

CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
November 07, 2013

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, 2013

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 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)

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 x No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if 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 x No _

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company x

(Do not check if a smaller reporting company)

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of November 6, 2013, the Registrant had 9,324,783 shares outstanding of its \$.01 par value common stock.

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Quarterly Report on FORM 10-Q
For The Quarterly Period Ended
September 30, 2013

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PART I

Item 1. FINANCIAL STATEMENTS

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

- ASSETS -

| | September 30, 2013 (Unaudited) | December 31, 2012 |
|---|--------------------------------------|----------------------|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$8,045,805 | \$2,951,859 |
| Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$58,000 at September 30, 2013 and December 31, 2012, respectively | 5,505,215 | 4,821,357 |
| Inventories | 3,747,181 | 2,488,071 |
| Prepaid expenses and other current assets | 708,615 | 747,463 |
| TOTAL CURRENT ASSETS | 18,006,816 | 11,008,750 |
| | | |
| FIXED ASSETS, net of accumulated depreciation | 1,822,746 | 1,427,646 |
| OTHER ASSETS: | | |
| Deferred tax asset, net of valuation allowance | 3,874,148 | 4,233,194 |
| License agreements, net of current portion | 353,750 | 400,000 |
| Deposits on manufacturing equipment | 224,773 | 223,584 |
| Deposits and other assets | 44,176 | 41,976 |
| | | |
| TOTAL ASSETS | \$24,326,409 | \$17,335,150 |
| - LIABILITIES AND STOCKHOLDERS' EQUITY - | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued liabilities | \$3,935,036 | \$3,303,923 |
| Current portion of loans payable | - | 51,236 |
| Customer deposits | - | 23,224 |
| TOTAL CURRENT LIABILITIES | 3,935,036 | 3,378,383 |
| OTHER LIABILITIES: | | |
| Loans payable - net of current portion | - | 82,247 |
| TOTAL LIABILITIES | 3,935,036 | 3,460,630 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY: | | |
| Preferred stock – 10,000,000 shares authorized, none outstanding | - | - |
| Common stock - \$.01 par value; 100,000,000 shares authorized, 9,324,783 and 8,036,232 shares issued and outstanding for September 30, 2013 and December 31, 2012, respectively | 93,248 | 80,362 |
| Additional paid-in capital | 46,827,310 | 41,116,149 |
| Accumulated deficit | (26,529,185) | (27,321,991) |
| TOTAL STOCKHOLDERS' EQUITY | 20,391,373 | 13,874,520 |
| | | |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$24,326,409 | \$17,335,150 |

See accompanying notes to condensed consolidated financial statements

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

| | For the three months ended | | For the nine months ended | |
|--|----------------------------|--------------------|---------------------------|--------------------|
| | September 30, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 |
| REVENUES: | | | | |
| Net product sales | \$9,044,714 | \$4,745,094 | \$20,419,595 | \$16,919,436 |
| License and royalty revenue | 898 | - | 898 | - |
| R&D, milestone and grant revenue | 572,027 | 262,292 | 1,268,821 | 825,093 |
| TOTAL REVENUES | 9,617,639 | 5,007,386 | 21,689,314 | 17,744,529 |
| Cost of product sales | 5,561,453 | 3,278,471 | 12,658,063 | 10,112,127 |
| GROSS MARGIN | 4,056,186 | 1,728,915 | 9,031,251 | 7,632,402 |
| OPERATING EXPENSES: | | | | |
| Research and development expenses | 1,602,297 | 1,005,645 | 4,148,201 | 3,363,819 |
| Selling, general and administrative expenses | 1,379,845 | 1,208,383 | 3,702,181 | 3,521,552 |
| | 2,982,142 | 2,214,028 | 7,850,382 | 6,885,371 |
| INCOME (LOSS) FROM OPERATIONS | 1,074,044 | (485,113) | 1,180,869 | 747,031 |
| OTHER INCOME (EXPENSE): | | | | |
| Gain on sale of fixed asset | - | - | 7,500 | - |
| Interest income | 1,477 | 2,269 | 3,712 | 5,386 |
| Interest expense | - | (2,815) | (335) | (7,573) |
| | 1,477 | (546) | 10,877 | (2,187) |
| INCOME (LOSS) BEFORE INCOME TAXES | 1,075,521 | (485,659) | 1,191,746 | 744,844 |
| Income tax provision | 358,850 | (193,310) | 398,940 | 295,220 |
| NET INCOME (LOSS) | \$716,671 | \$(292,349) | \$792,806 | \$449,624 |
| Basic earnings (loss) per share | \$0.08 | \$(0.04) | \$0.09 | \$0.06 |
| Diluted earnings (loss) per share | \$0.07 | \$(0.04) | \$0.08 | \$0.05 |
| Weighted average number of shares outstanding, basic | 9,324,783 | 8,001,472 | 8,886,998 | 7,974,447 |
| Weighted average number of shares outstanding, diluted | 9,824,019 | 8,001,472 | 9,433,152 | 8,616,917 |

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, 2013 | September 30, 2012 |
|---|-----------------------|-----------------------|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Cash received from customers and grants | \$21,005,456 | \$18,175,806 |
| Cash paid to suppliers and employees | (20,425,025) | (17,221,877) |
| Interest received | 3,712 | 5,386 |
| Interest paid | (335) | (7,573) |
| Net cash provided by operating activities | 583,808 | 951,742 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Acquisition of License | (30,000) | - |
| Acquisition of and deposits on fixed assets | (766,274) | (715,195) |
| Net cash used in investing activities | (796,274) | (715,195) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from option and warrant exercises | 31,433 | 98,815 |
| Proceeds from sale of common stock, net | 5,512,500 | - |
| Expenses from sale of common stock | (104,038) | - |
| Payment of loan obligation | (133,483) | (41,175) |
| Payment of capital lease obligation | - | (14,576) |
| Net cash provided by financing activities | 5,306,412 | 43,064 |
| INCREASE IN CASH AND CASH EQUIVALENTS | | |
| Cash and cash equivalents - beginning of the period | 5,093,946 | 279,611 |
| | 2,951,859 | 3,010,954 |
| Cash and cash equivalents - end of the period | \$8,045,805 | \$3,290,565 |
| RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES: | | |
| Net Income | \$792,806 | \$449,624 |
| Adjustments: | | |
| Depreciation and amortization | 446,235 | 404,570 |
| Provision for deferred taxes | 359,046 | 265,698 |
| (Recovery of) doubtful accounts | (34,000) | - |
| Share based compensation | 284,152 | 241,067 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (649,858) | 431,277 |
| Inventories | (1,259,110) | (737,594) |
| Deposits and other assets | (2,200) | 497 |
| Prepaid expenses and other current assets | 38,848 | (23,957) |
| Accounts payable and accrued liabilities | 631,113 | (102,664) |
| Customer deposits and deferred revenue | (23,224) | 23,224 |
| Net cash provided by operating activities | \$583,808 | \$951,742 |

Supplemental disclosures for non-cash investing and financing activities:

| | | |
|---|-----------|-----------|
| Deposits on manufacturing equipment transferred to fixed assets | \$296,788 | \$181,489 |
|---|-----------|-----------|

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2013
(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 77 % of the Company's product revenues in the first nine months of 2013. The Company's products based on its patented Dual Path Platform (DPP®) platform represented approximately 21 % of the Company's product revenues in the first nine months of 2013. The Company also has other rapid tests that together represented approximately 2 % of sales in the first nine months of 2013. 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. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company's products that are currently being developed are based on its patented DPP®, which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In December 2012, the Company received FDA approval for its DPP® HIV 1/2 Assay for the detection of HIV antibodies in saliva, whole blood, serum and plasma samples.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2012, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of September 30, 2013 and for the nine-month periods ended September 30, 2013 and 2012, 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, 2012, 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 reverse 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, 2013, its condensed consolidated results of operations for the three- and nine-month periods ended September 30, 2013 and 2012, respectively, and its condensed consolidated cash flows for the nine-month periods ended September 30, 2013 and 2012, 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2013
(UNAUDITED)

b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with ASC 605, which provides that 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, 2013 and December 31, 2012, 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.

c) Inventories:

Inventories consist of the following at:

| | September 30, 2013 | December 31, 2012 |
|-----------------|-----------------------|----------------------|
| Raw materials | \$1,945,929 | \$1,418,071 |
| Work in process | 879,806 | 561,530 |
| Finished goods | 921,446 | 508,470 |
| | \$3,747,181 | \$2,488,071 |

d) Earnings Per Share:

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 OTCQB 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.

Basic earnings per share is computed by dividing net income or loss by the weighted-average number of common shares outstanding for the period. Diluted income 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, 2013 and 2012, have been included in the earnings per share computations:

| | For the three months ended | | For the nine months ended | |
|---------|----------------------------|--------------------|---------------------------|--------------------|
| | September 30, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 |
| Basic | 9,324,783 | 8,001,472 | 8,886,998 | 7,974,447 |
| Diluted | 9,824,019 | 8,001,472 | 9,433,152 | 8,616,917 |

The following securities, presented on a common share equivalent basis for the three and nine-month periods ended September 30, 2013 and 2012, have been included in the diluted per share computations as the exercise prices of these securities were less than the stock price as of September 30, 2013 and 2012, respectively, or their inclusion would

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have been anti-dilutive as is the case with 617,680 options in the three months ended September 30, 2012, where the quarter showed a loss:

| | For the three months ended | | For the nine months ended | |
|----------------------------------|----------------------------|--------------------|---------------------------|--------------------|
| | September 30, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 |
| 1999 and 2008 Plan Stock Options | 499,236 | - | 546,154 | 642,470 |

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2013
(UNAUDITED)

The following securities, presented on a common share equivalent basis for the three and nine-month periods ended September 30, 2013 and 2012, have been excluded in the diluted per share computations as the exercise prices of these securities were greater than the stock price as of September 30, 2013 and 2012, respectively, except for 617,680 of the options reflected in the three months ended September 30, 2012 for which inclusion would have been dilutive due to the loss in the period:

| | For the three months ended | | For the nine months ended | |
|----------------------------------|----------------------------|--------------------|---------------------------|--------------------|
| | September 30, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 |
| 1999 and 2008 Plan Stock Options | 169,662 | 750,002 | 169,662 | 161,464 |

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, 2013, there were 93,750 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, 2013, there were 144,220 options exercised, 562,648 options outstanding and 43,132 options or shares still available to be issued under the SIP.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three- and nine-month periods ended September 30, 2013 and 2012 was \$5.39 and \$3.26 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 granted during the periods indicated are as follows (no options issued in the three months ended September 30, 2013):

| | For the three months ended | | For the nine months ended | |
|--------------------------|----------------------------|--------------------|---------------------------|--------------------|
| | September 30, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 |
| Expected term (in years) | n/a | 4 | 3 | 4 - 5 |
| Expected volatility | n/a | 99.60 % - 99.90 % | 93.80 % - 101.30 % | 99.60 % - 115.77 % |
| Expected dividend yield | n/a | 0 % | 0 % | 0 % |
| Risk-free interest rate | n/a | 0.33 % - 0.37 % | 0.34 % - 0.40 % | 0.33 % - 0.37 % |

The Company's results for the three-month periods ended September 30, 2013 and 2012 include share-based compensation expense totaling \$62,000 and \$59,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$14,000 and \$10,000, respectively), research and development (\$22,000 and \$8,000, respectively) and selling, general and administrative expenses (\$26,000 and \$41,000, respectively). The results for the nine-month periods ended September 30, 2013 and 2012 include share-based compensation expense totaling \$284,000 and \$236,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$70,000 and \$30,000, respectively), research and development (\$84,000 and \$65,000, respectively) and selling, general and administrative expenses (\$130,000 and \$141,000, 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, 2013 and 2012 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
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The following table provides stock option activity for the nine months ended September 30, 2013:

| Stock Options | Number of Shares | Weighted Average Exercise Price per Share | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|-----------------------------------|------------------|---|---|---------------------------|
| Outstanding at December 31, 2012 | 731,646 | \$ 2.23 | 2.19 years | \$3,460,686 |
| Granted | 51,360 | 5.39 | | |
| Exercised | (117,380) | 1.53 | | |
| Forfeited/expired/cancelled | (9,228) | 3.99 | | |
| Outstanding at September 30, 2013 | 656,398 | \$ 2.57 | 1.90 years | \$705,000 |
| Exercisable at September 30, 2013 | 504,022 | \$ 2.04 | 1.41 years | \$807,500 |

As of September 30, 2013, there was \$220,000 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 1.89 years. The total fair value of stock options vested during the nine-month periods ended September 30, 2013 and 2012 was approximately \$39,000 and \$245,000, respectively.

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, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 |
| Africa | \$1,030,108 | \$594,738 | \$2,887,328 | \$2,115,307 |
| Asia | 32,011 | 374,845 | 82,229 | 641,326 |
| Europe | 5,540 | 4,298 | 82,869 | 37,629 |
| North America | 2,199,090 | 1,235,074 | 7,484,668 | 6,501,210 |
| South America | 5,777,965 | 2,536,139 | 9,882,501 | 7,623,964 |
| | \$9,044,714 | \$4,745,094 | \$20,419,595 | \$16,919,436 |

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2013
(UNAUDITED)

g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

| | September 30, 2013 | December 31, 2012 |
|----------------------------------|-----------------------|----------------------|
| Accounts payable – suppliers | \$ 1,628,737 | \$ 1,686,431 |
| Accrued commissions | 173,110 | 238,150 |
| Accrued royalties / license fees | 976,421 | 583,923 |
| Accrued payroll | 226,220 | 262,439 |
| Accrued vacation | 223,412 | 181,636 |
| Accrued bonuses | 422,225 | 155,663 |
| Accrued expenses – other | 284,911 | 195,681 |
| TOTAL | \$ 3,935,036 | \$ 3,303,923 |

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 \$- and \$367,000 for the nine-month periods ended September 30, 2013 and 2012, respectively from this grant. The Company earned an aggregate of \$2,800,000 from this grant from inception through September 30, 2013, 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 \$470,000 and \$487,000 for the nine-month periods ended September 30, 2013 and 2012, respectively from this grant. The Company earned \$2,153,000 from this grant from inception through September 30, 2013 of which \$651,000 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 was modified in April 2013, increasing the agreement to \$953,000. The agreement contemplates a period of approximately nine months in which the follow-on development activity is to be completed. The Company earned \$316,000 and 18,000 for the nine-month periods ended September 30, 2013 and 2012, respectively from this agreement. The Company earned \$594,000 from this grant from inception through September 30, 2013.

c) Cooperative research agreement with a U.S. government agency:

In May 2013, the Company was awarded a cooperative research agreement with a U.S. government agency for up to \$753,000 for an eight month development project to develop rapid POC diagnostic tests for five infectious diseases associated with febrile illness. The Company earned \$470,000 for the nine-month period ended September 30, 2013 from this agreement. The Company earned \$470,000 from this grant from inception through September 30, 2013.

NOTE 4 — LOANS PAYABLE:

On April 30, 2013, the Company entered into a new demand loan agreement ("Demand Note") with HSBC Bank, USA ("HSBC"). The Demand Note allows the Company to draw on the line from time to time an amount up to an aggregate of \$2,000,000 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 for which the bank lender can demand repayment of the entire loan, with accrued interest, at any time. The loan is subject to annual reviews, as well as an annual 30-day clean-up, during which there can be no amounts outstanding.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2013
(UNAUDITED)

The Security Agreement, related to the Demand Note, 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 in the Company and in its business.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. As of September 30, 2013, nothing had been drawn down on the Demand Note.

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, which is defined below.

Until a Right is exercised, the holder thereof, in his capacity as a holder of Rights, 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:

The Company entered into an employment agreement effective May 22, 2013 ("Employment Agreement"), with Ms. Klugewicz to serve as the Company's Chief Operating Officer, which included issuing incentive stock options to purchase 5,000 shares of the Company's common stock. Of these stock options, options to purchase 2,500 shares vest on each of the first two anniversaries of the effective date of the Employment Agreement. The exercise price for these

options was to be equal to the last traded price for the Company's common stock on May 22, 2013, which was \$4.50 per share. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of the grant.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2013
(UNAUDITED)

The Company closed on an underwritten public offering of 1,200,000 shares of its common stock at \$5.00 per share on April 3, 2013. The net proceeds of the offering, after deducting the underwriters' discounts and other offering expenses payable by the Company, was approximately \$5,401,000. The Company intends to use the net proceeds for business expansion and working capital.

On February 26, 2013, the Company issued 16,360 options to purchase common stock to executives of the Company as part of their 2012 bonus. The options are exercisable immediately at \$5.56 per share, which was the last traded price of the common stock on that day, and they expire five years from the date of issue.

The Company entered into an employment agreement effective March 5, 2013 ("Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development, which included issuing incentive stock options to purchase 30,000 shares of the Company's common stock. Of these stock options, options to purchase 10,000 shares vest on each of the first three anniversaries of the effective date of the Employment Agreement. The exercise price for these options was to be equal to the last traded price for the Company's common stock on March 5, 2013, which was \$5.44 per share. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the effective date of the grant.

As of September 30, 2013, the Company had no warrants outstanding to purchase shares of common stock.

NOTE 7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Economic Dependency:

The following table discloses product sales the Company had to each customer that purchased in excess of 10% of the Company's net product sales for the periods indicated:

| Customer | For the three months ended | | | | For the nine months ended | | | | Accounts Receivable as of | |
|----------|----------------------------|------------|--------------------|------------|---------------------------|------------|--------------------|------------|---------------------------|--------------------|
| | September 30, 2013 | | September 30, 2012 | | September 30, 2013 | | September 30, 2012 | | September 30, 2013 | September 30, 2012 |
| | Sales | % of Sales | Sales | % of Sales | Sales | % of Sales | Sales | % of Sales | | |
| 1 | \$2,167,999 | 24 | \$1,187,124 | 25 | \$7,063,682 | 35 | \$5,780,030 | 34 | \$843,554 | \$648,084 |
| 2 | 1,887,166 | 21 | 2,522,405 | 53 | 3,756,262 | 33 | 7,241,430 | 44 | 715,310 | 1,326,098 |
| 3 | 3,866,894 | 43 | * | * | 5,924,900 | 18 | * | * | 2,365,950 | * |

(*) 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
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SEPTEMBER 30, 2013
(UNAUDITED)

The following table discloses purchases the Company made from each vendor that sold to the Company in excess of 10% of the Company's total purchases for the periods indicated:

| | For the three months ended | | For the nine months ended | | Accounts Payable as of | | | | | |
|----------|----------------------------|--------------------|---------------------------|--------------------|---------------------------|--------------------|-----------|----|----------|-----------|
| | September 30, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 | September 30, 2013 | September 30, 2012 | | | | |
| | Purchases | % of Purc. | Purchases | % of Purc. | Purchases | % of Purc. | | | | |
| Vendor 1 | \$299,648 | 12 | \$204,607 | 15 | \$675,765 | 8 | \$613,287 | 14 | \$95,170 | \$ 89,710 |
| Vendor 2 | 275,539 | 11 | 211,020 | 16 | 840,923 | 10 | 589,224 | 13 | 57,555 | 60,073 |

(*) Purchases did not exceed 10% for the period indicated

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 three key employees. The contracts call for salaries presently aggregating \$840,000 per year. The Klugewicz contract expires in May 2015, the Esfandiari contract expires in March 2016 and the Siebert employment contract expires in May 2014. In connection with the contract that expires in May 2015, the Company issued, in May 2013, 5,000 options to purchase common stock, with one-half vesting on each of the first and second anniversaries of the grant. In connection with the contract that expires in March 2016, the Company issued, in March 2013, 30,000 options to purchase common stock, with one-third vesting on each of the first, second and third anniversaries of the grant.

NOTE 8 — INCOME TAXES:

The Company's interim provision for income taxes is measured using an estimated annual effective tax rate of 35.1 % based on the 2012 statements. As per IRS rules, only 90 % of the taxable income can be offset by NOLs, and therefore 10 % of the tax rate equal to 3.5 %, or \$39,800, was added to accrued expenses as an estimate of the amount to be owed, the full rate of 35.1 %, or \$398,000, was expensed, and the balance of 31.6 %, or \$358,200, reduced the carrying value of the deferred tax asset for the nine months ended September 30, 2013.

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 as 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 have not changed significantly from December 31, 2012.

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.

All of the Company's future products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. The Company has completed development of several products that employ the DPP® technology, three of which are or will be marketed under Chembio's label (DPP® HIV 1/2 Assay, DPP® Syphilis Screen & Confirm, and DPP® HIV 1/2 –Syphilis Assay) and several others that have been developed specifically related to private label agreements with The Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market, as explained below.

All of the Company's products other than its lateral flow tests are based on the Company's patented Dual Path Platform (DPP®) technology. The Company has had very active research and development programs and has significantly increased its spending on research and development during the last three years. Third-party funding from

research and development contracts and grants have offset a significant portion of these increased research and development expenses. The principal product development activities are described below.

DPP® HIV Multiplex Antigen-Antibody Test - Development work continues on a DPP® HIV multiplex test that is being designed to detect acute (early stage) HIV infection by means of detecting P24 antigen, as well as antibodies, to HIV1/2, in whole blood samples. Recently the FDA approved the first point-of-care test that claims to detect acute HIV infection, and there are also two FDA- approved laboratory tests with such claims. The point-of-care test approved by the FDA, manufactured in Israel by a subsidiary of Alere, is called Determine® HIV Ag/Ab Combo.

This test, which Alere has reported is now undergoing CLIA waiver studies, claims earlier detection due to the ability to detect unbound p24 antigen. We believe that our development of such a test, combined with our patented DPP® point-of-care platform may better help identify HIV infections that cannot be identified by any of the currently FDA-approved rapid HIV tests, including the new Alere Determine test. Such a test can better serve an unmet market need, and help to maintain and potentially grow the already strong position Chembio's products have in the U.S. rapid HIV test market.

Given the recent developments with the Alere product we are reassessing our design plan and timetable.

DPP® Hepatitis-C (HCV) – Development work on our DPP® HCV point-of-care rapid test continues. Our development activity has been focused on creating a differentiated product that is at least capable of identifying antibody response in a more comprehensive manner than the currently available point-of-care test is able to do, and to also, in parallel, engage in efforts to differentiate those patients that are antibody positive from those that have an active infection, as up to 30% of patients that are HCV antibody-positive don't have an active infection.

In July 2012, the U.S. Centers for Disease Control finalized the recommendations for testing all individuals in the United States born between the years of 1945 and 1965 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 of their status. With a number of new anti-retroviral therapies approved, and even more anticipated pending approval in the years ahead by the FDA, we believe that over time, these new recommendations will be implemented. In fact, in May the United States Preventive Services Task Force revised its November 2012 recommendations to endorse the CDC recommendations by giving both hepatitis-C (HCV) screening for at-risk individuals and age-cohort screening a 'B' grade; under the Affordable Care Act, preventive services that have received an 'A' or 'B' grade from the USPSTF must be covered by insurance policies without cost-sharing, and be part of the essential health benefits for those individuals eligible for Medicare.

We plan to complete development activities of the antibody detection assay in mid-2014, and to begin activities to commercialize product, including regulatory submission, in the US by the end of 2015 or early 2016.

International Distribution & Manufacturing Agreements –

Labtest

During the second quarter the Company entered into an international assembly and distribution agreement with Labtest Diagnostica SA (Labtest), a leading diagnostics manufacturer and marketing organization based in Brazil, for products based upon Chembio's patented Dual Path Platform (DPP ®) in Brazil and potentially other markets outside the U.S.

Pursuant to the agreement, Chembio will manufacture and sell certain specialized test components to Labtest and also will receive a royalty based on sales by Labtest of DPP ® products. Labtest will produce certain reagents and perform assembly and packaging operations in a dedicated space at Labtest's manufacturing facilities near Belo Horizonte, Brazil. Chembio will provide Labtest with the training necessary to perform the operations specific to the DPP ® products. Labtest will also have responsibility for marketing, promotion and distribution of the products in Brazil. All products will be marketed under brand names that will include Chembio's DPP ® trademark together with trade names selected by Labtest, and each test kit will state that Chembio Diagnostic Systems, Inc. is the licensor of the DPP ® trademark and technology. The products selected for inclusion in this agreement will address both private as well as public health markets, and will enable Chembio to participate in significant market opportunities in Brazil. This agreement addresses market opportunities that are independent of those addressed by Chembio's ongoing collaboration with the Oswaldo Cruz Foundation.

Labtest expects to have the assembly equipment in place during the fourth quarter so that they can begin product registration activities for an initial group of infectious disease products with sales expected to commence during 2014. The agreement contemplates additional products and territories to be added by mutual agreement. In addition, the agreement offers the possibility for Labtest to assemble products for other global Chembio customers as a contract manufacturer.

Sponsored Research & Development

Multiplex Influenza Immunity Test –

During the second quarter we reported that the Company had entered into a follow-on, milestone-based development agreement with the private contracting organization that is engaged to enter into, implement and provide technical oversight of agreements relating to pandemic influenza preparedness on behalf of its client, the United States Centers for Disease Control and Prevention (CDC), for a multiplex, rapid, POC influenza immunity test utilizing Chembio's patented Dual Path Platform (DPP ®) technology. The follow-on agreement is for up to approximately \$472,000 and is expected to progress through to mid to late January 2014.

The early prototype development work for this product was successfully completed by Chembio in 2010 through 2013 pursuant to previous contracts with the same organization totaling approximately \$1.4 million. The objective of this follow-on project is to further develop a rapid influenza immunity test that can determine a person's influenza immunity status in the field or in an outpatient setting, while incorporating certain additional subunits of influenza virus proteins.

As a result of pandemic planning activities, the United States Department of Health and Human Services and the CDC have 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 this test is especially critical for the military, as evidenced by previous influenza outbreaks that spread rapidly through densely populated barracks and killed thousands of soldiers.

DPP® Febrile Illness Multiplex test – During the second quarter we entered into a cooperative research project agreement with a U.S. government agency for up to \$750,000 for an eight-month development project. The project is to develop a rapid POC diagnostic test for five infectious diseases associated with febrile illness and to multiplex them

into one assay. The project also contemplates that the test would be optimized for use with a mobile reader that incorporates cell phone technology to enable the results to be recorded, transmitted and monitored remotely via a cloud system, in real-time. This research project supports our efforts in developing multiplex products using our proprietary DPP® technology. Our DPP® technology, when combined with the mobile reader being used in the project, will enable real time data collection and monitoring capabilities. As these infectious diseases can all exhibit similar clinical symptoms, a rapid multiplex test that could distinguish them would be very useful, particularly in field conditions, so that correct diagnosis and treatment could be provided on a timely basis. We are on track to complete R&D activities for this project by early November as anticipated. The U.S. government agency that this test was developed for will receive approximately 2000 tests for initial evaluation, followed by an additional 10,000 for clinical trials. Chembio has an opportunity to explore commercial opportunities outside the scope of the government agreement.

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, several additional antigens were identified to enhance antibody detection by the DPP® test prototype designed in our Phase I studies. Antigen reagents have been finalized and test prototype evaluation using well-characterized clinical specimens is in progress. Funding for the third and final year of this Phase II grant was confirmed with a reduction of approximately 1%.

Chembio's work to finalize DPP assay design using various fusion proteins has been completed and production of an evaluation lot is in progress; these tests will be used for verification studies, internal and external evaluations at the selected collaborative sites (see below), QC protocol validation, and accelerated stability study. The target sensitivity is 80% and specificity is 95%. Study sites for external evaluations of DPP assay include Bangladesh, Brazil, China, Haiti, Peru, Venezuela, and South Africa. The grant is expected to be completed by early July 2014.

In addition to the above-mentioned research and development work sponsored by governmental agencies and/or their contractors for the influenza, febrile illnesses, and tuberculosis projects, we are discussing additional opportunities for sponsored research and development activity. We endeavor to select sponsored research projects where we believe there is an identifiable commercial opportunity and/or where other benefits to the Company are anticipated in connection with these projects.

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 can enhance or expand our current product portfolio, 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 – The Company's SURE CHECK® HIV 1/2 Assay has received CE Mark approval from European regulators and is therefore now cleared for commercialization within the European Union (EU) for rapid, point-of-care detection of HIV. Chembio is currently working with commercialization partners in Europe. We expect that our HIV 1/2 STAT PAK® lateral flow HIV test will receive the CE mark during the fourth quarter. We anticipated that the DPP® HIV 1/2 test will receive CE Mark approval in early 2014.

FDA Approval for DPP® HIV 1/2 Screening Assay for Use with oral fluid or blood samples – We received FDA approval of our Pre-Marketing Application (PMA) for this product on December 19, 2012 as we previously announced. We are now working towards a CLIA waiver. As of November 1, 2013, approximately 95% of the enrollment criteria had been completed for all sample matrices. The CLIA waiver will be submitted by mid-November and the CLIA waiver grant is now expected to be received in the first quarter of 2014.

DPP® HIV-Syphilis – We have developed this product for international and US marketing. For the international market, the product has been registered in Mexico. We have submitted this product both for evaluation by the CDC, acting on behalf of the United States Agency of International Development, and the WHO, which has accepted this product to be evaluated for pre-qualification in its global procurement scheme.

The FDA review timeline for this product, which we originally anticipated would be in mid-2014, has now been shifted to late 2014, with CLIA waiver now anticipated in early 2015. This development is due to this product being characterized by FDA as a PMA, not a 510(K), as the syphilis component performance will be compared to actual patient infection status, as compared to a predicate device allowed in 510(K). This change will be more time consuming due to the increased statutory review time, and potentially more costly. We plan to submit the PMA application for this product by the end of 2013 and therefore a PMA decision by the end of 2014. We would submit a CLIA waiver application upon receipt of the approved PMA.

DPP® Syphilis Screen & Confirm - In late February we received a response from the FDA that will enable us to pursue the regulatory pathway that we outlined in our submission. While we confirmed our intended study approach with the FDA, we have encountered problems with the supply of one of the key raw materials used in this test. Although progress toward a resolution of this had been made since we reported this in August, until we are able to fully resolve those problems, this project is on hold.

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, or 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.

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, 2012, see our Annual Report on Form 10-K for the twelve months ended December 31, 2012, which was filed with the SEC on March 7, 2013.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2013 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2012

Income:

For the three months ended September 30, 2013, income before income taxes was \$1,076,000 compared to loss before taxes of (\$486,000) for the three months ended September 30, 2012. Net loss for the 2012 period was (\$292,000) as compared to a net income of \$717,000 for 2013. The increase in net income is primarily attributable to a increased product sales. In the three months ended 2013, as a result of a 90.6% increase in net product sales and a 118% increase in non-product revenues along with a 69.6% increase in cost of products sold, the Company had a \$2,327,000, or 134.6%, increase in its gross margin, to \$4,056,000. This increased gross margin along with the increased operating expenses, the most significant of which was an increase in clinical trial expenses of \$397,000, accounted for most of the change from a net loss to a net income.

Revenues:

| Selected Product Categories: | For the three months ended | | | |
|---------------------------------------|----------------------------|--------------------|-------------|----------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Lateral Flow HIV Tests and Components | \$7,018,407 | \$2,179,238 | \$4,839,169 | 222.06 % |
| DPP Tests and Components | 1,879,866 | 2,531,725 | (651,859) | -25.75 % |
| Other | 146,441 | 34,131 | 112,310 | 329.06 % |
| Net Product Sales | 9,044,714 | 4,745,094 | 4,299,620 | 90.61 % |
| License and royalty revenue | 898 | - | 898 | 100.00 % |
| R&D, milestone and grant revenue | 572,027 | 262,292 | 309,735 | 118.09 % |
| Total Revenues | \$9,617,639 | \$5,007,386 | \$4,610,253 | 92.07 % |

Revenues for our lateral flow HIV tests and related components during the three months ended September 30, 2013 increased by approximately \$4,839,000 from the same period in 2012. This was attributable to increased sales to South America, excluding Brazil, of approximately \$3,902,000, increased sales to Africa of \$435,000, and increased sales to Alere from \$1,187,000 during the three months ended September 30, 2012 to \$2,168,000 during the three months ended September 30, 2013, these increases were partially offset by decreased sales to Asia of \$343,000.

Revenues for our DPP® products during the three months ended September 30, 2013 decreased by approximately \$652,000 over the same period in 2012, a decrease of 26%, which is attributable to a reduction in sales to the Oswald Cruz Foundation. The increase in R&D, milestone and grant revenue was due to revenue from certain development projects granted in the fourth quarter of 2012. R&D revenues include funds, recognized on an "as expenses are incurred" basis, from a Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009, and from a Phase II grant for Tuberculosis which was effective March 1, 2011 as well as a development contract with Battelle entered into in the fourth quarter of 2012.

Gross Margin:

| Gross Margin related to Net Product Sales: | For the three months ended | | | |
|---|----------------------------|--------------------|-------------|----------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Gross Margin per Statement of Operations | \$4,056,186 | \$1,728,915 | \$2,327,271 | 134.61 % |
| Less: R&D, milestone, grant, license and royalty revenues | 572,925 | 262,292 | 310,633 | 118.43 % |
| Gross Margin from Net Product Sales | \$3,483,261 | \$1,466,623 | \$2,016,639 | 137.50 % |
| Product Gross Margin % | 38.51 % | 30.91 % | | |

The gross margin dollar increase of \$2,327,000 included a \$2,017,000 increase in gross margin from product sales and a \$311,000 increase in non-product revenues. The increase in product gross margin dollars is primarily attributable to the higher product sales compared to the 2012 period which resulted in \$1,329,000 (this is calculated by taking the increase in sales times the gross margin percentage from 2012). The 7.6% increase in our product gross margin percentage, from 30.9% in 2012 to 38.5% in 2013, accounted for the \$688,000 balance, and was primarily due to decreased costs in products overhead application, together with a change in the product sales mix. The higher volume of product sales allowed the relatively fixed overhead, items such as rent, supervision, etc., to be spread over a greater number of products, thereby reducing their allocated cost. Partially offsetting these decreased costs was an increase in our scrap expenses due to issues related to vendor materials and to the increased volume of product produced in the quarter.

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 | | | |
|---|----------------------------|--------------------|------------|----------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| <u>Clinical and Regulatory Affairs:</u> | | | | |
| Wages and related costs | \$ 103,164 | \$ 101,288 | \$ 1,876 | 1.85 % |
| Consulting | 4,331 | 11,866 | (7,535) | -63.50 % |
| Stock-based compensation | 2,425 | 5,029 | (2,604) | -51.78 % |
| Clinical trials | 505,202 | 107,865 | 397,337 | 368.37 % |
| Other | 31,393 | 13,645 | 17,748 | 130.07 % |
| Total Regulatory | 646,515 | 239,693 | 406,822 | 169.73 % |
| <u>R&D Other than Regulatory:</u> | | | | |
| Wages and related costs | 581,663 | 487,093 | 94,570 | 19.42 % |
| Consulting | 46,642 | 59,887 | (13,245) | -22.12 % |
| Stock-based compensation | 19,206 | 3,080 | 16,126 | 523.57 % |
| Materials and supplies | 217,772 | 132,103 | 85,669 | 64.85 % |
| Other | 90,499 | 83,789 | 6,710 | 8.01 % |
| Total other than Regulatory | 955,782 | 765,952 | 189,830 | 24.78 % |
| Total Research and Development | \$ 1,602,297 | \$ 1,005,645 | \$ 596,652 | 59.33 % |

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2013 increased by \$407,000 as compared to the same period in 2012. This was primarily due to an increase of \$397,000 in clinical trial expenses which are mostly associated with CLIA waiver studies for our DPP® HIV 1/2 Assay.

R&D expenses other than Clinical & Regulatory Affairs increased by \$190,000 in the three months ended September 30, 2013, as compared with the same period in 2012. The increases were primarily related to an increase in wages and related costs and in material and supplies to support our sponsored research and internal development programs.

Selling, General and Administrative Expenses:

| Selected expense lines: | For the three months ended | | | |
|---------------------------------------|----------------------------|--------------------|------------|----------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Wages and related costs | \$ 500,768 | \$ 392,532 | \$ 108,236 | 27.57 % |
| Consulting | 77,562 | 91,841 | (14,279) | -15.55 % |
| Commissions | 265,262 | 302,847 | (37,585) | -12.41 % |
| Stock-based compensation | 40,217 | 40,901 | (684) | -1.67 % |
| Marketing materials | 33,623 | 11,214 | 22,409 | 199.83 % |
| Investor relations/investment bankers | 50,782 | 71,953 | (21,171) | -29.42 % |
| Legal, accounting and compliance | 151,758 | 118,769 | 32,989 | 27.78 % |
| Travel, entertainment and trade shows | 33,724 | 42,400 | (8,676) | -20.46 % |
| Bad debt allowance (recovery) | - | - | - | 100.00 % |
| Other | 226,149 | 135,926 | 90,223 | 66.38 % |
| Total S, G & A | \$ 1,379,845 | \$ 1,208,383 | \$ 171,462 | 14.19 % |

Selling, general and administrative expenses for the three months ended September 30, 2013, increased by \$171,000 as compared with the same period in 2012, a 14% increase. Significant increases in wages and related costs, marketing materials, professional fees and the Medical Device Tax (reflected in Other above) were partially offset by a \$38,000 decrease in commissions due to decreased sales to Brazil, along with a decrease in investor relations/investment bankers of \$21,000 .

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Other Income and (Expense):

| | For the three months ended September 30, | | | |
|----------------------------------|---|-----------------------|--------------|-------------|
| | 2013 | September 30, 2012 | \$ Change | % Change |
| Other income (expense) | \$- | \$ - | \$ - | 100.00 % |
| Interest income | 1,477 | 2,269 | (792) | -34.91 % |
| Interest expense | - | (2,815) | 2,815 | -100.00% |
| Total Other Income and (Expense) | \$ 1,477 | \$ (546) | \$ 2,023 | -370.35% |

Other income for the three months ended September 30, 2013 increased approximately \$2,000, to an income of \$1,000 from an expense of \$1,000 in the same period in 2012, 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, 2013 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2012

Income:

Income before income taxes for the nine months ended September 30, 2013 increased to \$1,192,000 from \$745,000 for the nine months ended September 30, 2012. Net income increased from \$450,000 for 2012 to \$793,000 for 2013. The increase is primarily attributable to an increase in net product sales. In 2013, as a result of a 20.7% increase in net product sales and a 54% increase in non-product revenues, along with a 25% increase in cost of products sold, the Company had a \$1,399,000, or 18%, increase in its gross margin, to \$9,031,000. This increased gross margin, offset by increased operating expenses, accounted for most of the increase in net income.

Revenues:

| Selected Product Categories: | For the nine months ended | | | |
|---------------------------------------|---------------------------|-----------------------|--------------|-------------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Lateral Flow HIV Tests and Components | \$ 16,113,622 | \$ 9,106,830 | \$ 7,006,792 | 76.94 % |
| DPP Tests and Components | 3,717,517 | 7,183,925 | (3,466,408) | -48.25 % |
| Other | 588,456 | 628,681 | (40,225) | -6.40 % |
| Net Product Sales | 20,419,595 | 16,919,436 | 3,500,159 | 20.69 % |
| License and royalty revenue | 898 | - | 898 | 100.00 % |
| R&D, milestone and grant revenue | 1,268,821 | 825,093 | 443,728 | 53.78 % |
| Total Revenues | \$ 21,689,314 | \$ 17,744,529 | \$ 3,944,785 | 22.23 % |

Revenues for our lateral flow HIV tests and related components during the nine months ended September 30, 2013 increased by approximately \$7,007,000 from the same period in 2012. This was attributable to increased sales to South America, excluding Brazil, of \$5,744,000, sales to Africa of \$772,000 and increased sales to Alere from \$5,780,000 during the nine months ended September 30, 2012 to \$7,064,000 during the nine months ended September 30, 2013. These increases were partially offset by decreased sales to Asia of \$559,000. Revenues for our DPP® products during the nine months ended September 30, 2013 decreased by approximately \$3,466,000 over the same period in 2012, a decrease of 48%, which decrease is attributable to a reduction in sales to the Oswaldo Cruz

Foundation. The increase in R&D, milestone and grant revenue was due to revenue from certain development projects granted in the fourth quarter of 2012. R&D revenues include funds, recognized on an "as expenses are incurred" basis, from a Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009, and from a Phase II grant for Tuberculosis which was effective March 1, 2011, as well as a development contract with Battelle entered into in the fourth quarter of 2012.

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Gross Margin:

| Gross Margin related to Net Product Sales: | For the nine months ended | | | |
|---|---------------------------|--------------------|-------------|----------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Gross Margin per Statement of Operations | \$9,031,251 | \$7,632,402 | \$1,398,849 | 18.33 % |
| Less: R&D, milestone, grant, license and royalty revenues | 1,269,719 | 825,093 | 444,626 | 53.89 % |
| Gross Margin from Net Product Sales | \$7,761,532 | \$6,807,309 | \$954,223 | 14.02 % |
| Product Gross Margin % | 38.01 % | 40.23 % | | |

The gross margin dollar increase of \$1,399,000 included a \$954,000 increase in gross margin from product sales and a \$445,000 increase in non-product revenues. The 2.2% decrease in our product gross margin percentage, from 40.2% in 2012 to 38.0% in 2013, was primarily due to increased royalty costs of approximately 2%. The increase in royalty expense is primarily due to the greater sales of lateral flow products in 2013 as compared with 2012 wherein we had increased sales to Brazil, which carries little or no royalty burden compared to our lateral flow products.

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, 2013 | September 30, 2012 | \$ Change | % Change |
| <u>Clinical and Regulatory Affairs:</u> | | | | |
| Wages and related costs | \$317,120 | \$350,969 | \$(33,849) | -9.64 % |
| Consulting | 29,520 | 21,196 | 8,324 | 39.27 % |
| Stock-based compensation | 17,057 | 25,722 | (8,665) | -33.69 % |
| Clinical trials | 1,024,746 | 663,399 | 361,347 | 54.47 % |
| Other | 59,937 | 46,363 | 13,574 | 29.28 % |
| Total Regulatory | 1,448,380 | 1,107,649 | 340,731 | 30.76 % |
| <u>R&D Other than Regulatory:</u> | | | | |
| Wages and related costs | 1,628,247 | 1,426,588 | 201,659 | 14.14 % |
| Consulting | 98,806 | 108,249 | (9,443) | -8.72 % |
| Stock-based compensation | 66,847 | 39,326 | 27,521 | 69.98 % |
| Materials and supplies | 650,668 | 448,616 | 202,052 | 45.04 % |
| Other | 255,253 | 233,391 | 21,862 | 9.37 % |
| Total other than Regulatory | 2,699,821 | 2,256,170 | 443,651 | 19.66 % |
| Total Research and Development | \$4,148,201 | \$3,363,819 | \$784,382 | 23.32 % |

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2013 increased by \$341,000 as compared to the same period in 2012. This was primarily due to the increase of \$361,000 in clinical trial expenses for our DPP® HIV 1/2 Assay CLIA studies.

R&D expenses other than Clinical & Regulatory Affairs increased by \$444,000 in the nine months ended September 30, 2013, as compared with the same period in 2012, and were primarily related to an increase in wages and related costs, and in material and supplies, as well as an increase in stock-based compensation.

Selling, General and Administrative Expenses:

| Selected expense lines: | For the nine months ended | | | |
|---------------------------------------|---------------------------|--------------------|-----------|----------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Wages and related costs | \$1,394,343 | \$1,107,368 | \$286,975 | 25.92 % |
| Consulting | 183,823 | 260,843 | (77,020) | -29.53 % |
| Commissions | 517,172 | 868,086 | (350,914) | -40.42 % |
| Stock-based compensation | 143,750 | 141,022 | 2,728 | 1.93 % |
| Marketing materials | 62,879 | 37,382 | 25,497 | 68.21 % |
| Investor relations/investment bankers | 164,668 | 192,232 | (27,564) | -14.34 % |
| Legal, accounting and compliance | 465,402 | 410,469 | 54,933 | 13.38 % |
| Travel, entertainment and trade shows | 131,029 | 106,689 | 24,340 | 22.81 % |
| Bad debt allowance (recovery) | (33,450) | - | (33,450) | 100.00 % |
| Other | 672,566 | 397,461 | 275,105 | 69.22 % |
| Total S, G &A | \$3,702,181 | \$3,521,552 | \$180,629 | 5.13 % |

Selling, general and administrative expenses for the nine months ended September 30, 2013, increased by \$181,000 as compared with the same period in 2012. The primary factor of this increase was a \$287,000 increase in wages and related expenses, \$85,000 in severance agreements and a new Medical Device tax of \$64,000, along with other increases. These increases were partially offset by decreases in commissions due to decreased sales to Brazil, consulting, bad debt allowance and other decreases.

Other Income and (Expense):

| | For the nine months ended | | | |
|----------------------------------|---------------------------|--------------------|-----------|-----------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Other income (expense) | \$7,500 | \$ - | \$7,500 | 100.00 % |
| Interest income | 3,712 | 5,386 | (1,674) | -31.08 % |
| Interest expense | (335) | (7,573) | 7,238 | -95.58 % |
| Total Other Income and (Expense) | \$10,877 | \$ (2,187) | \$13,064 | -597.35 % |

Other income for the nine months ended September 30, 2013 increased approximately \$13,000 from an expense of \$2,000 in the same period in 2012, primarily as a result of a gain on the sale of fixed assets and a decrease in interest expense due on the term loan with HSBC.

Income tax (benefit) provision:

For the nine months ended September 30, 2013 the Company charged \$399,000 to income tax expense and reduced its deferred tax assets by \$359,000. The Company maintains a full valuation allowance on research and development tax credits.

MATERIAL CHANGES IN FINANCIAL CONDITION

| Selected Changes in Financial Condition | As of | | \$ Change | % Change |
|--|--------------------|-------------------|-------------|----------|
| | September 30, 2013 | December 31, 2012 | | |
| Cash and cash equivalents | \$8,045,805 | \$2,951,859 | \$5,093,946 | 172.57 % |
| Accounts receivable, net of allowance for doubtful accounts of \$24,000 and \$58,000 at September 30, 2013 and December 31, 2012, respectively | 5,505,215 | 4,821,357 | 683,858 | 14.18 % |
| Inventories | 3,747,181 | 2,488,071 | 1,259,110 | 50.61 % |
| Fixed assets, net of accumulated depreciation | 1,822,746 | 1,427,646 | 395,100 | 27.67 % |
| Deferred tax asset, net of valuation allowance | 3,874,148 | 4,233,194 | (359,046) | -8.48 % |
| Accounts payable and accrued liabilities | 3,935,036 | 3,303,923 | 631,113 | 19.10 % |

Cash increased by \$5,094,000 from December 31, 2012, primarily due to the common stock funding completed in April 2013 which added \$5,409,000. Excluding the financing, the cash decreased by \$315,000. In addition there were increases in accounts receivable, net of allowance, of \$684,000, inventories of \$1,259,000, fixed assets of \$395,000 and accounts payable and accrued expenses of \$631,000. We experienced a decreases in deferred taxes of \$359,000.

The increase in accounts receivable was primarily attributable to a larger amount of credit sales at the end of September of 2013 versus December of 2012. The increase in inventories is due to production for orders received to be shipped in the fourth quarter of 2013, which partially explains the increase in accounts payable and other accrued expenses. The increase in fixed assets is due in part to delivery of equipment for which we had made deposits, this equipment included vial filling equipment, a reel-to-reel printer for R&D, some leasehold improvements, and other pieces of equipment. Deferred tax asset decrease is related to the provision for income tax expense.

LIQUIDITY AND CAPITAL RESOURCES

| | For the nine months ended | | | |
|--|---------------------------|--------------------|--------------------|------------------|
| | September 30, 2013 | September 30, 2012 | \$ Change | % Change |
| Net cash provided by operating activities | \$583,808 | \$951,742 | \$(367,934) | -38.66 % |
| Net cash used in investing activities | (796,274) | (715,195) | (81,079) | 11.34 % |
| Net cash provided by financing activities | 5,306,412 | 43,064 | 5,263,348 | 12222.15 % |
| INCREASE IN CASH AND CASH EQUIVALENTS | \$5,093,946 | \$279,611 | \$4,814,335 | 1721.80 % |

The Company's cash increased by \$5,094,000 from December 31, 2012, primarily due to the common stock funding completed in April 2013 which added \$5,409,000 and was partially offset by other uses of cash from financing activities, compared to an increase in cash of \$280,000 in the 2012 period.

The cash provided from operations in 2013 was \$584,000, primarily due to net income plus non-cash items of \$1,848,000 and an increase of \$631,000 in accounts payable and other accrued liabilities which were partially offset by an increase in accounts receivable of \$650,000 and an increase of \$1,259,000 in inventory. Net income plus non-cash items includes net income of \$793,000, plus \$446,000 in depreciation and amortization, \$284,000 in share-based compensation, \$359,000 in provision for deferred taxes and a reduction for the change in the provision for doubtful accounts of \$34,000. The use of cash from investing activities is primarily the purchase of fixed assets. The increase in cash from operations in 2012 was \$952,000, primarily due to net income net of non-cash items of \$1,361,000 a reduction in accounts receivable of \$431,000 and other items aggregating \$1,000, which were partially offset by a decrease of \$103,000 in accounts payable and accrued liabilities, and an increase of \$738,000 in inventory.

Net income net of non-cash items includes net income of \$450,000, \$405,000 in depreciation and amortization, \$241,000 in share-based compensation, \$265,000 in provision for deferred taxes. The use of cash from investing activities is primarily the purchase of fixed assets.

Fixed Asset Commitments

As of September 30, 2013, the Company had paid deposits on various pieces of equipment aggregating \$225,000, which is reflected in deposits on manufacturing equipment on the balance sheet. The Company has no further commits for additional equipment purchase obligations.

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

Our record revenues and operating income were achieved primarily due to the large \$5.3 million order we received during the second quarter, of which we shipped \$.78 million in the second quarter and \$3.87 million in the third quarter. The balance of the shipment of this order took place in October. As a result of this order and other ongoing revenues, we have increased our year-to-date revenues by over 20%, and our lateral flow HIV test sales by 77%, each as compared with the nine month period in 2012.

We have also more than offset the 48% decrease in our sales of DPP tests as compared with the nine-month period in 2012. That decrease has occurred due to the fact, as previously reported, that the scale-up of the Ministry of Health programs in Brazil that use the products we supply through our agreements with the Oswaldo Cruz Foundation of Brazil (FIOCRUZ) has occurred more slowly than the Ministry of Health had previously anticipated. We have shipped \$3.8 million to FIOCRUZ through the first nine months of this year versus \$7.2 million for the comparable 2012 period, and we expect to ship approximately \$2.03 million in the current quarter, or \$6.0 million for the year as compared with \$10.1 million in 2012. We are in dialog with FIOCRUZ about the 2014 forecast; although we currently believe that the 2014 shipments will be level with 2013, this can change as we have seen.

While the third quarter results incorporate some of the benefits we have realized from a number of manufacturing improvement and capacity utilization programs, substantial opportunities to lower costs and to increase productivity remain, and these opportunities are being vigorously pursued. The results of the third quarter demonstrate our ability to significantly and rapidly increase our production capacity in order to participate in large international procurement opportunities, though we remain more committed than ever to improving our productivity and gross margins.

Complementing results from these ongoing operational efforts, we believe that anticipated increased sales in the U.S. market over the long term will favorably impact our gross margins which will gradually better align our gross margins with industry norms. This is expected primarily due to the significantly higher average selling prices for rapid HIV and other FDA-approved point-of-care tests in the U.S. versus the average selling prices to donor-funded international procurement programs that still represent the largest portion of our revenue mix.

We continue nevertheless to invest in sales and marketing efforts to secure more of these international procurement opportunities. We believe this is good business, particularly as we launch our new products, such as our HIV-Syphilis, which is pending key international evaluations. We believe we are well positioned with our high quality product portfolio and that we will be successful in these sales and marketing efforts. These efforts include activities in many new countries and regions that the Company is pursuing opportunities in directly, through distributors, and through strategic partnerships. For example, we have a number of new opportunities in Africa which are being pursued and managed by a local representative. Also, as a result of our newly and pending CE-Marked products, we have launched a plan to at long last participate in certain new opportunities we have identified in the European market where it is estimated that 30% of HIV-positive individuals are unaware of their status (as compared to 20% now in the United States). Finally, we are working on a potential collaboration in Asia that could, if consummated, provide us with a cost-effective model for participating in opportunities in this region where Chembio has not had a presence. This is in addition to a similar collaboration we have ongoing and which is progressing with Labtest in Brazil, which we initiated a few months ago as announced and is progressing on schedule.

As we submit our CLIA waiver application to the FDA in November for our DPP® HIV 1/2 Assay, we will accelerate the implementation of our U.S. commercial launch plan for this product. We will do the same later in 2014 for our HIV-Syphilis product for which we are planning on submitting our PMA application to the FDA still this year. To this commercial organization we will add the other products that are in our pipeline and potentially other products licensed or acquired under Chembio brands.

Our plan to be ready to address the United States rapid HIV test market is in place and initial hires to staff key sales and marketing positions for executing this plan are being finalized. Contracts with key distribution partners that will support and complement our sales and marketing efforts are also progressing well.

As previously reported, Alere, the exclusive U.S. distributor of our two lateral flow HIV tests sold under their Clearview® brand (specifically Clearview® Complete HIV 1/2, which is the same product that Chembio internationally markets under its SURE CHECK® brand; and Clearview HIV 1/2 STAT PAK, which utilizes the Chembio STAT PAK® trademark also used by Chembio to market this product internationally), notified us, as was required under our agreements with Alere, that they intend to commercialize a new HIV test in the US which is

considered to be a "competitive" product with our products as defined in these agreements. This notification gives us the right, but not the obligation, to convert Alere's exclusive rights with respect to each of these products to non-exclusive rights; or (in the case of the STAT PAK® PRODUCT) we have the right to terminate the agreement.

The new Alere test, which claims earlier detection than all current FDA-approved rapid HIV tests, is FDA-approved; CLIA waiver studies are ongoing and not expected to be completed until late this year or early 2014.

Thus, as a result of this development, included among the products that Chembio could market under its own brands are also now the aforementioned lateral flow products currently marketed by Alere. In this scenario, Chembio would likely realize higher average unit prices for these products given that Alere retains a significant percentage of the product sales under the current agreements with Alere. However, depending on a number of variables, primarily whether and when Alere's new product receives CLIA waiver, its pricing, and how well the Alere product performs and is accepted by the market, these increased revenues may be accompanied by a reduced market share for Chembio's (and also for Chembio's competitors') products.

We have carefully analyzed scenarios based on various assumptions as to these variables and known information, and we are continually and carefully assessing developments. In the meantime, while these developments materialize, we are well on our way to another year of record growth for our product sales into the U.S. market through Alere, and our market share is increasing as it has every year. Our products are well established with many customers. Moreover we are in a dialog with Alere concerning an anticipated proposal to be submitted by Alere; Alere has stated its desire to extend the agreement for Alere to be our exclusive U.S. distributor for these two products even while they sell their new product.

Regardless of which of the scenarios concerning the introduction of the new Alere test, the impact if any on our lateral flow HIV test US sales, the results of the introduction of our DPP HIV 1/2 Assay, and any outcome of our negotiations with Alere, we believe that establishing our own commercial organization in the U.S. market to support a Chembio brand is fundamental to our long-term strategy for the US market and to create sustainable long-term stockholder value. We also believe that continuing to profitably grow our international sales, such as the Company is doing, will only assist our plan to implement this long-term US market strategy.

As stated elsewhere in this report, our development, regulatory and clinical programs are progressing well, even if delayed as compared with previous expectations. We expect to submit our CLIA waiver application to the FDA for our DPP® HIV 1/2 Assay very soon, as well as our PMA application to the FDA for our HIV-Syphilis test product.

We do expect a number of international approvals and registrations, as well as purchase orders for our HIV-Syphilis multiplex product, in the near term. Progress also continues on our fourth generation HIV test and Hepatitis-C test development programs, although they are still in the development stage.

Our strategic plan also includes identifying additional products and technologies that we could license and/or acquire to complement our organic growth plans. There are a number of projects we have ongoing in this regard.

Finally, our search for a new CEO is proceeding on schedule so that this position can be filled by the end of the first quarter of 2014, providing for a smooth transition.

We look forward to updating our stockholders on all of these operational, development, commercialization and organizational efforts as and when appropriate

ITEM 4. CONTROLS AND PROCEDURES

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,

- (a) 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 six months of fiscal 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS

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)
- 10.1* Employment Agreement dated June 15, 2006 with Lawrence A. Siebert, as extended. (7)(11)
- 10.2* Employment Agreement dated March 5, 2013 with Javan Esfandiari (10).
- 10.3* Employment Agreement dated May 22, 2013 with Sharon Klugewicz (12)
- 10.3 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (8)
- 10.4 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
- 10.5 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (8)
- 10.6 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (8)
- 10.8 Secured Revolving Demand Note, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
- 10.9 Loan and Security Agreement, dated as of April 30, 2013, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
- 14.1 Ethics Policy (9)
- 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.SCHXBRL Taxonomy Extension Schema Document
- 101.CALXBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Definition Linkbase Document
- 101.LABXBRL 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.
- 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.

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- 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 Current Report on Form 8-K filed with the Commission on October 5, 2006.
- 9 Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.
- 10 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 7, 2013.
- 11 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 25, 2013.
- 12 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 8, 2013.
- (*) 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 report.

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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 7, 2013 By: /s/ Lawrence A. Siebert
Lawrence A. Siebert
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2013 By: /s / Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principal Financial and Accounting Officer)