b><u>30, 2005</u></b>  |
| <b>1999 Plan</b> | <b>1,629,750</b>        | <b>1,256,500</b>        |
| <b>Stock</b>     |                         |                         |
| <b>Options</b>   |                         |                         |
| <b>Other</b>     | <b>144,625</b>          | <b>144,625</b>          |
| <b>Stock</b>     |                         |                         |
| <b>Options</b>   |                         |                         |

**Warrants** 24,713,994 21,263,966  
**Convertible** 16,835,036 16,311,602  
**Preferred  
Stock**

*(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.

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

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 nine month periods ended September 30, 2006 include share-based compensation expense totaling approximately \$33,100 and \$247,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold (\$3,100 and \$25,000), research and development (\$6,300 and \$62,000) and selling, general and administrative expenses (\$23,700 and \$160,000). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

Stock option compensation expense in the nine months 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 nine months ended September 30, 2006 and 2005 was none and \$.53 and \$.38 and \$.49 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:

|                          | <u>Three Months Ended</u> |                  | <u>Nine Months Ended</u> |                  |
|--------------------------|---------------------------|------------------|--------------------------|------------------|
|                          | <u>September</u>          | <u>September</u> | <u>September</u>         | <u>September</u> |
|                          | <u>30, 2006</u>           | <u>30, 2005</u>  | <u>30, 2006</u>          | <u>30, 2005</u>  |
| Expected term (in years) | n/a                       | 5                | 4 to 5                   | 5                |

|                         |            |        |   |                      |
|-------------------------|------------|--------|---|----------------------|
| Expected volatility     | <b>n/a</b> | 89.82% | <b>116.20%</b><br><b>to</b><br><b>118.03%</b> | 95.56% to<br>114.94% |
| Expected dividend yield | <b>n/a</b> | 0%     | <b>0%</b>                                     | 0%                   |
| Risk-free interest rate | <b>n/a</b> | 4.08%  | <b>4.66%</b> to<br><b>4.92%</b>               | 3.72% to<br>4.18%    |

There were no awards issued during the three months ended September 30, 2006.

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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><u>For the three<br/>months ended</u></b><br>September<br>30, 2005 | <b><u>For the nine<br/>months ended</u></b><br>September<br>30, 2005 |
|--|---|--|
| Net loss attributable to common stockholders, as reported  | \$ (1,038,238)  | \$ (5,627,830)   |
| 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) | (59,435)  | (130,906)  |
| Pro forma net loss attributable to common stockholders   | \$ (1,097,673)  | \$ (5,758,736)   |
| Net loss per share:  |   |  |
| Basic and diluted loss per share - as reported   | \$ (0.13)   | \$ (0.75)  |
| Basic and diluted loss per share - pro forma   | \$ (0.13)   | \$ (0.77)  |

The Company did not grant any options in the three months ended September 30, 2006. The Company granted 831,250 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.

The following table provides stock options activity for the nine months ended September 30, 2006:

| <b><u>Stock Options</u></b>    | <b><u>Number<br/>of Shares</u></b> | <b><u>Weighted<br/>Average<br/>Exercise<br/>Price<br/>per Share</u></b> | <b><u>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Term</u></b> | <b><u>Aggregate<br/>Intrinsic<br/>Value</u></b> |
|--------------------------------|------------------------------------|---|---|---|
| Outstanding at January 1, 2006 | 1,285,750                          | \$1.20  |   |   |
| Granted                        | 1,147,250                          | \$0.71  |   |   |
| Cancelled                      | (795,250)                          | \$1.56  |   |   |

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|                    |           |        |            |            |
|--------------------|-----------|--------|------------|------------|
| Exercised          | -         | -      |            |            |
|                    | (         |        |            |            |
| Forfeited/expired  | 8,000)    | \$0.75 |            |            |
| Outstanding at     |           |        |            |            |
| September 30, 2006 | 1,629,750 | \$0.69 | 3.90 years | \$148,179  |
| Exercisable at     |           |        |            |            |
| September 30, 2006 | 1,164,250 | \$0.68 | 3.75 years | \$ 114,219 |

As of September 30, 2006, there was \$51,363 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 .40 years. The total fair value of shares vested during the three months ended September 30, 2006 and 2005, was \$3,647 and none, respectively. The total fair value of shares vested during the nine months ended September 30, 2006 and 2005, was \$401,381 and \$66,252, respectively.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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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 nine months ended September 30, 2006 or September 30, 2005. For the three and nine months ended September 30, 2006, 7,500 and 8,000 options expired, respectively.

**(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<br/>ended</b> |                                      | <b>For the nine months<br/>ended</b> |                                      |
|------------------|---------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
|                  | <b><u>September<br/>30, 2006</u></b>  | <b><u>September<br/>30, 2005</u></b> | <b><u>September 30,<br/>2006</u></b> | <b><u>September 30,<br/>2005</u></b> |
| Africa           | \$ 493,922                            | \$ 95,550                            | \$ 1,229,083                         | \$ 313,261                           |
| Asia             | 53,945                                | 37,640                               | 205,234                              | 113,729                              |
| Australia        | 1,180                                 | 520                                  | 1,180                                | 13,598                               |
| Europe           | 16,313                                | 20,460                               | 62,642                               | 75,303                               |
| Middle<br>East   | 5,505                                 | 8,720                                | 13,245                               | 106,036                              |
| North<br>America | 130,349                               | 138,452                              | 279,620                              | 374,132                              |
| South<br>America | 240,874                               | 542,093                              | 1,892,595                            | 1,007,809                            |
|                  | <b>\$942,088</b>                      | \$843,435                            | <b>\$3,683,599</b>                   | \$2,003,868                          |

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

Accounts payable and accrued liabilities consists of:

|                                    | <b>September<br/>30, 2006</b> | December<br>31, 2005 |
|------------------------------------|-------------------------------|----------------------|
| Accounts<br>payable -<br>suppliers | \$ 1,220,443                  | \$ 550,247           |
|                                    | <b>160,734</b>                | 171,587              |

|                                 |                     |                     |
|---------------------------------|---------------------|---------------------|
| Accrued commissions             |                     |                     |
| Accrued royalties / licenses    | <b>509,261</b>      | 381,510             |
| Accrued payroll and other taxes | <b>135,392</b>      | 63,146              |
| Accrued vacation                | <b>185,355</b>      | 145,566             |
| Accrued legal and accounting    | <b>59,595</b>       | 50,024              |
| Accrued expenses - other        | <b>362,050</b>      | 115,845             |
| <b>TOTAL</b>                    | <b>\$ 2,632,830</b> | <b>\$ 1,477,925</b> |

*(h) Recent Accounting Pronouncements*SEC Staff Accounting Bulletin 108 ("SAB 108"), Considering the Effects of Prior Year Misstatements when Qualifying Misstatements in Current Year Financial Statements

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements." SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements.

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In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as a "dual approach" because it requires quantification of errors under both the iron curtain and the roll-over methods.

SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been used or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings.

We will adopt the provisions of SAB 108 in connection with the preparation of our annual financial statements for the year ending December 31, 2006. We currently do not believe that its adoption will have any impact on our financial statements

**Statement of Financial Accounting Standard 158, Fair Value Measurements ("SFAS 158")**

On September 15, 2006, the Financial Accounting Standard Board issued a standard that provides enhanced guidance for using fair value to measure assets and liabilities. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances.

This Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year, including financial statements for an interim period within that fiscal year. The Company will adopt this pronouncement effective periods beginning January 1, 2008. We currently do not believe that its adoption will have any impact on our financial statements.

**FSP FAS 123(R)-5, Amendment of FASB Staff Position FAS 123(R)-1**

FSP FAS 123(R)-5 was issued on October 10, 2006. The FSP provides that instruments that were originally issued as employee compensation and then modified, and that modification is made to the terms of the instrument solely to reflect an equity restructuring that occurs when the holders are no longer employees, no change in the recognition or the measurement (due to a change in classification) of those instruments will result if both of the following conditions are met: (a). There is no increase in fair value of the award (or the ratio of intrinsic value to the exercise price of the award is preserved, that is, the holder is made whole), or the antidilution provision is not added to the terms of the award in contemplation of an equity restructuring; and (b). All holders of the same class of equity instruments (for example, stock options) are treated in the same manner. The provisions in this FSP shall be applied in the first reporting period beginning after the date the FSP is posted to the FASB website. We will adopt this FSP from its effective date. We currently do not believe that its adoption will have any impact on our financial statements.

**NOTE**

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**LONG-TERM DEBT:**

In connection with the Series B offering, interest that had accrued on certain debt through December 29, 2004 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 accrued liability. As of September 30, 2006 the total remaining outstanding interest was \$123,160.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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**NOTE 4—STOCKHOLDERS' EQUITY:**

*(a) Common Stock*

During the three and nine months ended September 30, 2006 the Company issued 25,000 and 147,082 shares, respectively of its Common Stock to a consultant as compensation.

The number of shares issued was a fixed number set forth in the consultant's contract, with specific issue dates and without regard to the market price of the stock on the date of issuance. For accounting purposes, the shares were valued based on the closing market price on date of issuance from \$0.55 to \$0.91 per share and the related compensation expense for the three and nine months ended September 30, 2006 was \$20,167 and \$115,028 respectively.

In July 2006, the Company issued to a member of the Board of Directors 15,000 shares of common stock as additional compensation for services as the audit committee chair. This stock was valued based on the market closing price on the date of the grant and \$10,650 was charged to expense.

There was no conversion activity in the three months ended September 30, 2006. During the nine months ended September 30, 2006 Series A Preferred shareholders converted 8.75980 shares into 437,989 shares of Common Stock and Series B Preferred shareholders converted 12.05966 shares into 988,494 shares of Common Stock.

During the nine months ended September 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 nine months ended September 30, 2006 the Company issued 399,121 shares of its Common Stock as payment of dividends on its Series A Preferred Stock and 416,440 shares of its Common Stock as payment of dividends on its Series B Preferred Stock, These shares were valued using a 10 day volume weighted average price for the ten trading days immediately preceding the issue date.

*(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. These warrants have an exercise price of \$0.61 per share and a five year life.

Warrants to purchase 520,000 shares of Common Stock were issued in connection with the bridge loan and were assigned an initial value of \$328,341. As of September 30, 2006, the warrants were revalued at \$331,114 and were charged to interest expense in the three months ended September 30, 2006. These warrants have an exercise price of \$0.75 per share and a five year life.

Warrants to purchase 1,250,000 shares of Common Stock were issued in connection with the completed Series C Offering and were assigned a value of \$638,560. These warrants have an exercise price of \$1.00 per share and a five year life.

During the three and nine months ended September 30, 2006, the Company issued warrants to purchase 25,000 and 183,599 shares, respectively of Common Stock at exercise prices from \$0.55 to \$0.883 per share to a sales agent 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 nine months ended September 30, 2006 was \$15,500 and \$38,324, respectively). These warrants have a five year life.

All of the above warrants were valued using a Black-Scholes option pricing model based on assumptions for expected volatilities from 116.2% to 118.03%, expected lives of 5 years and expected risk free interest rates from 4.55% to 5.13%.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
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**(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 \$982.15 per share, an aggregate for all such shares of \$4,644,882. Accrued but unpaid dividends of \$147,246 are included in the preferred stock carrying value as at September 30, 2006.

Dividends: The 8% per annum dividend is payable semi-annually, in cash or, at the Company's option, in Common Stock, except as to Vicis Capital which is to be paid in cash unless it opts to take its dividends 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 \$1,104.72 per share, an aggregate for all such shares of \$5,822,663. Accrued but unpaid dividends of \$125,867 are included in the preferred stock carrying value as at September 30, 2006. The accrued but unpaid dividend was paid on January 2, 2006 by the issuance of 4.60249 shares Series B Preferred Stock valued at the stated value of \$50,000 per share. 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 amendments, 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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**(e) Series C 7% Convertible Preferred Stock:**

On September 29, 2006, the Company sold \$4 million of Series C Preferred Stock (see note 6) pursuant to provisions of the September 29, 2006 Series C 7% Preferred Stock financing agreements. In addition the Company issued 1,250,000 warrants to the investors. See note 4(b) for information on the warrants. See note 1- Recent Developments for additional information. A summary of the significant terms as amended on October 5, 2006 are as follows:

*Dividends.* Holders of series C preferred stock are entitled to a 7% per annum dividend per share. The dividend accrues and is payable semi-annually in cash or in shares of common stock, at our option. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of series C preferred stock and upon a liquidation event.

*Conversion.* The series C preferred stock is convertible, at the option of the holders, into shares of our common stock at a conversion price of \$.80 per share. Based on the original purchase price of \$50,000 per share, each share of series C preferred stock is convertible into 62,500 shares of our common 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 C Preferred Stock. The redemption value is greater of (i) 130% of the stated value or \$65,000 and (ii) the product of (a) daily volume weighted average price of the Company's common stock and (b) a quotient of \$65,000 divided by the then existing conversion price, plus accrued and unpaid dividends and all liquidated damages.

*Liquidation preference:* The liquidation preference is \$50,000 per share plus accrued and unpaid dividends and all liquidated damages. There are no accrued but unpaid dividends at September 30, 2006. The aggregate liquidation preference as of September 30, 2006 is \$4,000,000

The Company has accounted for the Series C Offering 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 allocated the value received between the preferred stock and the related warrants. The allocated value for the preferred stock and the related warrants were \$3,361,440 and \$638,560, respectively. Further, the Company has determined the redemption feature in the Series C Preferred Stock needs to be bifurcated and has valued the same at \$218,025. The warrant value and the value of the redemption feature is treated as discount and the preferred stock is reflected net of this discount. Due to the contingent redemption feature, the Series C Preferred Stock is reflected as temporary equity. The Series C 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 carrying value up to its redemption value. The liability for the value of the redemption feature will be "marked to market" in future accounting periods until such time as the redemption is exercised or the feature meets the criteria for equity classification. See footnote 4(b) for the valuation of warrants.

In addition, as per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments", the Company evaluated the Series C Preferred Stock transaction that occurred in September 2006 and found that there were associated beneficial conversion features totaling \$538,560; the preferred stock was further discounted by this amount. The beneficial conversion amount related to the valuation of the preferred stock (\$538,560) was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately. The accretion was reflected as dividend expense.

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**NOTE**                    **5**                    —                    **COMMITMENTS AND CONTINGENCIES:**

*(f) Economic Dependency:*

The Company had sales to two customers in excess of 10% of total sales in the three months ended September 30, 2006. Sales to these customers approximated \$363,000 and \$232,000, respectively.

The Company had sales to one customer in excess of 10% of total sales in the three months ended September 30, 2005. Sales to this customer approximated \$510,000.

The Company had sales to three customers in excess of 10% of total sales in the nine months ended September 30, 2006. Sales to these customers approximated \$1,197,000, \$685,000 and \$640,000, respectively.

The Company had sales to one customer in excess of 10% of total sales in the nine months ended September 30, 2005. Sales to this customer approximated \$862,000.

The Company had purchases from one vendor in excess of 10% of total purchases for the three months ended September 30, 2006. Purchases from this vendor approximated \$70,000

The Company had purchases from one vendor in excess of 10% of total purchases for the nine months ended September 30, 2006. Purchases from this vendor approximated \$202,000.

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

*(g) 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.

*(h) Litigation:*

On September 29, 2006, the Company and StatSure Diagnostic Systems, Inc. ("StatSure) entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure' barrel patent and other matters were settled. In addition the parties entered into the Joint HIV Barrel Product Commercialization Agreement, which provides that the parties will equally share in the profits relating to all SURE CHECK® HIV 1/2 after reimbursement to the Company of its manufacturing and related costs, as defined, and that they will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to the Company of its barrel patent for all HIV applications, thereby ensuring the Company's exclusive right to manufacture.

**NOTE**                    **6**                    —                    **Subsequent events:**

***Series C Financing:***

On October 5, 2006 the Company completed its private offering by selling \$4,150,000 of its Series C Preferred Stock. \$600,245 of the debentures sold on June 29, 2006 was converted into the Series C Offering at a discount of 12.5% pursuant to the terms of the debenture offering. Some of the proceeds from this offering were used to pay the \$199,755 balance of remaining debentures with interest. The Company paid \$50,000 and issued 62,500 warrants (at an exercise price of \$1.00 per share with a five year life) to an investment banker in connection with \$1.0 million of the financing.

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**NOTE**                      **7**                      **—**                      **comparative information:**

Certain amounts for fiscal 2005 have been reclassified to conform with the current year's financial statement presentation.

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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 ongoing 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 the Company and its subsidiaries, 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. The Company has sustained significant operating losses in the nine months of 2006 and the years 2005 and 2004. At September 30, 2006, the Company had a Stockholders' Deficiency of \$898,030, and a working capital surplus of \$1,836,636. Including the funds received from the Series C 7% Convertible Preferred Stock offering, (the "Series C Offering" - see below), the Company believes its resources are sufficient to fund its needs through the end of 2007. 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. If the

Company's resources are not sufficient to fund its needs through 2007 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 the Company to market its rapid HIV tests to clinical laboratories and hospitals in the United States. FDA approval also allows the Company 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 was repaid in part on September 29, 2006 and the balance converted on October 5, 2006. The loan was secured by a lien on the assets of the Company. See Note 1 of the financial statements for further details.

On September 29, 2006 and October 5, 2006, the Company completed the Series C Preferred Stock Offering for \$8,150,000. Some of the proceeds were used to repay the loan borrowed on June 29, 2006.

### **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, accounting for complex financial instruments 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, see note 2-e) see our annual report on Form 10-KSB for the period ended December 31, 2005 which was filed with the S.E.C. on March 30, 2006.

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

#### **Revenues:**

Revenues are comprised of \$942,000 in net product sales and \$76,000 in grants and development income for the three months ended September 30, 2006 as compared with \$843,000 in net product sales and \$101,000 in grant and development income for the three months ended September 30, 2005. The increase in net product sales is attributable to increased sales of our Chagas tests of \$231,000 from \$28,000 to \$259,000, partially offset by decreased sales of our HIV products of \$46,000, pregnancy test kit (a deemphasized product) of \$40,000 and decreases in other product sales aggregating \$48,000. The decrease in grant and development income of \$25,000 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 September 30, 2006 increased 12% compared to the same period in 2005. HIV net product sales decreased 8% in this period compared to the same period in 2005. The Company had a \$465,000 order from Brazil that would have resulted in increased HIV sales in the third quarter of 2006 if our customer had completed the necessary import documentation on a timely basis. The necessary documentation has since been completed and this order was shipped in late October 2006. This order was for \$465,000 and would have resulted in increased HIV sales if it could have been shipped in the third quarter of 2006. The Company believes that sales of its HIV products will increase in the fourth quarter of 2006 as compared to the fourth quarter of 2005 as a result of shipping the Brazil order mentioned earlier and the international marketing strategies that were implemented in 2005. 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 \$950,000 in the first half of 2006 and the balance of \$230,000 in the third quarter of 2006.

#### **Gross Margin:**

Gross margin on net product sales for the three months ended September 30, 2006 was 11.8%, as compared to 20.6% for the three months ended September 30, 2005. The decrease in gross margin percentage is attributable to the decreased sales of HIV products and the delay of the Brazil order mentioned above, which were at a higher margin than other product lines, and because the Company has had to increase overhead expenses due to the FDA approval of its two HIV products.

#### **Research and Development:**

Research and development expenses for the three months ended September 30, 2006 were \$318,000 compared with \$292,000 for the three months ended September 30, 2005.

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs totaled \$71,000 for the three months ended September 30, 2006, a decrease of \$1,000 compared to the three months ended September 30, 2005. While the overall change was immaterial the components changed. There was also a decrease due to reductions in costs for clinical studies of \$14,000. This decrease was offset by increases in salaries and related expenses. 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 \$27,000 and were related to increased salaries and wage-related costs of \$41,000 for new hires in the R&D group and the cost related to employee stock options vesting in the period of \$6,000, additional temporary labor of \$15,000, increase in travel and entertainment costs of \$2,000 offset by a reduction in the cost of materials of \$25,000, and a reduction in grant funding of \$10,000.

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 that will drive revenue growth. The Company will continue to focus its development efforts on its HIV and tuberculosis rapid test products, some of which incorporate patent-pending technologies.

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™. A final set of clinical reproducibility trials is scheduled to start during the fourth 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 first or second quarter of 2007. The Company anticipates that additional commercialization will begin in the second 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 family name for the technology is VetTB STAT-PAK™. Application to the USDA is targeted for the fourth quarter of 2006 for the ElephantTB STAT-PAK Assay with the other to follow in early 2007. The Company anticipates commercialization of these products to start in the second quarter of 2007 for at least the ElephantTB STAT-PAK to be followed by veterinary tests for cervids (CervidTB STAT-PAK), cattle (BovidTB STAT-PAK) and camelids (CamelidTB STAT-PAK), although there are no assurances that it will be successful.

**Dual Path Platform (DPP™)**

During the third quarter of 2006 significant additional progress was made in developing prototypes of the Dual Path Platform, including the testing of our current HIV test strip with DPP and identifying an oral fluid collection system that would be used with an oral fluid HIV test incorporating DPP. We have also generated interest in this platform as a result of our initial business development efforts for collaborative and licensing opportunities for this technology, and we are in preliminary discussions with several parties in this regard. We believe we can extend this technology to many applications within the infectious disease field, as well as other medical fields.

**Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$288,000 to \$1,110,000 in the three months ended September 30, 2006 compared with \$822,000 for the same period in 2005. This increase was attributable to increased staff costs in the accounting, administration and sales and marketing departments of \$126,000 and the cost related to employee stock options vesting in the period of \$15,000. In addition there was an increase of \$71,000 in costs classified as investor relations, \$21,000 of which resulted from an increase in the number of members of the Company's Board of Directors, \$27,000 from increased travel and entertainment costs, \$16,000 from increased trade show costs, \$16,000 in increased license fees, increased legal expenses of \$44,000 related to patent litigation, \$65,000 related to general patent and other legal services offset by a reduction in royalties and commissions of \$101,000.

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 September 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 \$358,000 for the three months ended September 30, 2006 compared with the three months ended September 30, 2005. Almost all of this increase was due to the valuation of the warrants associated with debentures issued on June 29, 2006 and amortized over the three month life which totaled \$331,000. In addition, the accrued interest on this debt was \$26,000. Interest income for the three months ended September 30, 2006 decreased \$8,000 due to less availability of funds to invest. In addition the Company received \$25,000 from a New York State grant related to marketing research.

**RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2006 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2005**

**Revenues:**

Revenues are comprised of \$3,684,000 in net product sales and \$209,000 in grants and development income for the nine months ended September 30, 2006 as compared with \$2,004,000 in net product sales, \$250,000 in license revenue and \$328,000 in grant and development income for the nine months ended September 30, 2005. The increase in net product sales is attributable to increased sales of our HIV tests of \$793,000 and increased sales of our Chagas tests of \$1,137,000 from \$64,000 to \$1,201,000, partially offset by decreased sales of our pregnancy test kit (a deemphasized product) of \$150,000 and decreases in other product sales aggregating \$100,000. 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 \$119,000 was due to certain grants received in 2005 that weren't continued or awarded in 2006.

Net product sales for the nine month period ended September 30, 2006 increased 84% compared to the same period in 2005. HIV net product sales increased 67% in this period compared to the same period in 2005. The Company had a \$465,000 HIV product order from Brazil that it would have shipped in the third quarter but for a delay in our customer completing required import documentation on a timely basis. The documentation was completed in October and this order was shipped in late October 2006. 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 in 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, which it shipped in the nine months of 2006.

**Gross Margin:**

Gross margin on net product sales for the nine months ended September 30, 2006 was 26.5%, as compared to 11.6% for the nine months ended September 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 nine months ended September 30, 2006 were \$1,062,000 compared with \$1,054,000 for the nine months ended September 30, 2005.

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$250,000 for the nine months ended September 30, 2006, a decrease of \$132,000 compared to the nine months ended September 30, 2005. Most of this decrease is due to reductions in costs for clinical studies of \$105,000, outside regulatory consultants of \$32,000, and an increase in salary and related expenses of \$8,000. 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 \$141,000 and were related to increased salaries and wage-related costs of \$93,000 for new hires in the R&D group, the cost related to employee stock options vesting in the period of \$54,000, increased cost of materials of \$25,000, additional temporary labor of \$30,000, net of a reduction in travel and entertainment costs of \$19,000 and a reduction in grant funding of \$45,000.

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 currently plans to continue to focus its development efforts on its HIV and tuberculosis related products, some of which incorporate patent-pending



technologies.

**Selling, General and Administrative Expense:**

Selling, general and administrative expense increased \$1,632,000 to \$3,741,000 in the nine months ended September 30, 2006 compared with \$2,109,000 for the same period in 2005. This increase was attributable to increased staff costs in the accounting, administration and sales and marketing departments of \$374,000 and the cost related to employee stock options vesting in the period of \$118,000. Increased sales also resulted in an increase in royalties and commissions of \$208,000. In addition there was an increase of \$261,000 in costs regarding investor relations, \$94,000 of which resulted from an increase in the number of members of the Company's Board of Directors, \$81,000 from increased travel and entertainment costs, \$67,000 related to marketing consultants, \$38,000 from increased trade show costs, \$50,000 in increased license fees, increased legal expenses of \$200,000 related to patent litigation and \$110,000 related to general patent and other legal services.

**Other Income and Expense:**

Interest expense increased by \$371,000 for the nine months ended September 30, 2006 compared with the nine months ended September 30, 2005. Most of this increase was due to the valuation of the warrants associated with debentures issued on June 29, 2006 and amortized over the three month life which totaled \$331,000. In addition the accrued interest on this debt was \$26,000. Interest income for the nine months ended September 30, 2006 decreased \$30,000 due to less availability of funds to invest. In addition the Company sold a piece of equipment which was fully depreciated for \$5,000 as well as receiving \$25,000 from New York State grant related to marketing research.

**LIQUIDITY AND CAPITAL RESOURCES**

The Company had a working capital surplus of \$1,837,000 at September 30, 2006 and a working capital surplus of \$650,000 at December 31, 2005. On September 29, 2006 and October 5, 2006, the Company completed the Series C Preferred Stock Offering for \$8,150,000. On June 29, 2006, the Company borrowed \$1,300,000 which was partially repaid from the Series C Preferred Stock Offering proceeds, 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 Preferred Stock 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 Series C Offering, the June 29, 2006 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, intellectual property, and also for working capital, investor relations and capital expenditures.

The Company believes its resources are sufficient to fund its needs through the end of 2007. 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 September 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<br>Debt(1)              | \$ 923,160          | \$ 920,000                  | \$ 3,160          | \$ -             | \$ -                                |
| Capital Leases<br>(2)             | \$ 54,407           | \$ 41,293                   | \$ 13,113         | \$ -             | \$ -                                |
| Operating Leases                  | \$ 50,225           | \$ 50,225                   | \$ -              | \$ -             | \$ -                                |
| Other Long Term<br>Obligations(3) | \$ 1,085,000        | \$ 820,000                  | \$ 177,500        | \$ 25,000        | \$ 62,500                           |
| <b>Total Obligations</b>          | <b>\$ 2,112,792</b> | <b>\$ 1,831,518</b>         | <b>\$ 193,773</b> | <b>\$ 25,000</b> | <b>\$ 62,500</b>                    |

(1) This includes the balance of \$800,000 still due from the funds 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.

On September 29, 2006, the Company executed several agreements by and among the Company, Inverness Medical Innovations, Inc. ("Inverness") and StatSure Diagnostic Systems, Inc. ("StatSure"). Pursuant to these agreements, as described below, the Company will engage in marketing, licensing and distribution activities with these two companies. These agreements contain gross margin sharing formulae among Inverness, the Company and StatSure. In addition, the Company has the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and it has the right to subcontract manufacturing, but not sublicense or subcontract its rights or obligations.

First, the Company executed an HIV Barrel License, Marketing and Distribution Agreement between the Company, Inverness and StatSure. This agreement covers the Company's FDA-approved SURE CHECK® HIV 1/2 ("SURE CHECK"), a lateral flow rapid HIV test employing a proprietary barrel system that is an integrated single-use rapid HIV antibody detection screening test. Some terms of the agreement are:

- Inverness will market the SURE CHECK product under Inverness brands globally [subject only to certain existing international agreements that the Company and StatSure may keep in place for up to one year];
- Inverness will exclusively market SURE CHECK under the agreement as well as any new HIV products in the "barrel field" that are developed, and may not compete with any products in this field worldwide as defined;
- The Company and StatSure have each granted Inverness exclusive rights to their intellectual property in the HIV barrel field; and
- Inverness has a first right to negotiate any agreements to market and distribute any of the Company's new HIV antibody detection tests, including products that may incorporate the Company's patent-pending Dual Path Platform (DPP(TM))

In addition, the Company executed an HIV Cassette License, Marketing and Distribution Agreement with Inverness. This agreement covers the Company's FDA-approved STAT-PAK(TM) HIV 1/2, a lateral flow rapid HIV test employing a cassette system that is a single-use rapid HIV antibody detection screening test. Some of the terms of the agreement are:

- Inverness will market this product in the U.S. market only, and the Company has a non-exclusive license under the Inverness lateral flow patents to continue to market the product under the Company's brand in the rest of the world; and
- Inverness may bring a competitive HIV cassette product to the U.S. market, but in that event the Company may expand its lateral flow license for this product to the U.S. and have other options under the agreement.

The Company and Inverness also executed a Non-Exclusive License, Marketing and Distribution Agreement, which covers the Company's FDA-approved STAT-PAK(TM) HIV 1/2. Some of the terms of this agreement are as follows:

- The Company received a non-exclusive license under the Inverness lateral flow patents for its HIV 1/2 Dipstick for marketing outside the U.S.;
- The Company received a worldwide non-exclusive license to manufacture and market a number of other Company-branded products, including all the Company's rapid tests for human and veterinary and tuberculosis, Chagas disease, and tests for other defined emerging and neglected diseases; and
- Inverness has the right to market each of these products (except the HIV 1/2 STAT PAK Dipstick) under an Inverness brand pursuant to an agreed-upon pricing and margin sharing formula similar to the other agreements.

The Company and StatSure also entered into a Settlement Agreement pursuant to which all matters in their litigation regarding StatSure's barrel patent and other matters were settled. Under the terms of this agreement, the parties will equally share in the profits relating to SURE CHECK after reimbursement to the Company of its manufacturing and related costs, as defined, and the parties will act jointly in the HIV barrel field. The settlement combines each company's HIV barrel intellectual property, including an exclusive manufacturing license from StatSure to the Company of its barrel patent for all HIV applications, thereby ensuring the Company's exclusive right to manufacture, as well as Inverness' right to market though the marketing license that StatSure granted Inverness under the three way

agreement. In addition, pursuant to this Agreement, StatSure and the Company will share equally the net sales to Inverness of SURE CHECK after these deductions.

In July 2006 the Company submitted to the FDA CLIA (“Clinical Laboratory Improvement Act”) waiver applications for its HIV 1/2 STAT-PAK™ and SURE CHECK® HIV 1/2 products. These waivers are essential in order to market FDA approved products to the physician office laboratory and public health segments of the United States market. These applications are pending at the FDA.

Upon receipt of a CLIA waiver, the Company will then submit proposed labeling changes that it will have agreed upon with Inverness principally related to the brand name changes. The Company currently anticipates that this process will be completed to enable Inverness to launch the CLIA-waived products in the United States during the first quarter of 2007.

There have been many developments recently regarding the market for HIV testing in the United States. For example, the United States Centers for Disease Control recently issued final revised recommendations advocating routine 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 which must be overcome before these developments become a reality that will result in realizable opportunities for the Company, and there is no assurance that any of these developments 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 STAT-PAK 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. 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 \$670,000 of HIV rapid test components to this customer in the nine months ended September 30, 2006, a 20% decrease over the same period in 2005. However, the Company delivered another \$465,000 in October of 2006 and expects to deliver an additional \$465,000 of HIV rapid test components 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 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 the Company hopes to receive USDA approval during the first quarter of 2007 provided its tests meet certain performance and other criteria. The Company plans to submit additional veterinary TB products to the USDA, including a cattle TB test, subject to having the necessary performance data.

During the third 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, based on significant interest for a number of different applications of this technology from various potential users, we believe we can also extend this technology to other medical fields.

### **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 July 5, 2006, as payment of dividends on the series B preferred stock, the Company issued 322,577 shares of common stock to holders of the 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.

On July 10, 2006, Bio Business Science and Development, LTDA, exercised warrants to purchase 29,838 shares of common stock. The exercise price was \$0.75 per share and the Company received \$22,378 in cash for this exercise. 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 investor in the issuance was an accredited investor.

On July 18, 2006, the Company issued 15,000 shares of common stock to one of the Company's non-employee directors: Alan Carus. 5,000 of these shares vest immediately, 5000 vest on July 1, 2007, and 5,000 vest on July 1, 2008. 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 investor in the issuance was an accredited investor.

On July 31, 2006, August 31, 2006 and on September 29, 2006, the Company issued to Investor Relations Group, Inc., in payment for consulting services, warrants to purchase an aggregate of 25,000 shares, of the Company's Common Stock having an exercise price of \$0.70 per share and an aggregate of 25,000 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

On August 18, 2006, due to a calculation error related to the payment of dividends on the series B preferred stock on July 5, 2006, the Company issued 4,484 shares of common stock to holders of the 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.



On September 29, 2006, the Company sold 80 shares of its 7% series C convertible preferred stock, together with warrants to purchase 1,250,000 shares of common stock, exercisable at \$1.00 per share. This issuance was made in connection with the Company's private placement for \$8,150,000, consisting of 165 shares of 7% series C convertible preferred stock, together with warrants to purchase 2,578,125 shares of its common stock. For each \$0.80 of consideration received, an investor received (a) \$0.80 of face amount of series C preferred stock, which shall pay cumulative dividends in cash or shares at the rate of 7% per annum payable semiannually beginning in the year 2007, and which is convertible into one share of the common stock, and (b) a five-year warrant to acquire shares of the Company's common stock, equal to 25% of the investor's subscription amount divided by \$0.85, with an exercise price of \$1.00 share. Each full share of the series C preferred stock was purchased for \$50,000, with fractional shares of series C preferred stock being purchased by investments of less than \$50,000. 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.

**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)
- 4.1 Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (4)
- 4.2 Registration Rights Agreement, dated June 29, 2006. (4)
- 4.3 Certificate of Designation of Preferences, Rights and Limitations of Series C 7% Convertible Preferred Stock of the Registrant. (6)
- 4.4 Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 4.5 Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (6)
- 10.1 Employment Agreement dated June 15, 2006 w/ Lawrence A. Siebert. (5)
- 10.2 Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
- 10.3 Form of Secured Debenture, dated June 29, 2006. (4)
- 10.4 Security Agreement, dated June 29, 2006, among the Company, Chembio Diagnostic Systems, Inc., and purchasers of the Company's Secured Debentures. (4)
- 10.5 Subsidiary Guarantee, dated June 29, 2006, made by Chembio Diagnostic Systems, Inc., in favor of Purchasers of the Company's Secured Debentures. (4)
- 10.6 Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 10.7 Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (6)
- 10.8 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (6)
- 10.9 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.10 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.11 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (6)
- 10.12 Settlement Agreement, dated September 29, 2006, between the Registrant and StatSure. (6)
- 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

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**(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.**

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

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**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: November 13, 2006 By: /s/ Lawrence

A. Siebert  
Lawrence A.  
Siebert  
Chief Executive  
Officer  
(Principal  
Executive Officer)

Date: November 13, 2006 By: /s/ Richard J.

Larkin  
Richard J. Larkin  
Chief Financial  
Officer  
(Principal  
Financial and  
Accounting  
Officer)