

CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
November 13, 2012

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

FORM 10 - Q

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

For the quarterly period ended September 30, 2012

OR

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

For the transition period from: _____ to _____

000-30379
(Commission File Number)

Chembio Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Nevada 88-0425691
(State or other (IRS Employer
jurisdiction of Identification
incorporation) 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)

____N/A____
(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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if

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any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer [] Accelerated filer []
Non-accelerated filer [] Smaller reporting company [X]
(Do not check if a smaller reporting company)

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

As of November 9, 2012, the Registrant had 8,007,168 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-Q For The Quarterly Period Ended

September 30, 2012

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PART I

Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
AS OF

- ASSETS -

| | September 30, 2012 (UNAUDITED) | December 31, 2011 |
|---|-----------------------------------|----------------------|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 3,290,565 | \$ 3,010,954 |
| Accounts receivable, net of allowance for doubtful accounts of \$30,000 at September 30, 2012 and December 31, 2011 | 2,567,172 | 2,998,449 |
| Inventories | 3,037,880 | 2,300,286 |
| Prepaid expenses and other current assets | 705,850 | 681,893 |
| TOTAL CURRENT ASSETS | 9,601,467 | 8,991,582 |
| FIXED ASSETS, net of accumulated depreciation | | |
| | 1,334,751 | 1,062,276 |
| OTHER ASSETS: | | |
| Deferred tax asset, net of valuation allowance | 4,483,924 | 4,749,622 |
| License agreements, net of current portion | 425,000 | 500,000 |
| Deposits on manufacturing equipment | 252,941 | 139,790 |
| Deposits and other assets | 41,976 | 42,474 |
| TOTAL ASSETS | \$ 16,140,059 | \$ 15,485,744 |

- LIABILITIES AND STOCKHOLDERS' EQUITY -

| | | |
|---|------------------|------------------|
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued liabilities | \$ 2,686,836 | \$ 2,789,500 |
| Current portion of loans payable | 50,538 | 53,550 |
| Customer deposits | 23,224 | - |
| Current portion of obligations under capital leases | - | 14,576 |
| TOTAL CURRENT LIABILITIES | 2,760,598 | 2,857,626 |
| OTHER LIABILITIES: | | |
| Loans payable - net of current portion | 95,321 | 133,484 |
| TOTAL LIABILITIES | 2,855,919 | 2,991,110 |

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY:

| | | |
|--|---|---|
| Preferred stock – 10,000,000 shares authorized, none outstanding | - | - |
|--|---|---|

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Common stock - \$.01 par value; 100,000,000
 shares authorized, 8,007,168 and 7,921,021
 shares issued and outstanding for 2012 and
 2011, respectively

| | | |
|-----------------------------------|-------------------|-------------------|
| | 80,072 | 79,210 |
| Additional paid-in capital | 41,017,716 | 40,678,696 |
| Accumulated deficit | (27,813,648 | (28,263,272) |
| TOTAL STOCKHOLDERS' EQUITY | 13,284,140 | 12,494,634 |

| | | |
|---|----------------------|----------------------|
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 16,140,059 | \$ 15,485,744 |
|---|----------------------|----------------------|

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

| | For the three months ended | | For the nine months ended | |
|--|----------------------------|--------------------|---------------------------|--------------------|
| | September 30, 2012 | September 30, 2011 | September 30, 2012 | September 30, 2011 |
| REVENUES: | | | | |
| Net product sales | \$ 4,745,094 | \$ 5,526,883 | \$ 16,919,436 | \$ 11,516,325 |
| License and royalty revenue | - | 25,000 | - | 125,322 |
| R&D, milestone and grant revenue | 262,292 | 369,904 | 825,093 | 1,529,972 |
| TOTAL REVENUES | 5,007,386 | 5,921,787 | 17,744,529 | 13,171,619 |
| Cost of product sales | 3,278,471 | 3,251,054 | 10,112,127 | 6,524,266 |
| GROSS MARGIN | 1,728,915 | 2,670,733 | 7,632,402 | 6,647,353 |
| OPERATING EXPENSES: | | | | |
| Research and development expenses | 1,005,645 | 1,242,295 | 3,363,819 | 3,697,309 |
| Selling, general and administrative expenses | 1,208,383 | 949,237 | 3,521,552 | 2,412,867 |
| | 2,214,028 | 2,191,532 | 6,885,371 | 6,110,176 |
| INCOME (LOSS) FROM OPERATIONS | (485,113) | 479,201 | 747,031 | 537,177 |
| OTHER INCOME (EXPENSE): | | | | |
| Interest income | 2,269 | 1,278 | 5,386 | 4,315 |
| Interest expense | (2,815) | (4,874) | (7,573) | (13,345) |
| | (546) | (3,596) | (2,187) | (9,030) |
| INCOME (LOSS) BEFORE INCOME TAXES | (485,659) | 475,605 | 744,844 | 528,147 |
| Income tax provision (benefit) | (193,310) | - | 295,220 | - |
| NET INCOME (LOSS) | \$ (292,349) | \$ 475,605 | \$ 449,624 | \$ 528,147 |
| Basic earnings (loss) per share | \$ (0.04) | \$ 0.06 | \$ 0.06 | \$ 0.07 |
| Diluted earnings (loss) per share | \$ (0.04) | \$ 0.06 | \$ 0.05 | \$ 0.06 |

| | | | | |
|--|-----------|-----------|-----------|-----------|
| Weighted average number of shares outstanding, basic | 8,001,472 | 7,913,081 | 7,974,447 | 7,860,904 |
| Weighted average number of shares outstanding, diluted | 8,001,472 | 8,508,740 | 8,616,917 | 8,644,940 |

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED
(UNAUDITED)

| | September 30, 2012 | September 30, 2011 |
|---|--------------------|--------------------|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Cash received from customers and grants | \$ 18,175,806 | \$ 14,460,236 |
| Cash paid to suppliers and employees | (17,221,877) | (12,897,517) |
| Interest received | 5,386 | 1,278 |
| Interest paid | (7,573) | (4,874) |
| Net cash provided by operating activities | 951,742 | 1,559,123 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Acquisition of and deposits on fixed assets | (715,195) | (282,175) |
| Net cash used in investing activities | (715,195) | (282,175) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from option and warrant exercises | 98,815 | 280,393 |
| Payment of license obligation | - | (875,000) |
| Payment of loan obligation | (41,175) | 244,858 |
| Payment of capital lease obligation | (14,576) | (18,202) |
| Net cash provided by (used in) financing activities | 43,064 | (367,951) |
| INCREASE IN CASH AND CASH EQUIVALENTS | | |
| | 279,611 | 908,997 |
| Cash and cash equivalents - beginning of the period | 3,010,954 | 2,136,351 |
| Cash and cash equivalents - end of the period | \$ 3,290,565 | \$ 3,045,348 |
| RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES: | | |
| Net Income | \$ 449,624 | 528,147 |
| Adjustments: | | |
| Depreciation and amortization | 404,570 | 321,590 |
| Provision for deferred taxes | 265,698 | - |
| Provision for doubtful accounts | - | (15,000) |
| Share based compensation | 241,067 | 136,321 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 431,277 | 1,303,617 |
| Inventories | (737,594) | (1,239,064) |

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| | | |
|---|------------|--------------|
| Prepaid expenses and other current assets | (23,957) | 15,983 |
| Deposits and other assets | 497 | (208,460) |
| Accounts payable and accrued liabilities | (102,664) | 290,467 |
| Customer deposits and deferred revenue | 23,224 | 425,522 |
| Net cash provided by operating activities | \$ 951,742 | \$ 1,559,123 |

Supplemental disclosures for non-cash investing and financing activities:

| | | |
|---|------------|------|
| Deposits on manufacturing equipment transferred to fixed assets | \$ 181,489 | \$ - |
|---|------------|------|

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012
(UNAUDITED)

NOTE 1- DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the “Company” or “Chembio”) and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company’s main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Lateral Flow Rapid HIV tests represented nearly 54% of the Company’s product revenues in the first nine months of 2012. The Company’s products based on its patented Dual Path Platform (DPP®) platform represented approximately 42% of the Company’s product revenues in the first nine months of 2012. The Company also has other rapid tests that together represented approximately 6% of sales in the first nine months of 2012. The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio’s products are sold under the Company’s STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners. For example the Clearview® label is owned by Alere, Inc. (“Alere”), which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. All of the products that are currently being developed by the Company are based on its patented DPP®, which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology.

NOTE 2- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2011, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of September 30, 2012 and for the three- and nine-month periods ended September 30, 2012 and 2011, respectively, have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures, which are normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, 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-K for the fiscal year ended December 31, 2011, previously filed with the SEC.

On May 30, 2012, the Company effected a 1-for-8 reverse split of its common stock. This was done to allow the Company to move to the NASDAQ trading market from the QTCQB market, which occurred on June 7, 2012. As a result of the stock split, the outstanding 63,967,263 common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012. The effect of the reverse stock split has been retroactively reflected for all periods in these financial statements.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of the Company’s condensed consolidated financial position as of September 30, 2012, its condensed consolidated results of operations for the three- and nine-month periods ended September 30, 2012 and 2011, respectively, and its condensed consolidated cash flows for the nine-month periods ended September 30, 2012 and 2011, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, "Revenue Recognition" ("SAB 104"). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, the Company recognizes revenue from non-milestone contracts and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned. As of September 30, 2012 and December 31, 2011, all advanced revenues were earned.

The Company follows Financial Accounting Standards Board ("FASB") authoritative guidance ("guidance") prospectively for the recognition of revenue under the milestone method. The Company applies the milestone method of revenue recognition for certain collaborative research projects defining milestones at the inception of the agreement.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012
(UNAUDITED)

c) Inventories:

Inventories consist of the following at:

| | September 30, 2012 | December 31, 2011 |
|-----------------|-----------------------|----------------------|
| Raw materials | \$ 1,439,199 | \$ 1,340,177 |
| Work in process | 593,725 | 390,162 |
| Finished goods | 1,004,956 | 569,947 |
| | \$ 3,037,880 | \$ 2,300,286 |

d) Earnings (Loss) Per Share:

Basic earnings (loss) per share is computed by dividing net income or loss by the weighted-average number of common shares outstanding for the period. Diluted income or (loss) per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. The following securities, presented on a common share equivalent basis for the three- and nine-month periods ended September 30, 2012 and 2011, have been included in the earnings per share computations:

| | For the three months ended | | For the nine months ended | |
|---------|----------------------------|-----------------------|---------------------------|-----------------------|
| | September 30, 2012 | September 30, 2011 | September 30, 2012 | September 30, 2011 |
| Basic | 8,001,472 | 7,913,081 | 7,974,447 | 7,860,904 |
| Diluted | 8,001,472 | 8,508,740 | 8,616,917 | 8,644,940 |

The following securities, presented on a common share equivalent basis for the three- and nine-month periods ended September 30, 2012 and 2011, have been included in the diluted per share computations as these securities exercise prices were less than the stock price as of September 30, 2012 and 2011, respectively:

| | For the three months ended | | For the nine months ended | |
|-------------------------------------|----------------------------|-----------------------|---------------------------|--------------------|
| | September 30, 2012 | September 30, 2011 | September 30, 2012 | September 30, 2011 |
| 1999 and 2008 Plan Stock Options | - | 595,659 | 642,470 | 784,036 |

There were 642,470 and 243,367 options and warrants outstanding as of September 30, 2012 and 2011, respectively, that were not included in the calculation of diluted per common share equivalent for the nine months ended September 30, 2012 and 2011, respectively, because the effect would have been anti-dilutive as of September 30, 2012 and 2011,

respectively.

e) Employee Stock Option Plan:

The Company had a 1999 Stock Option Plan (“SOP”). The total number of options available under the SOP was 375,000. As of September 30, 2012, there were 141,441 outstanding options under this SOP. No additional options may be issued under the SOP because it is more than 10 years after its adoption.

Effective June 3, 2008, the Company’s stockholders voted to approve the 2008 Stock Incentive Plan (“SIP”), initially with 625,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011, the Company’s stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, the Compensation Committee of the Company’s Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of September 30, 2012, there were 62,708 options exercised, 619,267 options outstanding and 68,025 options or shares still available to be issued under the SIP.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012
(UNAUDITED)

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month periods ended September 30, 2012 and 2011 was \$3.72 and \$2.11 per share, respectively. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the nine-month periods ended September 30, 2012 and 2011 was \$3.26 and \$1.58 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon the historical volatility of our stock. The expected term is based on historical information.

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

| | For the three months ended | | For the nine months ended | |
|--------------------------|----------------------------|-----------------------|---------------------------|-----------------------|
| | September 30, 2012 | September 30, 2011 | September 30, 2012 | September 30, 2011 |
| Expected term (in years) | 4 | 3.75 | 4-5 | 3.75 |
| Expected volatility | 99.6-99.9% | 97.1-117.9% | 99.6-115.77% | 97.1-117.9% |
| Expected dividend yield | 0% | n/a | 0% | n/a |
| Risk-free interest rate | .33-.37% | .57-1.24% | .33-.37% | .57-1.24% |

The Company's results for the three-month periods ended September 30, 2012 and 2011 include share-based compensation expense totaling \$59,000 and \$80,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$10,000 and \$6,000, respectively), research and development (\$8,000 and \$14,000, respectively) and selling, general and administrative expenses (\$41,000 and \$60,000, respectively). The Company's results for the nine-month periods ended September 30, 2012 and 2011 include share-based compensation expense totaling \$236,000 and \$136,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$30,000 and \$12,000, respectively), research and development (\$65,000 and \$40,000, respectively) and selling, general and administrative expenses (\$141,000 and \$84,000, respectively). The income tax benefit has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three- and nine-month periods ended September 30, 2012 and 2011 is based on the estimated fair value, at the date of issuance, of options outstanding, which is being amortized on a straight-line basis over the requisite service period for each vesting portion of the award, except for those that vested immediately and for which the estimated fair value was expensed immediately.

The following table provides stock option activity for the nine months ended September 30, 2012:

| Stock Options | Number of Shares | Weighted Average Exercise Price per Share | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|----------------------------------|---------------------|--|---|------------------------------|
| Outstanding at December 31, 2011 | 765,901 | \$ 1.68 | 2.61 years | \$ 1,339,693 |
| Granted | 97,391 | \$ 4.58 | | |
| Exercised | (83,333) | \$ 1.04 | | |

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| | | | | | |
|-----------------------------------|-----------|----|------|------------|--------------|
| Forfeited/expired/cancelled | (19,251) | \$ | 3.87 | | |
| Outstanding at September 30, 2012 | 760,708 | \$ | 1.80 | 2.40 years | \$ 2,032,675 |
| Exercisable at September 30, 2012 | 539,941 | \$ | 1.06 | 1.80 years | \$ 1,784,290 |

As of September 30, 2012, there was \$151,000 of net unrecognized compensation cost related to stock options that have not vested, which is expected to be recognized over a weighted average period of approximately 1.1 years. The total fair value of stock options vested during the nine-month periods ended September 30, 2012 and 2011 was approximately \$245,000 and \$149,000, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012
(UNAUDITED)

f) Geographic Information:

U.S. GAAP establishes standards for the manner in which 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 products and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as “rapid medical tests”. Management believes that it operates in a single business segment. Net product sales by geographic area are as follows:

| | For the three months ended | | For the nine months ended | |
|---------------|----------------------------|-----------------------|---------------------------|--------------------|
| | September 30, 2012 | September 30, 2011 | September 30, 2012 | September 30, 2011 |
| Africa | \$ 594,738 | \$ 456,303 | \$ 2,115,307 | \$ 1,549,274 |
| Asia | 374,845 | 221,261 | 641,326 | 314,884 |
| Europe | 4,298 | 7,286 | 37,629 | 49,605 |
| North America | 1,235,074 | 2,820,017 | 6,501,210 | 6,628,629 |
| South America | 2,536,139 | 2,022,016 | 7,623,964 | 2,973,933 |
| | \$ 4,745,094 | \$ 5,526,883 | \$ 16,919,436 | \$ 11,516,325 |

g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

| | September 30, 2012 | December 31, 2011 |
|----------------------------------|--------------------|-------------------|
| Accounts payable – suppliers | \$ 1,228,014 | \$ 1,258,465 |
| Accrued commissions | 298,420 | 205,588 |
| Accrued royalties / license fees | 336,903 | 480,297 |
| Accrued payroll | 150,616 | 174,398 |
| Accrued vacation | 198,176 | 156,884 |
| Accrued bonuses | 442,675 | 284,375 |
| Accrued expenses – other | 32,032 | 229,493 |
| TOTAL | \$ 2,686,836 | \$ 2,789,500 |

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a) National Institutes of Health (NIH) Grant:

In June 2009, the Company received a \$2.8 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. The Company earned \$367,000 and \$519,000 for the nine-month periods ended September 30, 2012 and 2011, respectively from this grant. The Company earned an aggregate of \$2,800,000 from this grant from inception through September 30, 2012, of which \$897,000 was paid to sub-contractors.

In March 2011, the Company received a \$2.9 million, three-year grant from the United States National Institutes of Health to complete development of a test for Tuberculosis. Grants are invoiced after expenses are incurred. The Company earned \$487,000 and \$252,000 for the nine-month periods ended September 30, 2012 and 2011, respectively from this grant. The Company earned \$1,182,000 from this grant from inception through September 30, 2012 of which \$345,000 was paid to sub-contractors.

b) Battelle/CDC DPP® Influenza Immunity Test:

In July 2012, the Company entered into a follow-on, milestone-based development agreement of up to \$480,000 based on Chembio's previous successful initial development of a multiplex rapid point-of-care ("POC") influenza immunity test utilizing its patented Dual Path Platform (DPP®) technology. The agreement contemplates a period of approximately nine months in which the follow-on development activity is to be completed. As of September 30, 2012 the Company has earned \$18,000.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012
(UNAUDITED)

NOTE 4 — LOANS PAYABLE:

In June 2010, the Company entered into three agreements with HSBC Bank, NA (“HSBC”). The three agreements were: 1) a secured term note (“Term Note”) of \$250,000 to be repaid over sixty months; 2) a secured revolving demand note (“Demand Note”) up to \$250,000; and 3) a loan and security agreement (“Security Agreement”).

The Term Note is payable at \$4,775 per month in arrears. The payment was calculated by amortizing the \$250,000 note over 60 months at an interest rate of 5.5% per annum. The Term Note matures June, 2015 and is secured under the terms of the Security Agreement.

The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$250,000 outstanding at any one time. The accrued interest on the Demand Note is payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company can repay any or all of the principal balance outstanding at any time. This is a demand note and is subject to annual reviews, as well as an annual 30-day clean-up, during which there can be no amounts outstanding.

The Security Agreement contains covenants that place restrictions on the Company’s operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, and restrictions on fundamental changes. The Security Agreement also requires that the Company maintain a minimum tangible net worth, as defined in the agreement, at all times of greater than \$3,000,000, and EBITDA to CMLTD plus interest cannot be less than 1.25 to 1.00 for any fiscal year. (EBITDA is earnings before interest, taxes, depreciation and amortization; CMLTD is defined as, for any one-year period, the current scheduled principal payments required to be paid for the applicable period.). The Company was in compliance with all required financial covenants at September 30, 2012.

In July 2011, the Company entered into additional agreements with HSBC. The agreements were: 1) a secured revolving demand note for equipment (Equipment Note”) up to \$500,000, convertible to a term note after one year; and 2) a loan and security agreement (“Security Agreement”).

The Equipment Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$500,000 outstanding at any one time. The accrued interest on the Equipment Note is payable monthly at an interest rate equal to one-quarter percent above prime per annum. The Company can repay any or all of the principal balance outstanding at any time. The Equipment Note will be converted into a 60-month term note at the end of one year.

The Security Agreement contains covenants that place restrictions on the Company’s operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, and restrictions on fundamental changes. The Company was in compliance with all required financial covenants at September 30, 2012.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of September 30, 2012 was \$146,000, and as of September 30, 2012 nothing had been drawn down on the Demand or Equipment Note.

Future minimum payments under the Term Note, excluding interest, as of September 30, 2012 were as follows:

Periods ending September 30,

| | |
|--------------------------|-----------|
| 2013 | \$50,538 |
| 2014 | 53,389 |
| 2015 | 41,932 |
| | 145,859 |
| Less: current maturities | (50,538) |
| | \$ 95,321 |

In June 2009, the Company purchased a vehicle for use by the CEO and obtained financing in the amount of \$29,228. The financing is for a period of 3 years, is secured by the vehicle, and is guaranteed by the CEO. The financing agreement provides for monthly principal and interest payments of \$849 and carries an interest rate of 2.9% per annum. This loan was fully paid as of September 30, 2012.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012
(UNAUDITED)

NOTE 5 — RIGHTS AGREEMENT:

In March 2010, the Company entered into a Rights Agreement dated March 8, 2010 (the "Rights Agreement") between the Company and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, the Company declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of Common Stock, \$0.01 par value (the "Common Stock"), of the Company. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2010, and the Rights were distributed to the Company's shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

Rights Initially Not Exercisable. The Rights are not exercisable until a Distribution Date. Until a Right is exercised, the holder thereof, as such, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

Separation and Distribution of Rights. The Rights will be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 15% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 15% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

NOTE 6 — COMMON STOCK, WARRANTS AND OPTIONS:

In March 2012, June 2012 and September 2012, the Company issued 938 shares of common stock on each date to a consultant as part of the consultant's compensation. As long as the consultant continues with the Company, the consultant will receive one more tranche of 938 shares in December of 2012.

In March 2012, the Company issued 3,750 options to purchase shares of the Company's common at an exercise price of \$4.00 per share to consultant as part of the consultant's compensation. On each of March 19, 2012, June 19, 2012 and September 19, 2012, 938 of these options vested. The final 936 of these options will vest on December 19, 2012, provided that the consultant continues to work with the Company through that date. These options were valued using a Black-Scholes model at \$8,570, of which \$2448 and \$4959 was expensed in the three- and nine-month periods, respectively, ended September 30, 2012. The options are being accounted for under the variable method as per EITF-96-18 and \$279 of the expense was attributable to this method.

On February 16, 2012, the Company issued 25,391 options to purchase common stock to executives of the Company as part of their 2011 bonus. The options are exercisable immediately at \$4.00 per share, which was the last traded price of the common stock on that day, and they expire five years from date of issue.

During the third quarter of 2012, the Company issued 72,000 options to purchase common stock to newly-hired vice-presidents of the Company. The options are exercisable in three equal annual installments on the anniversary of the issuance starting one year from date of issue. An allotment of 36,000 options issued to one of the new vice presidents and have an exercise price of \$5.11 per share, and the 36,000 options were issued to the other new vice president have an exercise price of \$4.45 per share, which in each case was the last traded price of the common stock on the day issued. The options expire five years from date of issue.

As of September 30, 2012, the Company had no warrants outstanding to purchase shares of common stock.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2012
(UNAUDITED)

NOTE 7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Economic Dependency:

The following table discloses product sales the Company had to customers in excess of 10% of net product sales for the periods indicated:

| | For the three months ended | | | | For the nine months ended | | | | Accounts Receivable As of |
|------------|----------------------------|---------------|--------------------|---------------|---------------------------|---------------|--------------------|---------------|---------------------------------|
| | September 30, 2012 | | September 30, 2011 | | September 30, 2012 | | September 30, 2011 | | September 30, 2012 |
| | Sales | % of Sales | Sales | % of Sales | Sales | % of Sales | Sales | % of Sales | |
| Customer 1 | \$ 1,187,124 | 25 | \$ 1,912,199 | 35 | \$ 5,780,030 | 34 | \$ 5,386,670 | 47 | \$ 648,084 |
| Customer 2 | 2,522,405 | 53 | 2,012,425 | 36 | 7,421,430 | 44 | 2,936,270 | 25 | 1,326,098 |
| Customer 3 | * | * | 573,957 | 10 | * | * | * | * | * |

(*) Product sales did not exceed 10% for the period indicated.

Note that sales include product sales only while accounts receivable reflects the total due from the customer, which includes freight.

The following table discloses purchases the Company made from vendors in excess of 10% of total purchases for the periods indicated:

| | For the three months ended | | | | For the nine months ended | | | | Accounts Payable As of |
|----------|----------------------------|---------------|--------------------|---------------|---------------------------|---------------|--------------------|---------------|---------------------------|
| | September 30, 2012 | | September 30, 2011 | | September 30, 2012 | | September 30, 2011 | | September 30, 2012 |
| | Purchases | % of Purc. | Purchases | % of Purc. | Purchases | % of Purc. | Purchases | % of Purc. | |
| Vendor 1 | \$ 204,607 | 15 | \$ 174,278 | 13 | \$ 613,287 | 14 | \$ 432,577 | 11 | \$ 89,710 |
| Vendor 2 | 211,020 | 16 | 160,218 | 12 | 589,224 | 13 | 412,086 | 11 | 60,073 |

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which could adversely affect operating results.

b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration, United States Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product

testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

c) Employment Agreement:

The Company has employment contracts with two key employees. The contracts call for salaries presently aggregating \$545,000 per year. One contract expires in May 2013 and one contract expires in March 2013. In connection with the contract that expires in March 2013, the Company issued, in March 2010, 37,500 options to purchase common stock, with one-third vesting immediately and one-third vesting on each of the second and third anniversaries of the grant.

NOTE 8 — INCOME TAXES:

During 2011, the Company reversed its valuation allowance, in regard to net operating loss (NOL) carry- forwards, previously recorded against its deferred tax assets. As such the Company now records an income tax expense (benefit) for income (loss) for periods starting after December 31, 2011. The Company's interim provision for income taxes is measured using an estimated annual effective tax rate of 39.7%. As per IRS rules, only 90% of the taxable income can be offset by NOLs, and therefore 3.97%, or \$29,522, was added to accrued expenses, 39.7%, or \$295,220, was expensed, and the balance of 35.73%, or \$265,698, reduced the carrying value of the deferred tax asset for the nine months ended September 30, 2012.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The terms "Chembio", "Company," "we", "us", and "our" refer to Chembio Diagnostics, Inc. and its subsidiary a consolidated entity, unless the context suggests otherwise.

Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. The 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 generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP 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. On an ongoing basis we review our estimates and assumptions. 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 other than as stated in Note 2 (b), have not changed significantly from December 31, 2011.

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 are 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," "could", "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.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

The following discussion and analysis relates to the business of the Company, which consists of the development, manufacture and marketing of rapid diagnostic tests that detect infectious diseases. All of the Company's future products that are currently being developed are based on our patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care ("POC") platform that has certain advantages over lateral flow technology. The Company has completed development of five products that employ the DPP® technology, two of which will be marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® Syphilis Screen & Confirm) and three that have been developed specifically related to technology transfer, supply and license agreements with The Oswaldo Cruz

Foundation (“FIOCRUZ”) for the Brazilian public health market, as explained below. The DPP® HIV 1/2 Screening Assay will be manufactured as an OEM product only for the Brazilian market pursuant to one of our agreements with FIOCRUZ.

During the first nine months of 2012, the Company had a total of \$2,256,170 of research and development expenses, excluding regulatory, as compared with \$2,243,502 during the first nine months of 2011.

The Company has a number of additional products under development that employ the DPP® technology. In addition, the Company has current and potential collaborations and grant awards that involve or would involve use of the DPP®. These activities are further described below.

Multiplex Influenza Immunity Test – In July 2012 we entered into a follow-on, milestone-based development agreement of up to \$480,000 based on Chembio’s previous successful initial development of a multiplex rapid point-of-care (“POC”) influenza immunity test utilizing our patented Dual Path Platform (DPP®) technology. The agreement contemplates a period of approximately six months in which the follow-on development activity is to be completed.

Chembio entered this agreement with a private contracting organization that is engaged to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of its client, the United States Centers for Disease Control and Prevention (“CDC”).

As a result of pandemic planning activities, the United States Department of Health and Human Services (“HHS”) and CDC identified POC and high-throughput testing as a gap in influenza diagnostics. Rapid responses in the field, such as the vaccination, prophylactic treatment, or isolation of patients, require POC diagnostic tests for influenza infection and immunity. Ideally, these tests should be fast, portable, self-contained, and non-technical. Development of these tests is especially critical for military forces, as evidenced by previous influenza outbreaks that spread rapidly through densely populated barracks and have killed thousands of soldiers

The previous development work for this product was completed by Chembio in 2010-11 pursuant to an initial \$900,000 contract with this same organization. The objective of this follow-on project is to further develop a rapid influenza immunity test which can be administered in the field to determine a person’s influenza immunity status or in an outpatient setting incorporating certain additional subunits of influenza virus proteins. Work commenced on this follow on development project during the third quarter and has accelerated during the fourth quarter.

DPP® Hepatitis-C (HCV) Test – Development work on our DPP® HCV point-of-care rapid test continues. In June, we reported data from a study evaluating performance characteristics (sensitivity and specificity) of our first generation test, which data was published in the Journal of Clinical Virology. The study authors concluded that the Chembio blood rapid assay demonstrated acceptable sensitivity and specificity, and was comparable to conventional assays currently in use. The study results showed that the Chembio DPP® HCV finger-stick blood test had a sensitivity of 92.8% against a laboratory-based enzyme immunoassay (EIA) screening assay reference while it demonstrated 97.1% sensitivity against The Centers for Disease Control and Prevention (CDC) reference method algorithm which utilizes a third generation recombinant immunoblot assay (RIBA). The DPP® finger-stick blood test achieved 99.0% specificity on both reference methods.

During the third quarter we completed a feasibility study on proprietary materials which we believe will enable us to develop an HCV rapid test that is equivalent to the only directly competitive product; we are waiting to receive additional proprietary materials that we believe could enable us to improve performance and features of the test as compared to the competitive product. If these objectives are achieved, we will proceed with a full development program, and we could complete development and commence clinical trials before the end of 2013.

In July 2012, the U.S. Centers for Disease Control finalized the recommendations for testing all individuals in the United States between the ages of 45 and 65 for HCV, which age cohort represents a substantial portion of the estimated over three million individuals in the United States that are infected with HCV infection but unaware. With a number of new anti-retroviral therapies approved, and even more pending approval in the years ahead by the FDA, we believe that over time these new recommendations will be implemented. However, it is clear that if implemented that this will take time to be funded.

DPP® Syphilis/HIV Combination Test – We have developed a combination Syphilis and HIV test and we are considering various opportunities with respect to this product for the international market at least. This is an example of the multiplexing capabilities that we expect to drive the Company’s revenues and growth. We may manufacture this

product as a Chembio-branded product and/or as a component for final assembly in other markets where we are considering collaborations. We believe there are opportunities for this product in donor-funded pre-natal testing programs aimed at the prevention of mother-to-child transmission, and potentially additional markets as well.

DPP® Tuberculosis – In February 2011, we were awarded a three-year \$2.9 million, Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to continue our successful Phase I grant work to develop a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings. During 2012, we have continued this development work with our DPP® technology. Several additional antigens have been identified recently to enhance antibody detection by the DPP® test prototype designed in our Phase I studies. In addition, new detection technologies are being evaluated to further increase sensitivity.

Other Potential Products and Collaborations - We are currently completing development of certain other products for single parameter and multiplex tests, utilizing our patented DPP®. We also are discussing exclusive collaborations for these products or proprietary components thereof, with certain potential international partners that, if consummated, would provide us with local assembly and distribution, a co-branded DPP® product in the designated market, and a more meaningful stake in the success of the distribution program.

In general, we are considering certain new DPP® product opportunities, either as OEM development projects and/or as Chembio-branded products. These products are being identified based upon our assessment of opportunities in the market and upon whether they can be addressed with our proprietary technology, along with our development and manufacturing capabilities and experience. We are also identifying and assessing additional technologies that we believe could provide us with additional products and capabilities, and thereby provide additional revenue streams, although there is no assurance that we will be able to obtain or utilize any of them profitably.

Regulatory Activities

CE Mark for FDA-approved HIV tests – We were audited by our notified body in September and our technical file is being reviewed. We expect a decision on CE Marking of these products during the fourth quarter.

FDA Approval for DPP® HIV 1/2 Screening Assay for Use with oral fluid or blood samples - Our Pre-Approval Inspection was completed during October, and we believe the inspection was completed satisfactorily such that we still anticipate an FDA approval, or at least an approvable PMA decision, before year-end 2012. We are currently communicating with the FDA discussing the studies required for a CLIA waiver based upon the new CLIA guidance. We anticipate working towards a CLIA waiver by end of 4Q12 and expect CLIA waiver to be granted in 2013.

DPP® Syphilis Screen & Confirm - During the current quarter we received data that we had been pursuing and that we believe support a De Novo FDA 510(K) clearance regulatory pathway for the product. We will soon request a meeting with the FDA to discuss this data so that we can re-initiate clinical trials and submit our 510(k) application by the middle of 2013. We are also pleased to report that the large study that was conducted with this product in 2010-2011 in China has been accepted for publication in an international scientific journal and we believe this data will also be useful in supporting our regulatory file.

There is no point-of-care test for Syphilis that differentiates between active and past, previously treated cases, and there continues to be a substantial interest in this product by public health groups in the United States and abroad. But we need to establish that our DPP® Syphilis Screen & Confirm test detects primary infections at least as well as the legacy laboratory test known as Rapid Plasma Reagin (“RPR”). We are optimistic that we can achieve this.

DPP® HIV-Syphilis – We have submitted this product for evaluation by the CDC Global AIDS Program laboratory in Atlanta and the evaluation is ongoing. This product will also be submitted for prequalification by the WHO. We are also in the process of determining the pathways for getting this multiplex combination product approved/cleared by the FDA.

SURE CHECK® HIV OTC Study - We are in the process of completing the self-testing study to meet the requirements for submitting an IDE (“Investigational Device Exemption”) application in order to commence clinical trials for this product in 2013. The current self-testing study is expected to be completed in December or January and the IDE application will be filed upon completion of this study. Thereafter, assuming the IDE is granted, the Phase II observed user clinical trials could be completed during 2013 and the pivotal trial could be completed by mid-2014. This would enable a PMA approval in by mid-2015.

There have been very significant recent developments related to this market opportunity, as the first rapid HIV test for home use was recommended for approval by the FDA’s Blood Products Advisory Committee (“BPAC”) in a unanimous vote, and the test was in fact approved by the FDA in early July with widespread media attention. The manufacturer of this product, OraSure Technologies, Inc. (“OraSure”), launched this product in retail drug stores during October.

OraSure’s final clinical trial for the home-use version enrolled 5,798 subjects from 17 high prevalence sites and three low prevalence sites across the country. OraSure gave subjects the test to take home and perform themselves, but also collected blood samples to compare to the results of the home-based testing. The specificity of the test remained relatively high, 99.98% (95% CI: 99.90–100%), and above BPAC’s recommended threshold. However, sensitivity dropped in comparison to professional use of the kit to 92.98% from 99.3%.

Given this low performance threshold, we believe we are very well positioned with our SURE CHECK® HIV 1/2 blood test. We believe that the development of this market will take time, and that its development will likely require OraSure to invest significantly in its development, as it is now. Nevertheless, Chembio is the only other company that

for all practical purposes has a product, let alone multiple products, that can participate in this new market. Moreover, because OraSure's product was approved with lower sensitivity than was previously expected by the FDA, this provides an opportunity for Chembio's product(s) to achieve improved performance – either with its blood and/or oral fluid HIV tests. We believe it is critical to go to this market with a substantially improved sensitivity and comparable specificity to OraSure's product, and our current efforts include maximizing the possibility of meeting this objective.

There can be no assurance that any of the aforementioned Research & Development and/or Regulatory products or activities will result in any product approvals or commercialization, nor that any of the existing research and development activities, or any new potential development programs or collaborations will materialize or that they will meet regulatory or any other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if they are successfully completed, can or will be successfully commercialized.

Recent Events

On May 30, 2012, the Company effected a 1-for-8 reverse split of its common stock. This was done to allow the Company to move to the NASDAQ trading market from the QTCQB market, which occurred on June 7, 2012. As a result of the reverse stock split, the 63,967,265 outstanding common shares were reduced to 7,995,918 outstanding common shares on May 30, 2012.

Critical Accounting Policies and Estimates

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2011, see our Annual Report on Form 10-K for the twelve months ended December 31, 2011, which was filed with the SEC on March 8, 2012.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2012 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2011

Revenues:

| Selected Product Categories: | For the three months ended | | | |
|---------------------------------------|----------------------------|--------------------|----------------|-----------|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
| Lateral Flow HIV Tests and Components | \$ 2,179,238 | \$ 3,777,682 | \$ (1,598,444) | -42.31 % |
| DPP Tests and Components | 2,531,725 | 1,705,150 | 826,575 | 48.48 % |
| Other | 34,131 | 44,051 | (9,920) | -22.52 % |
| Net Product Sales | 4,745,094 | 5,526,883 | (781,789) | -14.15 % |
| License and royalty revenue | - | 25,000 | (25,000) | -100.00 % |
| R&D, milestone and grant revenue | 262,292 | 369,904 | (107,612) | -29.09 % |
| Total Revenues | \$ 5,007,386 | \$ 5,921,787 | \$ (914,401) | -15.44 % |

Revenues for our lateral flow HIV tests and related components during the three months ended September 30, 2012 decreased by approximately \$1,598,000 from the same period in 2011. This was attributable to decreased sales to Alere from \$1,912,000 during the three months ended September 30, 2011 to \$1,187,000 during the three months ended September 30, 2012, a decrease of \$725,000, or 38%; as well as decreased sales to North America (other than Alere) of \$860,000, these decreases were partially offset by increased sales to Asia of \$154,000; and increased sales to Africa of \$139,000. Revenues for our DPP® products during the three months ended September 30, 2012 increased by approximately \$827,000 over the same period in 2011, an increase of 48%, which increase is attributable to the launch of our DPP® products that were approved in Brazil during 2010 and 2011. The decrease in R&D, milestone and grant revenue was due to revenue from milestones and certain development projects in the 2011 third quarter that were not repeated. License and royalty revenue in 2011 is from royalties from Brazil under our 2004 technology transfer and license agreement, which ended prior to April 1, 2012.

Gross Margin:

Gross Margin related to Net

| Product Sales: | For the three months ended | | | |
|--|----------------------------|--------------------|---------------|----------|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
| Gross Margin per Statement of Operations | \$ 1,728,915 | \$ 2,670,733 | \$ (941,818) | -35.26 % |
| Less: R&D, milestone, grant, license and royalties | 262,292 | 394,904 | (132,612) | -33.58 % |
| Gross Margin from Net Product Sales | \$ 1,466,623 | \$ 2,275,829 | \$ (809,206) | -35.56 % |
| Gross Margin % | 30.91 % | 41.18 % | | |

The decrease in our product gross margin percentage was primarily due to increased costs in scrap, incoming freight and other costs together with a change in the product sales mix. Some of the product mix change was due to the decreased sales to Alere as they decreased as a percentage of overall sales from 35% to 25%. Partially offsetting these increased costs was an increase in our DPP® products sold in Brazil which are at a higher margin than as compared with developing world markets. DPP® sales represented approximately 53% of sales in the three months ended September 30, 2012 as compared to approximately 31% in the three months ended September 30, 2011.

Research and Development:

Research and development expenses include costs incurred for product development, regulatory approvals, clinical trials, and product evaluations.

Selected expense lines:

| | For the three months ended | | \$ Change | % Change |
|---|----------------------------|-----------------------|----------------------|-----------------|
| | September 30, 2012 | September 30, 2011 | | |
| Clinical and Regulatory Affairs: | | | | |
| Wages and related costs | \$ 101,288 | \$ 111,452 | \$ (10,164) | -9.12 % |
| Consulting | 11,866 | 4,065 | 7,801 | 191.91 % |
| Stock-based compensation | 5,029 | 6,011 | (982) | -16.34 % |
| Clinical trials | 107,865 | 320,516 | (212,651) | -66.35 % |
| Other | 13,645 | 18,904 | (5,259) | -27.82 % |
| Total Regulatory | 239,693 | 460,948 | (221,255) | -48.00 % |
| R&D Other than Regulatory: | | | | |
| Wages and related costs | 487,093 | 508,424 | (21,331) | -4.20 % |
| Consulting | 59,887 | 12,726 | 47,161 | 370.59 % |
| Stock-based compensation | 3,080 | 8,181 | (5,101) | -62.35 % |
| Materials and supplies | 132,103 | 185,567 | (53,464) | -28.81 % |
| Other | 83,789 | 66,449 | 17,340 | 26.10 % |
| Total other than Regulatory | 765,952 | 781,347 | (15,395) | -1.97 % |
| Total Research and Development | \$ 1,005,645 | \$ 1,242,295 | \$ (236,650) | -19.05 % |

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2012 decreased by \$221,000 as compared to the same period in 2011. This was primarily due to the reduction of \$213,000 in clinical trial expenses which were mostly associated with clinical studies for our DPP® HIV 1/2 Assay which studies were completed during the first half of 2012.

R&D expenses other than Clinical & Regulatory Affairs decreased by \$15,000 in the three months ended September 30, 2012 as compared with the same period in 2011 and were primarily related to a decrease in wages and related costs and material and supplies partially offset by an increase in consulting.

Selling, General and Administrative Expenses:

Selected expense lines:

| | For the three months ended | | \$ Change | % Change |
|---------------------------------------|----------------------------|-----------------------|-----------|----------|
| | September 30, 2012 | September 30, 2011 | | |
| Wages and related costs | \$ 392,532 | \$ 323,789 | \$ 68,743 | 21.23 % |
| Consulting | 91,841 | 50,347 | 41,494 | 82.42 % |
| Commissions | 302,847 | 221,128 | 81,719 | 36.96 % |
| Stock-based compensation | 40,901 | 59,921 | (19,020) | -31.74 % |
| Marketing materials | 11,214 | 19,571 | (8,357) | -42.70 % |
| Investor relations/investment bankers | 71,953 | 40,408 | 31,545 | 78.07 % |
| Legal, accounting and compliance | 118,769 | 92,240 | 26,529 | 28.76 % |

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| | | | | | |
|---------------------------------------|--------------|------------|------------|--------|---|
| Travel, entertainment and trade shows | 42,400 | 13,849 | 28,551 | 206.16 | % |
| Bad debt allowance (recovery) | - | - | - | 100.00 | % |
| Other | 135,926 | 127,984 | 7,942 | 6.21 | % |
| Total S, G &A | \$ 1,208,383 | \$ 949,237 | \$ 259,146 | 27.30 | % |

Selling, general and administrative expenses for the three months ended September 30, 2012, increased by \$259,000 as compared with the same period in 2011. The primary factor of this increase was a \$82,000 increase in commissions due to increased sales to Brazil. The following expense categories experienced an increase of greater than \$30,000, which also contributed to the overall increase: wages and related expenses (partially as a result of new hires and the accruing year-end bonuses on a quarterly basis), consulting (for sales and marketing) and investor relations.

Other Income and (Expense):

| | For the three months ended | | | |
|----------------------------------|----------------------------|-----------------------|-----------|-------------|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
| Interest income | \$ 2,269 | \$ 1,278 | \$ 991 | 77.54% |
| Interest expense | (2,815) | (4,874) | 2,059 | -42.24% |
| Total Other Income and (Expense) | \$ (546) | \$ (3,596) | \$ 3,050 | -84.82% |

Other expense for the three months ended September 30, 2012 decreased approximately \$3,000, to \$546 from \$3,596 as compared with the same period in 2011, primarily as a result of a decrease in interest expense due on the term loan with HSBC .

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2011

Revenues:

Selected Product Categories:

| | For the nine months ended | | | |
|---------------------------------------|---------------------------|-----------------------|--------------|-----------|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
| Lateral Flow HIV Tests and Components | \$ 9,106,830 | \$ 8,712,985 | \$ 393,845 | 4.52 % |
| DPP Tests and Components | 7,183,925 | 2,604,185 | 4,579,740 | 175.86 % |
| Other | 628,681 | 199,155 | 429,526 | 215.67 % |
| Net Product Sales | 16,919,436 | 11,516,325 | 5,403,111 | 46.92 % |
| License and royalty revenue | - | 125,322 | (125,322) | -100.00 % |
| R&D, milestone and grant revenue | 825,093 | 1,529,972 | (704,879) | -46.07 % |
| Total Revenues | \$ 17,744,529 | \$ 13,171,619 | \$ 4,572,910 | 34.72 % |

Revenues for our lateral flow HIV tests and related components during the nine months ended September 30, 2012 increased by approximately \$394,000 over the same period in 2011. This was primarily attributable to increased sales to Alere from \$5,400,000 during the first nine months of 2011 to \$5,800,000 during the nine months ended September 30, 2012, an increase of \$400,000, or 7%, increased sales to Asia of \$326,000 and increased sales to Africa of \$186,000, which were partially offset by decreased sales to North America (other than Alere) of \$528,000. Revenues for our DPP® products during the nine months ended September 30, 2012 increased by approximately \$4,580,000 over the same period in 2011, which is attributable to the launch of our DPP® products that were approved in Brazil during 2010 and 2011. The decrease in R&D, milestone and grant revenue was due to revenue from milestones and certain development projects in the first nine months of 2011, which were not repeated. License and royalty revenue in 2011 is from royalties from Brazil under our 2004 technology transfer and license agreement, which ended prior to January 1, 2012.

Gross Margin:

Gross Margin related to Net
Product Sales:

For the nine months ended

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| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
|--|-----------------------|-----------------------|--------------|----------|
| Gross Margin per Statement of Operations | \$ 7,632,402 | \$ 6,647,353 | \$ 985,049 | 14.82 % |
| Less: R&D, milestone, grant, license and royalties | 825,093 | 1,655,294 | (830,201) | -50.15 % |
| Gross Margin from Net Product Sales | \$ 6,807,309 | \$ 4,992,059 | \$ 1,815,250 | 36.36 % |
| Gross Margin % | 40.23 % | 43.35 % | | |

The decrease in our product gross margin percentage was primarily due to increased costs in scrap, incoming freight and other costs, along with a change in the product sale mix. Part of the sales mix difference was due to sales to Alere, which are at higher margins, representing a smaller percentage of the overall product sales from 47% to 34%. Partially offsetting these increased costs was an increase in our DPP® products sold in Brazil, which are at slightly higher margins than other international products we sell. The increased sales to Asia and Africa were at lower margins. DPP® sales represented approximately 42% of sales in the nine months ended September 30, 2012 as compared to approximately 23% in the nine months ended September 30, 2011.

Research and Development:

Research and development expenses include costs incurred for product development, regulatory approvals, clinical trials, and product evaluations.

Selected expense lines:

| | For the nine months ended | | | |
|---|---------------------------|-----------------------|----------------------|-----------------|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
| Clinical and Regulatory Affairs: | | | | |
| Wages and related costs | \$ 350,969 | \$ 336,120 | \$ 14,849 | 4.42 % |
| Consulting | 21,196 | 4,065 | 17,131 | 421.43 % |
| Stock-based compensation | 25,722 | 12,847 | 12,875 | 100.22 % |
| Clinical trials | 663,399 | 1,054,684 | (391,285) | -37.10 % |
| Other | 46,363 | 46,091 | 272 | 0.59 % |
| Total Regulatory | 1,107,649 | 1,453,807 | (346,158) | -23.81 % |
| R&D Other than Regulatory: | | | | |
| Wages and related costs | 1,426,588 | 1,485,766 | (59,178) | -3.98 % |
| Consulting | 108,249 | 61,034 | 47,215 | 77.36 % |
| Stock-based compensation | 39,326 | 27,603 | 11,723 | 42.47 % |
| Materials and supplies | 448,616 | 478,603 | (29,987) | -6.27 % |
| Other | 233,391 | 190,496 | 42,895 | 22.52 % |
| Total other than Regulatory | 2,256,170 | 2,243,502 | 12,668 | 0.56 % |
| Total Research and Development | \$ 3,363,819 | \$ 3,697,309 | \$ (333,490) | -9.02 % |

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2012 decreased by \$346,000 as compared to the same period in 2011. This was primarily due to approximately \$391,000 of expenses in 2011 for clinical trials primarily conducted for our DPP® HIV Screen Assay, which was completed in early 2012. This was partially offset by increased costs of wages and related costs, consulting and stock-based compensation.

R&D expenses other than Clinical & Regulatory Affairs increased by \$13,000 in the nine months ended September 30, 2012 as compared with the same period in 2011 and were primarily related to an increase in material and supplies, along with an increase in stock-based compensation, which were partially offset by a decrease in wages and related costs.

Selling, General and Administrative Expenses:

Selected expense lines:

| | For the nine months ended | | | |
|---------------------------------------|---------------------------|-----------------------|------------|----------|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
| Wages and related costs | \$ 1,107,368 | \$ 844,228 | \$ 263,140 | 31.17 % |
| Consulting | 260,843 | 142,518 | 118,325 | 83.02 % |
| Commissions | 868,086 | 406,354 | 461,732 | 113.63 % |
| Stock-based compensation | 141,022 | 83,689 | 57,333 | 68.51 % |
| Marketing materials | 37,382 | 35,044 | 2,338 | 6.67 % |
| Investor relations/investment bankers | 192,232 | 135,520 | 56,712 | 41.85 % |

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| | | | | | |
|---------------------------------------|--------------|--------------|--------------|---------|---|
| Legal, accounting and compliance | 410,469 | 331,909 | 78,560 | 23.67 | % |
| Travel, entertainment and trade shows | 106,689 | 37,794 | 68,895 | 182.29 | % |
| Bad debt allowance (recovery) | - | (15,000) | 15,000 | -100.00 | % |
| Other | 397,461 | 410,811 | (13,350) | -3.25 | % |
| Total S, G &A | \$ 3,521,552 | \$ 2,412,867 | \$ 1,108,685 | 45.95 | % |

Selling, general and administrative expenses for the nine months ended September 30, 2012, increased by \$1,109,000 as compared with the same period in 2011. The primary factor of this increase was commissions of \$462,000 due to increased sales to Brazil as well as an increase in wages and related expenses of \$263,000 (partially as a result of accruing year-end bonuses on a quarterly basis), an increase of \$57,000 in stock-based compensation and \$118,000 in consulting, an increase of \$79,000 in professional fees, and an increase of \$57,000 in investor relations.

Other Income and (Expense):

| | For the nine months ended | | | | |
|----------------------------------|---------------------------|-----------------------|-----------|----------|---|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change | |
| Interest income | \$ 5,386 | \$ 4,315 | \$ 1,071 | 24.82 | % |
| Interest expense | (7,573) | (13,345) | 5,772 | -43.25 | % |
| Total Other Income and (Expense) | \$ (2,187) | \$ (9,030) | \$ 6,843 | -75.78 | % |

Other expense for the nine months ended September 30, 2012 decreased approximately \$6,800, to \$2,187 from \$9,030 as compared with the same period in 2011, primarily as a result of a decrease in interest expense due on the term loan with HSBC as well as an increase in interest income due to an increase in cash in interest-bearing accounts.

Income Taxes:

During 2011, the Company reversed its valuation allowance, in regard to net operating loss (NOL) carry-forwards, previously recorded against its deferred tax assets. As such the Company now records an income tax expense (benefit) for income (loss) for periods starting after December 31, 2011. The Company's interim provision for income taxes is measured using an estimated annual effective tax rate of 39.7%. As per IRS rules, only 90% of the taxable income can be offset by NOLs, and therefore, 3.97%, or \$29,522, was added to accrued expenses, 39.7%, or \$295,220, was expensed, and the balance of 35.73%, or \$265,698, reduced the carrying value of the deferred tax asset.

MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition

| | As of | | | | |
|---|-----------------------|-------------------|------------|----------|---|
| | September 30, 2012 | December 31, 2011 | \$ Change | % Change | |
| Cash and cash equivalents | \$ 3,290,565 | \$ 3,010,954 | \$ 279,611 | 9.29 | % |
| Accounts receivable, net of allowance for doubtful accounts of \$30,000 at September 30, 2012 and December 31, 2011 | 2,567,172 | 2,998,449 | (431,277) | -14.38 | % |
| Inventories | 3,037,880 | 2,300,286 | 737,594 | 32.07 | % |
| Prepaid expenses and other current assets | 705,850 | 681,893 | 23,957 | 3.51 | % |
| Deposits on manufacturing equipment | 252,941 | 139,790 | 113,151 | 80.94 | % |
| Accounts payable and accrued liabilities | 2,686,836 | 2,789,500 | (102,664) | -3.68 | % |

Cash increased by \$280,000 from December 31, 2011, primarily due to net income, net of non-cash items, of \$1,361,000 together with the decrease of accounts receivable by \$431,000 and an increase in customer deposits of

\$23,000, which was partially offset by an increase in inventories of \$738,000, an increase in fixed assets and deposits of \$715,000 (see table below), decrease in accrued expenses and payables of \$103,000 and an increase in prepaid assets of \$24,000.

The decrease in accounts receivable was primarily attributable to a larger amount of credit sales at the end of December 2011 versus September of 2012. The inventory increase is primarily due to a larger amount of materials ordered and manufactured for orders due to ship in the fourth quarter of 2012.

LIQUIDITY AND CAPITAL RESOURCES

| | For the nine months ended | | | |
|---|---------------------------|-----------------------|----------------------|-----------------|
| | September 30, 2012 | September 30, 2011 | \$ Change | % Change |
| Net cash provided by operating activities | \$ 951,742 | \$ 1,559,123 | \$ (607,381) | -38.96 % |
| Net cash used in investing activities | (715,195) | (282,175) | (433,020) | 153.46 % |
| Net cash provided by (used in) financing activities | 43,064 | (367,951) | 411,015 | -111.70 % |
| INCREASE IN CASH AND CASH EQUIVALENTS | \$ 279,611 | \$ 908,997 | \$ (629,386) | -69.24 % |

The Company's cash increased for the nine months ended September 30, 2012 by \$280,000 as compared to an increase in cash for the same period in 2011 of \$909,000. The increase in the 2012 period is enumerated above under Material Changes in Financial Condition. The increase during the 2011 period are primarily attributable to the change in receivables of \$1,304,000, along with non-cash expenses aggregating \$443,000, an increase in accruals and payables of \$290,000, an increase in customer deposits and deferred revenue of \$426,000, partially offset by a decrease in other assets of \$208,000 and an increase in inventories of \$1,239,000. The increase in the 2012 period includes non-cash items from the change in deferred tax assets of \$266,000. The Company's other non-cash expenses totaled \$646,000, which consisted of \$405,000 from depreciation and amortization expense and \$241,000 in share-based compensation expense.

Fixed Asset Commitments

As of September 30, 2012, the Company had paid deposits on various pieces of equipment aggregating \$252,940, which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligations of \$17,228 as various milestones are achieved by the various vendors.

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

In the quarter ended September 30, 2012, Chembio had lower product revenues as a result of lower sales in the U.S. rapid HIV test market through Alere and lower sales to international customers, partially offset by strong increases in our sales to FIOCRUZ in Brazil.

The lower sales to Alere are attributable to Alere having reduced purchase orders in the third quarter after unusually high purchase order rates during the first half of 2012. Sales to Alere grew by more than of 35% in 2011 as compared with 2010 and by 32% in the first half of 2012 as compared with the first half of 2011. Based on the year to date sales to Alere and our anticipated sales to Alere during the fourth quarter, we still anticipate solid growth in this business in 2012, although not at the rate of growth experienced in 2011 or during the first half of 2012. During 2012 we believe the U.S. market share held by our rapid HIV tests in the U.S. will increase. We also believe that a gradual shift will occur over the next couple of years from CDC grants to insured routine testing under the Affordable Care Act, particularly if and when the U.S. Preventive Health Task Force revises its recommendations to routine testing for HIV, as some anticipate.

The lower sales to international customers are attributable to the fact that the completion of production for large orders can span from one period to the next because of capacity constraints, production delays, or customer requests. We are pleased to report however that we have a record amount of orders on hand that will both enable us to finish the year and fourth quarter again with record revenues, and to also begin 2013 with a strong outlook.

During the third quarter and the fourth quarter to date, we have made good progress in our efforts to gain FDA approval and therefore to commercialize in the U.S. market our DPP® HIV 1/2 assay for use with oral fluids and blood samples. If this product is approved, which we anticipate it will be by the end of this year, it will be our first FDA-approved product incorporating our DPP® technology. After submitting the last of the required modules to the FDA in June, and responding to follow-up requests for further information by the FDA during the third quarter, a manufacturing facility pre-approval inspection (PAI) was conducted by the FDA in October. Based on the results of this inspection, there is no change to our estimate that we anticipate an approved or at least approvable Pre-Marketing Application (PMA) for this product by the end of 2012. Upon receipt of an approval, we would then be permitted to apply for a Clinical Laboratory Improvement Act (CLIA) waiver in order to enable the product to be sold in the point-of-care market segments where these tests are primarily used. We are in discussions with the FDA to confirm the requirements for such CLIA waiver application as they relate to this product based on the most recent agency guidance. Combined with our two already FDA-approved lateral flow blood tests that are currently marketed by Alere, we believe the availability of an alternative oral fluid HIV rapid test, which test also performs very well on all blood matrices, will enable Chembio to participate in market segments not currently addressed by the products sold through Alere. We are engaged in preliminary discussions with potential distributors to distribute this product in certain market segments. At the same time, we will likely retain the option to develop a public health sales and marketing organization that would market this product together, which sales would be complemented by our unique DPP® Syphilis Screen & Confirm test and our Hepatitis- C (HCV) test, which still have substantial development or regulatory steps before they can be commercialized, though progress is being made.

The Company has a number of new product opportunities in addition to the aforementioned oral fluid HIV, Syphilis and HCV tests. These new products include our proprietary Sure Check HIV 1/2 test for home use that is already approved in the United States professional market, and for which we are working on completing the requirements for submitting an Investigational Device Exemption in order to begin clinical trials next year to pursue FDA approval for home use.

We are working on a number of new potential projects based on, and/or that complement, our patented DPP® point-of-care technology, and in some cases we are now conducting feasibility studies in order to move these

opportunities forward. These include potential products with application to the areas of women's health, veterinary diagnostics, and blood viruses, as well as technologies that improve the detection limits of our technology platform. We believe that these projects can ultimately result in potential new revenue streams in future periods, although there can be no assurance of this.

In addition to the core development programs that we have in place that we believe will drive long-term growth and shareholder value, we have also developed new distribution and OEM collaborations for existing products which, if successful, will help to produce additional revenue opportunities in markets where we already have an established record of success, including but not limited to Brazil, as well as certain new developing world markets.

ITEM 4. CONTROLS AND PROCEDURES

- (a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.
- (b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the Company's first 2012 fiscal nine months that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS

(see next page)

EXHIBITS INDEX

| Number | Description |
|---------|---|
| 3.1 | Articles of Incorporation, as amended. (1) |
| 3.2 | Amended and Restated Bylaws. (2) |
| 4.1* | Form of Employee Option Agreement. (3) |
| 4.2 | 1999 Equity Incentive Plan. (4) |
| 4.3 | 2008 Stock Incentive Plan. (5) |
| 4.4 | Rights Agreement, dated March 8, 2010 (6) |
| 4.5 | Form of Warrant (to be filed by amendment) [to be revised] |
| 10.1* | Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (7) |
| 10.2* | Employment Agreement dated March 5, 2010 with Javan Esfandiari. (8) |
| 10.3 | HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (9) |
| 10.4 | HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9) |
| 10.5 | Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9) |
| 10.6 | Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (9) |
| 10.7 | Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10) |
| 10.8 | Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10) |
| 10.9 | Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10) |
| 10.10 | Revolving Term Note, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11) |
| 10.11 | Loan and Security Agreement, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11) |
| 14.1 | Ethics Policy (12) |
| 21 | List of Subsidiaries (13) |
| 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. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Presentation Linkbase Document |
| 1 | Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005. |
| 2 | Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008. |
| 3 | Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008. |

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- 4 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
 - 5 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
 - 6 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
 - 7 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
 - 8 Incorporated by reference to the Registrant's registration statement on Form S-1/A filed with the Commission on March 11, 2010.
 - 9 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
 - 10 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
 - 11 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 3, 2011.
 - 12 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 30, 2006.
 - 13 Incorporated by reference to the Registrant's annual report on Form 10-K filed with the Commission on March 8, 2012.
- (*) An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this document.

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: November 13, 2012 By: /s/ Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2012 By: /s / Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principal Financial and Accounting Officer)

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