

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 June 30, 2012

OR

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

For the transition period from: \_\_\_\_\_ to \_\_\_\_\_

**000-30379**

(Commission File Number)



**ChemBio Diagnostics, Inc.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of incorporation)

**88-0425691**

(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 ☒ 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 ☒ 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 ☒

(Do not check if a smaller reporting company)

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

Yes ☐ No ☒

As of August 3, 2012, the Registrant had 7,996,855 shares outstanding of its \$.01 par value common stock.

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

June 30, 2012

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

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

- ASSETS -

	<u>June 30, 2012</u>	<u>December 31, 2011</u>
	<u>(UNAUDITED)</u>	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 4,390,041	\$ 3,010,954
Accounts receivable, net of allowance for doubtful accounts of \$30,000 at June 30, 2012 and December 31, 2011	2,215,477	2,998,449
Inventories	3,141,322	2,300,286
Prepaid expenses and other current assets	736,458	681,893
<b>TOTAL CURRENT ASSETS</b>	<b>10,483,298</b>	<b>8,991,582</b>
<b>FIXED ASSETS</b> , net of accumulated depreciation	<b>1,144,296</b>	<b>1,062,276</b>
<b>OTHER ASSETS:</b>		
Deferred tax asset, net of valuation allowance	4,309,945	4,749,622
License agreements, net of current portion	450,000	500,000
Deposits on manufacturing equipment	285,495	139,790
Deposits and other assets	41,976	42,474
<b>TOTAL ASSETS</b>	<b>\$ 16,715,010</b>	<b>\$ 15,485,744</b>

- LIABILITIES AND STOCKHOLDERS' EQUITY -

<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,640,267	\$ 2,789,500
Current portion of loans payable	49,850	53,550
Customer deposits	415,919	-
Current portion of obligations under capital leases	-	14,576
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,106,036</b>	<b>2,857,626</b>
<b>OTHER LIABILITIES:</b>		
Loans payable - net of current portion	108,217	133,484
<b>TOTAL LIABILITIES</b>	<b>3,214,253</b>	<b>2,991,110</b>

**COMMITMENTS AND CONTINGENCIES**

**STOCKHOLDERS' EQUITY:**

Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 7,996,855 and 7,921,021 shares issued and outstanding for 2012 and 2011, respectively	79,969	79,210
Additional paid-in capital	40,942,087	40,678,696
Accumulated deficit	(27,521,299)	(28,263,272)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>13,500,757</b>	<b>12,494,634</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 16,715,010</b>	<b>\$ 15,485,744</b>

*See accompanying notes to condensed consolidated financial statements*

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

	For the three months ended		For the six months ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
<b>REVENUES:</b>				
Net product sales	\$ 5,811,190	\$ 2,974,379	\$ 12,174,342	\$ 5,989,442
License and royalty revenue	-	71,468	-	100,322
R&D, milestone and grant revenue	272,701	568,304	562,801	1,160,068
<b>TOTAL REVENUES</b>	<b>6,083,891</b>	<b>3,614,151</b>	<b>12,737,143</b>	<b>7,249,832</b>
Cost of product sales	3,513,267	1,563,873	6,833,656	3,273,212
<b>GROSS MARGIN</b>	<b>2,570,624</b>	<b>2,050,278</b>	<b>5,903,487</b>	<b>3,976,620</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	979,044	1,164,872	2,358,174	2,455,014
Selling, general and administrative expenses	1,079,201	688,259	2,313,169	1,463,630
	2,058,245	1,853,131	4,671,343	3,918,644
<b>INCOME FROM OPERATIONS</b>	<b>512,379</b>	<b>197,147</b>	<b>1,232,144</b>	<b>57,976</b>
<b>OTHER INCOME (EXPENSES):</b>				
Interest income	1,598	1,726	3,117	3,036
Interest expense	(2,317)	(4,034)	(4,758)	(8,470)
	(719)	(2,308)	(1,641)	(5,434)
<b>INCOME BEFORE INCOME TAXES</b>	<b>511,660</b>	<b>194,839</b>	<b>1,230,503</b>	<b>52,542</b>
Income tax provision	203,130	-	488,530	-
<b>NET INCOME</b>	<b>\$ 308,530</b>	<b>\$ 194,839</b>	<b>\$ 741,973</b>	<b>\$ 52,542</b>
<b>Basic earnings per share</b>	<b>\$ 0.04</b>	<b>\$ 0.02</b>	<b>\$ 0.09</b>	<b>\$ 0.01</b>
<b>Diluted earnings per share</b>	<b>\$ 0.04</b>	<b>\$ 0.02</b>	<b>\$ 0.09</b>	<b>\$ 0.01</b>
<b>Weighted average number of shares outstanding, basic</b>	<b>7,987,105</b>	<b>7,882,573</b>	<b>7,960,714</b>	<b>7,834,384</b>
<b>Weighted average number of shares outstanding, diluted</b>	<b>8,525,199</b>	<b>8,716,228</b>	<b>8,512,770</b>	<b>8,647,045</b>

*See accompanying notes to condensed consolidated financial statements*

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

	June 30, 2012	June 30, 2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$ 13,520,115	\$ 9,553,481
Cash paid to suppliers and employees	(11,733,120)	(8,625,009)
Interest received	3,117	1,726
Interest paid	(4,758)	(4,034)
<b>Net cash provided by operating activities</b>	<b>1,785,354</b>	<b>926,164</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of and deposits on fixed assets	(447,621)	(288,402)
<b>Net cash used in investing activities</b>	<b>(447,621)</b>	<b>(288,402)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option and warrant exercises	84,897	278,876
Payment of license obligation	-	(875,000)
Payment of loan obligation	(28,967)	(26,734)
Payment of capital lease obligation	(14,576)	(11,926)
<b>Net cash provided by (used in) financing activities</b>	<b>41,354</b>	<b>(634,784)</b>
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>1,379,087</b>	<b>2,978</b>
Cash and cash equivalents - beginning of the period	3,010,954	2,136,351
<b>Cash and cash equivalents - end of the period</b>	<b>\$ 4,390,041</b>	<b>\$ 2,139,329</b>
<b>RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:</b>		
<b>Net Income</b>	<b>\$ 741,973</b>	<b>\$ 52,542</b>
Adjustments:		
Depreciation and amortization	269,896	216,957
Provision for deferred taxes	439,677	-
Provision for doubtful accounts	-	(15,000)
Share based compensation	179,253	56,327
Changes in assets and liabilities:		
Accounts receivable	782,972	2,318,649
Inventories	(841,036)	(1,568,312)
Prepaid expenses and other current assets	(54,565)	(9,802)
Deposits and other assets	498	-
Accounts payable and accrued liabilities	(149,233)	(60,197)
Customer deposits and deferred revenue	415,919	(65,000)
<b>Net cash provided by operating activities</b>	<b>\$ 1,785,354</b>	<b>\$ 926,164</b>
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$ 55,794	\$ -

*See accompanying notes to condensed consolidated financial statements*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2012**  
**(UNAUDITED)**

**NOTE 1 — DESCRIPTION OF BUSINESS:**

Chembio Diagnostics, Inc. (the “Company” or “Chembio”) and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company’s main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Lateral Flow Rapid HIV tests represented nearly 57% of the Company’s product revenues in the first six months of 2012. The Company’s products based on its patented Dual Path Platform (DPP®) platform represented approximately 38% of the Company’s product revenues in the first six months of 2012. The Company also has other rapid tests that together represented approximately 5% of sales in the first six months of 2012. The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio’s products are sold under the Company’s STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners. For example the Clearview® label is owned by Alere, Inc. (“Alere”), which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. All of the products that are currently being developed by the Company are based on its patented DPP®, which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology.

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

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

The preceding (a) condensed consolidated balance sheet as of December 31, 2011, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of June 30, 2012 and for the three- and six-month periods ended June 30, 2012 and 2011, respectively, have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures, which are normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations, although we believe that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the Financial Statements and the notes thereto, included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2011, previously filed with the SEC.

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

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

***b) Revenue Recognition***

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

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2012**  
**(UNAUDITED)**

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 June 30, 2012 and December 31, 2011, all advanced revenues were earned.

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

**c) Inventories:**

Inventories consist of the following at:

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
<b>Raw materials</b>	<b>\$ 1,522,256</b>	<b>\$ 1,340,177</b>
<b>Work in process</b>	<b>647,323</b>	<b>390,162</b>
<b>Finished goods</b>	<b>971,743</b>	<b>569,947</b>
	<b><u>\$ 3,141,322</u></b>	<b><u>\$ 2,300,286</u></b>

**d) Earnings Per Share:**

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 or (loss) per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. The following securities, presented on a common share equivalent basis for the three- and six-month periods ended June 30, 2012 and 2011, have been included in the earnings per share computations:

	<b>For the three months ended</b>		<b>For the six months ended</b>	
	<b>June 30, 2012</b>	<b>June 30, 2011</b>	<b>June 30, 2012</b>	<b>June 30, 2011</b>
<b>Basic</b>	<b>7,987,105</b>	<b>7,882,573</b>	<b>7,960,714</b>	<b>7,834,384</b>
<b>Diluted</b>	<b>8,525,199</b>	<b>8,716,228</b>	<b>8,512,770</b>	<b>8,647,045</b>

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

	<b>For the three months ended</b>		<b>For the six months ended</b>	
	<b>June 30, 2012</b>	<b>June 30, 2011</b>	<b>June 30, 2012</b>	<b>June 30, 2011</b>
<b>1999 and 2008 Plan Stock Options</b>	<b>538,094</b>	<b>833,655</b>	<b>552,056</b>	<b>812,661</b>

There were 99,594 and 170,073 options and warrants outstanding as of June 30, 2012 and 2011, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended June 30, 2012 and 2011, respectively, because the effect would have been anti-dilutive as of June 30, 2012 and 2011, respectively.

**e) Employee Stock Option Plan:**

The Company had a 1999 Stock Option Plan ("SOP"). The total number of options available under the SOP was 375,000. As of June 30, 2012, there were 159,438 outstanding options under this SOP. No additional options may be issued under the SOP because it is more than 10 years after its adoption.

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

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), initially available 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 June 30, 2012, there were 53,333 options exercised, 539,254 options outstanding and 157,413 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-month periods ended June 30, 2012 and 2011 was none and \$.72 per share, respectively. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six-month periods ended June 30, 2012 and 2011 was \$2.80 and \$.72 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 determined using the simplified method as permitted by SAB 107, as the Company has limited history of employee exercise of options to date.

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

	<b>For the three months ended</b>		<b>For the six months ended</b>	
	<b>June 30, 2012</b>	<b>June 30, 2011</b>	<b>June 30, 2012</b>	<b>June 30, 2011</b>
<b>Expected term (in years)</b>	n/a	3.75	5	3.75
<b>Expected volatility</b>	n/a	92.11%	115.77%	92.11%
<b>Expected dividend yield</b>	n/a	n/a	0%	n/a
<b>Risk-free interest rate</b>	n/a	1.39%	0.36%	1.39%

The Company's results for the three-month periods ended June 30, 2012 and 2011 include share-based compensation expense totaling \$44,000 and \$29,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$5,000 and \$3,000, respectively), research and development (\$9,000 and \$14,000, respectively) and selling, general and administrative expenses (\$30,000 and \$12,000, respectively). The Company's results for the six-month periods ended June 30, 2012 and 2011 include share-based compensation expense totaling \$177,000 and \$56,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$20,000 and \$6,000, respectively), research and development (\$57,000 and \$26,000, respectively) and selling, general and administrative expenses (\$100,000 and \$24,000, 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 six-month periods ended June 30, 2012 and 2011 represents the estimated fair value 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**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 2012**  
**(UNAUDITED)**

The following table provides stock option activity for the six months ended June 30, 2012:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Outstanding at December 31, 2011</b>	<b>765,901</b>	<b>\$ 1.68</b>	<b>2.61 years</b>	<b>\$ 1,339,693</b>
Granted	25,391	\$ 4.00		
Exercised	(73,958)	\$ 1.04		
Forfeited/expired/cancelled	(18,625)	\$ 3.86		
<b>Outstanding at June 30, 2012</b>	<b>698,709</b>	<b>\$ 1.80</b>	<b>2.39 years</b>	<b>\$ 1,907,476</b>
<b>Exercisable at June 30, 2012</b>	<b>530,571</b>	<b>\$ 1.38</b>	<b>1.97 years</b>	<b>\$ 1,671,299</b>

As of June 30, 2012, there was \$192,000 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 1.4 years. The total fair value of stock options vested during the six-month periods ended June 30, 2012 and 2011 was approximately \$206,000 and \$100,000, 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 six months ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
<b>Africa</b>	<b>\$ 442,833</b>	<b>\$ 280,126</b>	<b>\$ 1,520,569</b>	<b>\$ 1,092,971</b>
<b>Asia</b>	<b>254,003</b>	<b>57,506</b>	<b>266,481</b>	<b>93,624</b>
<b>Europe</b>	<b>7,753</b>	<b>4,260</b>	<b>33,331</b>	<b>42,320</b>
<b>North America</b>	<b>2,545,376</b>	<b>1,734,475</b>	<b>5,266,136</b>	<b>3,808,612</b>
<b>South America</b>	<b>2,561,225</b>	<b>898,012</b>	<b>5,087,825</b>	<b>951,915</b>
	<b>\$ 5,811,190</b>	<b>\$ 2,974,379</b>	<b>\$ 12,174,342</b>	<b>\$ 5,989,442</b>

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

**g) Accounts Payable and Accrued Liabilities**

Accounts payable and accrued liabilities consist of:

	June 30, 2012	December 31, 2011
Accounts payable – suppliers	\$ 1,186,841	\$ 1,258,465
Accrued commissions	231,350	205,588
Accrued royalties / license fees	389,642	480,297
Accrued payroll	190,526	174,398
Accrued vacation	213,506	156,884
Accrued bonuses	289,000	284,375
Accrued expenses – other	139,402	229,493
<b>TOTAL</b>	<b>\$ 2,640,267</b>	<b>\$ 2,789,500</b>

During the first quarter of 2012, the Company received an invoice related to ongoing clinical trials which included the costs associated with certain patients that were seen in 2011. This resulted in an additional \$191,000 research and development charge in the first quarter that should have been recorded in the quarter ended December 31, 2011, had the Company been aware of the services rendered. In accordance with the Securities and Exchange Commission Staff Accounting Bulletin No. 108 (SAB 108), the Company has determined this error to be immaterial, from both a quantitative and qualitative perspective, and has therefore chosen to record this charge in the first quarter of 2012 and not restate the applicable previously filed financial statements.

**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 \$363,000 and \$369,000 for the six-month periods ended June 30, 2012 and 2011, respectively from this grant. The Company earned an aggregate of \$2,800,000 from this grant from inception through June 30, 2012, of which \$850,000 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 \$252,000 and \$149,000 for the six-month periods ended June 30, 2012 and 2011, respectively from this grant. The Company earned \$904,000 from this grant from inception through June 30, 2012 of which \$302,000 was paid to sub-contractors.

**b) Battelle/CDC DPP® Influenza Immunity Test:**

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

**NOTE 4 — LOANS PAYABLE:**

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

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

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

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

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

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

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

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of June 30, 2012 was \$158,000 and as of June 30, 2012 nothing had been drawn down on the Demand or Equipment Note.

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

Periods ending June 30,

2013	\$	49,850
2014		52,662
2015		55,555
		<u>158,067</u>
Less: current maturities		<u>(49,850)</u>
	\$	<u>108,217</u>

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

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**NOTE 5 — RIGHTS AGREEMENT:**

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

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

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

**NOTE 6 — COMMON STOCK, WARRANTS AND OPTIONS:**

On March 19, 2012 and June 18, 2012, the Company issued 938 shares of common stock on each date to a consultant as part of the consultant's compensation. As long as the consultant continues with the Company, the consultant will receive two more tranches of 938 shares every three months for the following six months. In addition 3,750 options to purchase common stock were issued to the consultant as part of its compensation. The options vest in four equal installments starting three months from the issue date and every three months for the following nine months. These options were valued using a Black-Scholes model at \$8,570, of which \$5,246 and \$6,734 was expensed in the three- and six-month periods, respectively, ended June 30, 2012. The options are being accounted for under the variable method as per ITF-96-18 and \$272 of the expense was attributable to this method.

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

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

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**NOTE 7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:**

**a) Economic Dependency:**

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

	For the three months ended				For the six months ended				Accounts Receivable
	June 30, 2012		June 30, 2011		June 30, 2012		June 30, 2011		As of
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	June 30, 2012
Customer 1	\$ 2,144,051	37	\$ 1,419,261	48	\$ 4,592,906	38	\$ 3,474,471	58	\$ 616,969
Customer 2	2,383,025	41	872,734	29	4,899,025	40	923,845	15	597,987

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

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

	For the three months ended				For the six months ended				Accounts Payable
	June 30, 2012		June 30, 2011		June 30, 2012		June 30, 2011		As of
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	June 30, 2012
Vendor 1	\$ 231,043	13	*	*	\$ 408,679	13	\$ 258,300	11	\$ 67,945
Vendor 2	237,550	13	174,952	11	378,204	12	251,869	11	60,755

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

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**NOTE      8 — INCOME TAXES:**

During 2011, the Company reversed its valuation allowance, in regard to net operating loss (NOL) carry forwards, previously recorded against its deferred tax assets. As such the Company now records an income tax expense (benefit) for income (loss) for periods starting after December 31, 2011. The Company's interim provision for income taxes is measured using an estimated annual effective tax rate, or 39.7%. As per IRS rules, only 90% of the loss can be offset by NOLs, and therefore 3.97%, or \$48,853, was added to accrued expenses, 39.7%, or \$488,530, was expensed, and the balance of 35.73%, or \$439,677, reduced the carrying value of the deferred tax asset for the six months ended June 30, 2012.

## 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 other than as stated in Note 2 (b), have not changed significantly from December 31, 2011.

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

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

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

During the first six months of 2012, the Company had a total of \$2,358,174 of research and development expenses as compared with \$2,455,014 during the first six months of 2011.

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

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

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

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

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

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

Building on these development milestones, we recently received proprietary antigens that we will employ in a feasibility study to determine whether and to what extent these proprietary materials can improve the performance as compared to the above-referenced first generation test and competitive products. If we can improve the performance, we would proceed with a full development program, and we could complete development and commence clinical trials before the end of 2013.

In May the U.S. Centers for Disease Control published for public comment draft recommendations for testing all individuals in the United States between the ages of 45 and 65, which age cohort represents a substantial portion of the estimated over three million individuals in the United States that are infected with HCV infection but unaware. With a number of new anti-retroviral therapies approved or pending approval by the FDA, we believe that over time these new recommendations will be implemented. However this will take time, similar to the implementation of the new HIV testing recommendations issued in 2006.

**DPP® Syphilis/HIV Combination Test** – We have developed a combination Syphilis and HIV test and we are considering various opportunities with respect to this product for the international market at least. This is an example of the multiplexing capabilities that we expect to drive the Company’s revenues and growth. We may manufacture this product as a Chembio-branded product and/or as a component for final assembly in other markets where we are considering collaborations. We believe there are opportunities for this product in donor-funded pre-natal testing programs aimed at the prevention of mother-to-child transmission, and potentially additional markets as well.

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



**DPP® Leptospirosis** – In the second quarter of 2012, our work under the three-year \$2.8 million Small Business Innovative Research (SBIR) Phase II grant we were awarded in 2009 by the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide was completed. The test was developed with our DPP® technology and utilizes proprietary reagents developed by Yale University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. The test was developed in collaboration with the Division of Infectious Diseases, Yale University in New Haven, CT and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America.

In a large clinical evaluation study performed in Brazil, the DPP Leptospirosis test was demonstrated to have equal or better performance characteristics than IgM ELISA or the microagglutination test (MAT), the gold standard methods for detection of leptospirosis. In June 2012, the results of this work were submitted for publication.

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

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

## **Regulatory Activities**

**CE Mark for FDA-approved HIV tests** – As previously reported, we chose an alternative strategy for the CE Marking of our two FDA-approved lateral flow tests, and eventually our DPP® test. We remain on schedule to have both a) our submission file reviewed and b) the inspection completed by the notified body before year-end 2012.

**FDA Approval for DPP® HIV 1/2 Screening Assay for Use with oral fluid or blood samples** - We began submitting the PMA (Pre-Marketing Approval) application to the FDA using the Modular PMA option, and we have now submitted all three Modules: Module I containing manufacturing information; Module II containing non-clinical data, and Module III which contains the results of the 3,000 patient clinical trial we conducted during 2010-2012 at a cost of approximately \$2.5 million. We are confident that all three modules support product design and performance that will meet or exceed the requirement for a PMA approval on oral fluid, finger-stick whole blood, venous whole blood, serum and plasma samples. We anticipate an FDA approval, or at least an approvable PMA decision, before year-end 2012. We would then immediately apply for a CLIA waiver which, based upon new CLIA guidance, is expected to take approximately six months to be granted.

**DPP® Syphilis Screen & Confirm** - During the current quarter, we made progress in initiating studies and developing strategies to support a *De Novo* FDA 510(K) clearance regulatory pathway for the product, and expect to have clarity on this during the fourth quarter, so that we can re-initiate clinical trials and submit our 510(k) application by the middle of 2013. We also believe that the results of the study performed last year in China will be submitted for publication soon.

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

In June 2012, our product was presented at a conference in the United Kingdom, where we have established distribution, and we have received some small orders to date.

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

**SURE CHECK® HIV OTC Study** - We have made progress toward completing the requirements for submitting an IDE (“Investigational Device Exemption”) application to the FDA in order to commence clinical trials for this product in 2013.

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

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

Given this low performance threshold, we believe we are therefore very well positioned with our SURE CHECK® HIV 1/2 blood test, for the following reasons:

- We believe that the development of this market will take time, and that its development will likely require OraSure to invest significantly in its development.
- Chembio is the only other company that for all practical purposes has a product, let alone multiple products, that can participate in this new market.
- OraSure’s product was approved with lower sensitivity than was previously expected by the FDA, thereby providing an opportunity for Chembio’s product(s) to achieve improved performance - with its blood and/or oral fluid HIV tests.
- Chembio’s SURE CHECK® HIV 1/2 is a simple blood test that is easy to use.

During the third and fourth quarters we will complete the untrained user study with a plan toward submitting the IDE to the FDA and it being granted before the end of 2012. The exemption must be granted in order to begin clinical studies that would be necessary to gain FDA approval of this product, which approval could take two or three years from the time that we initiate such clinical studies.

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

## **Recent Events**

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

## **Critical Accounting Policies and Estimates**

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

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

**Revenues:**

**Selected Product Categories:**

	For the three months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
<b>Lateral Flow HIV Tests and Components</b>	\$ 3,159,657	\$ 2,044,223	\$ 1,115,434	54.57%
<b>DPP Tests and Components</b>	2,226,200	848,035	1,378,165	162.51%
<b>Other</b>	425,333	82,121	343,212	417.93%
<b>Net Product Sales</b>	<b>5,811,190</b>	<b>2,974,379</b>	<b>2,836,811</b>	<b>95.37%</b>
<b>License and royalty revenue</b>	-	71,468	(71,468)	-100.00%
<b>R&amp;D, milestone and grant revenue</b>	272,701	568,304	(295,603)	-52.01%
<b>Total Revenues</b>	<b>\$ 6,083,891</b>	<b>\$ 3,614,151</b>	<b>\$ 2,469,740</b>	<b>68.34%</b>

Revenues for our lateral flow HIV tests and related components during the three months ended June 30, 2012 increased by approximately \$1,115,000 over the same period in 2011. This was primarily attributable to increased sales to Alere from \$1,419,000 during the three months ended June 30, 2011 to \$2,144,000 during the three months ended June 30, 2012, an increase of \$725,000, or 51%; increased sales to Asia of \$196,000; and increased sales to Africa of \$163,000; as well as increased sales to North America (other than Alere) of \$86,000. Revenues for our DPP® products during the three months ended June 30, 2012 increased by approximately \$1,378,000 over the same period in 2011, which is attributable to the launch of our DPP® products that were approved in Brazil during 2010 and 2011. The decrease in R&D, milestone and grant revenue was due to revenue from milestones and certain development projects in the 2011 second quarter that were not repeated. License and royalty revenue in 2011 is from royalties from Brazil under our 2004 technology transfer and license agreement, which ended prior to April 1, 2012.

**Gross Margin:**

**Gross Margin related to Net Product Sales:**

	For the three months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
<b>Gross Margin per Statement of Operations</b>	\$ 2,570,624	\$ 2,050,278	\$ 520,346	25.38%
<b>Less: R&amp;D, milestone, grant, license and royalties</b>	272,701	639,772	(367,071)	-57.38%
<b>Gross Margin from Net Product Sales</b>	<b>\$ 2,297,923</b>	<b>\$ 1,410,506</b>	<b>\$ 887,417</b>	<b>62.91%</b>
<b>Gross Margin %</b>	<b>39.54%</b>	<b>47.42%</b>		

The decrease in our product gross margin percentage was primarily due to increased costs in scrap, incoming freight and other costs together with a change in the product sale mix. Although sales to Alere increased, it decreased as a percentage of overall sales from 48% to 37%. Partially offsetting these increased costs was an increase in our DPP® products sold in Brazil which are at a higher margin than other products we sell. DPP® sales represented approximately 38% of sales in the three months ended June 30, 2012 as compared to approximately 28% in the three months ended June 30, 2011.

**Research and Development:**

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

**Selected expense lines:**

	For the three months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
<b><u>Clinical and Regulatory Affairs:</u></b>				
Wages and related costs	\$ 125,956	\$ 111,648	\$ 14,308	12.82%
Consulting	5,081	-	5,081	100.00%
Stock-based compensation	5,268	4,715	553	11.73%
Clinical trials	71,845	282,104	(210,259)	-74.53%
Other	19,517	8,322	11,195	134.52%
<b>Total Regulatory</b>	<b>227,667</b>	<b>406,789</b>	<b>(179,122)</b>	<b>-44.03%</b>
<b><u>R&amp;D Other than Regulatory:</u></b>				
Wages and related costs	467,570	502,066	(34,496)	-6.87%
Consulting	43,362	47,808	(4,446)	-9.30%
Stock-based compensation	3,080	9,104	(6,024)	-66.17%
Materials and supplies	161,305	134,187	27,118	20.21%
Other	76,060	64,918	11,142	17.16%
<b>Total other than Regulatory</b>	<b>751,377</b>	<b>758,083</b>	<b>(6,706)</b>	<b>-0.88%</b>
<b>Total Research and Development</b>	<b>\$ 979,044</b>	<b>\$ 1,164,872</b>	<b>\$ (185,828)</b>	<b>-15.95%</b>

Expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2012 decreased by \$179,000 as compared to the same period in 2011. This was primarily due to the reduction of \$210,000 in clinical trial expenses which were completed in 2012 for clinical trials primarily conducted for our DPP® HIV Screen Assay.

R&D expenses other than Clinical & Regulatory Affairs decreased by \$7,000 in the three months ended June 30, 2012 as compared with the same period in 2011 and were primarily related to a decrease in wages and related costs, including stock-based compensation and material partially offset by an increase in materials and supplies.

**Selling, General and Administrative Expenses:****Selected expense lines:**

	For the three months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
Wages and related costs	\$ 358,167	\$ 251,041	\$ 107,126	42.67%
Consulting	105,432	54,600	50,832	93.10%
Commissions	275,745	119,574	156,171	130.61%
Stock-based compensation	30,078	12,219	17,859	146.16%
Marketing materials	15,710	14,738	972	6.60%
Investor relations/investment bankers	73,769	44,083	29,686	67.34%
Legal, accounting and compliance	133,523	56,769	76,754	135.20%
Travel, entertainment and trade shows	37,213	11,502	25,711	223.54%
Bad debt allowance (recovery)	(95,000)	-	(95,000)	100.00%
Other	144,564	123,733	20,831	16.84%
<b>Total S, G &amp; A</b>	<b>\$ 1,079,201</b>	<b>\$ 688,259</b>	<b>\$ 390,942</b>	<b>56.80%</b>

Selling, general and administrative expenses for the three months ended June 30, 2012, increased by \$391,000 as compared with the same period in 2011. The primary factor of this increase was a \$156,000 increase in commissions due to increased sales to Brazil, partially offset by a decrease in bad debt allowance of \$95,000 due to collection of a previously reserved amount from a customer in the second quarter of 2012. The following expense categories experienced an increase of greater than \$50,000, which also contributed to the overall increase: wages and related expenses (partially as a result of accruing year-end bonuses on a quarterly basis), consulting (for sales and marketing) and professional fees (in regards to the stock split and moving to the NASDAQ exchange).

**Other Income and (Expense):**

	For the three months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
Interest income	\$ 1,598	\$ 1,726	\$ (128)	-7.42%
Interest expense	(2,317)	(4,034)	1,717	-42.56%
<b>Total Other Income and (Expense)</b>	<b>\$ (719)</b>	<b>\$ (2,308)</b>	<b>\$ 1,589</b>	<b>-68.85%</b>

Other expense for the three months ended June 30, 2012 decreased approximately \$1,600, to \$719 from \$2,308 as compared with the same period in 2011, primarily as a result of a decrease in interest expense due to the term loan with HSBC.

**RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2012 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2011**
**Revenues:****Selected Product Categories:**

	For the six months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
Lateral Flow HIV Tests and Components	\$ 6,927,593	\$ 4,935,302	\$ 1,992,291	40.37%
DPP Tests and Components	4,652,200	899,035	3,753,165	417.47%
Other	594,549	155,105	439,444	283.32%
<b>Net Product Sales</b>	<b>12,174,342</b>	<b>5,989,442</b>	<b>6,184,900</b>	<b>103.26%</b>
License and royalty revenue	-	100,322	(100,322)	-100.00%
R&D, milestone and grant revenue	562,801	1,160,068	(597,267)	-51.49%
<b>Total Revenues</b>	<b>\$ 12,737,143</b>	<b>\$ 7,249,832</b>	<b>\$ 5,487,311</b>	<b>75.69%</b>

Revenues for our lateral flow HIV tests and related components during the six months ended June 30, 2012 increased by approximately \$1,992,000 over the same period in 2011. This was primarily attributable to increased sales to Alere from \$3,474,000 during the first six months of 2011 to \$4,593,000 during the six months ended June 30, 2012, an increase of \$1,118,000, or 32%, increased sales to Asia of \$173,000 and increased sales to Africa of \$428,000, as well as increased sales to North America (other than Alere) of \$339,000. Revenues for our DPP® products during the six months ended June 30, 2012 increased by approximately \$3,753,000 over the same period in 2011, which is attributable to the launch of our DPP® products that were approved in Brazil during 2010 and 2011. The decrease in R&D, milestone and grant revenue was due to revenue from milestones and certain development projects in the first half of 2011, which were not repeated. License and royalty revenue in 2011 is from royalties from Brazil under our 2004 technology transfer and license agreement, which ended prior to January 1, 2012.

**Gross Margin:**
**Gross Margin related to Net Product Sales:**

	For the six months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 5,903,487	\$ 3,976,620	\$ 1,926,867	48.45%
Less: R&D, milestone, grant, license and royalties	562,801	1,260,390	(697,589)	-55.35%
<b>Gross Margin from Net Product Sales</b>	<b>\$ 5,340,686</b>	<b>\$ 2,716,230</b>	<b>\$ 2,624,456</b>	<b>96.62%</b>
<b>Gross Margin %</b>	<b>43.87%</b>	<b>45.35%</b>		

The decrease in our product gross margin percentage was primarily due to increased costs in scrap, incoming freight and other costs along with a change in the product sale mix. Part of the sales mix difference was due to sales to Alere, which are at higher margins, representing a smaller percentage of the overall product sales from 58% to 38%, partially offsetting these increased costs was an increase in our DPP® products sold in Brazil, which are at slightly higher margins than other products we sell. The increased sales to Asia and Africa were at lower margins. DPP® sales represented approximately 38% of sales in the six months ended June 30, 2012 as compared to approximately 15% in the six months ended June 30, 2011.

**Research and Development:**

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

**Selected expense lines:**

	For the six months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
<b><u>Clinical and Regulatory Affairs:</u></b>				
Wages and related costs	\$ 249,681	\$ 224,668	\$ 25,013	11.13%
Consulting	9,331	-	9,331	100.00%
Stock-based compensation	20,692	6,836	13,856	202.69%
Clinical trials	555,534	734,168	(178,634)	-24.33%
Other	32,718	27,218	5,500	20.21%
<b>Total Regulatory</b>	<b>867,956</b>	<b>992,890</b>	<b>(124,934)</b>	<b>-12.58%</b>
<b><u>R&amp;D Other than Regulatory:</u></b>				
Wages and related costs	939,495	977,343	(37,848)	-3.87%
Consulting	48,362	48,308	54	0.11%
Stock-based compensation	36,247	19,422	16,825	86.63%
Materials and supplies	316,513	293,036	23,477	8.01%
Other	149,601	124,015	25,586	20.63%
<b>Total other than Regulatory</b>	<b>1,490,218</b>	<b>1,462,124</b>	<b>28,094</b>	<b>1.92%</b>
<b>Total Research and Development</b>	<b>\$ 2,358,174</b>	<b>\$ 2,455,014</b>	<b>\$ (96,840)</b>	<b>-3.94%</b>

Expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2012 decreased by \$125,000 as compared to the same period in 2011. This was primarily due to approximately \$179,000 of expenses in 2011 for clinical trials primarily conducted for our DPP® HIV Screen Assay, which was completed in early 2012. This was partially offset by increased costs of wages and related costs, consulting and stock-based compensation.

R&D expenses other than Clinical & Regulatory Affairs increased by \$28,000 in the six months ended June 30, 2012 as compared with the same period in 2011 and were primarily related to an increase in material and supplies along with an increase in stock-based compensation which were partially offset by a decrease in wages and related costs.

**Selling, General and Administrative Expenses:****Selected expense lines:**

	For the six months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
Wages and related costs	\$ 714,836	\$ 520,439	\$ 194,397	37.35%
Consulting	169,001	92,171	76,830	83.36%
Commissions	565,239	185,226	380,013	205.16%
Stock-based compensation	100,383	23,768	76,615	322.35%
Marketing materials	26,168	15,472	10,696	69.13%
Investor relations/investment bankers	120,017	95,113	24,904	26.18%
Legal, accounting and compliance	291,700	239,669	52,031	21.71%
Travel, entertainment and trade shows	64,289	23,945	40,344	168.49%
Bad debt allowance (recovery)	-	(15,000)	15,000	-100.00%
Other	261,536	282,827	(21,291)	-7.53%
<b>Total S, G &amp; A</b>	<b>\$ 2,313,169</b>	<b>\$ 1,463,630</b>	<b>\$ 849,539</b>	<b>58.04%</b>

Selling, general and administrative expenses for the six months ended June 30, 2012, increased by \$850,000 as compared with the same period in 2011. The primary factor of this increase was commissions of \$380,000 due to increased sales to Brazil as well as an increase in wages and related expenses of \$194,000 (partially as a result of accruing year-end bonuses on a quarterly basis), an increase of \$77,000 in each of stock-based compensation and consulting, an increase of \$52,000 in professional fees, and an increase of \$35,000 in investor relations.

**Other Income and (Expense):**

	For the six months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
Interest income	\$ 3,117	\$ 3,036	\$ 81	2.67%
Interest expense	(4,758)	(8,470)	3,712	-43.83%
<b>Total Other Income and (Expense)</b>	<b>\$ (1,641)</b>	<b>\$ (5,434)</b>	<b>\$ 3,793</b>	<b>-69.80%</b>

Other expense for the six months ended June 30, 2012 decreased approximately \$3,800, to \$1,641 from \$5,434 as compared with the same period in 2011, primarily as a result of a decrease in interest expense due to the term loan with HSBC as well as an increase in interest income due to an increase in cash in interest-bearing accounts.

**Income Taxes:**

During 2011, the Company reversed its valuation allowance, in regard to net operating loss (NOL) carry forwards, previously recorded against its deferred tax assets. As such the Company now records an income tax expense (benefit) for income (loss) for periods starting after December 31, 2011. The Company's interim provision for income taxes is measured using an estimated annual effective tax rate, or 39.7%. As per IRS rules, only 90% of the loss can be offset by NOLs, and therefore, 3.97%, or \$48,853, was added to accrued expenses, 39.7%, or \$488,530, was expensed, and the balance of 35.73%, or \$439,677, reduced the carrying value of the deferred tax asset.

**MATERIAL CHANGES IN FINANCIAL CONDITION**

Selected Changes in Financial Condition	As of		\$ Change	% Change
	June 30, 2012	December 31, 2011		
Cash and cash equivalents	\$ 4,390,041	\$ 3,010,954	\$ 1,379,087	45.80%
Accounts receivable, net of allowance for doubtful accounts of \$30,000 at June 30, 2012 and December 31, 2011	2,215,477	2,998,449	(782,972)	-26.11%
Inventories	3,141,322	2,300,286	841,036	36.56%
Prepaid expenses and other current assets	736,458	681,893	54,565	8.00%
Deposits on manufacturing equipment	285,495	139,790	145,705	104.23%
Accounts payable and accrued liabilities	2,640,267	2,789,500	(149,233)	-5.35%

Cash increased by \$1,379,000 from December 31, 2011, primarily due to net income, net of non-cash items, of \$1,630,000 together with the decrease of accounts receivable by \$783,000 and an increase in customer deposits of \$416,000, which was partially offset by an increase in inventories of \$841,000, an increase in fixed assets and deposits of \$448,000 (see table below), decrease in accrued expenses and payables of \$149,000 and an increase in prepaid assets of \$55,000.

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

## LIQUIDITY AND CAPITAL RESOURCES

	For the six months ended			
	June 30, 2012	June 30, 2011	\$ Change	% Change
Net cash provided by operating activities	\$ 1,785,354	\$ 926,164	\$ 859,190	92.77%
Net cash used in investing activities	(447,621)	(288,402)	(159,219)	55.21%
Net cash provided by (used in) financing activities	41,354	(634,784)	676,138	-106.51%
INCREASE IN CASH AND CASH EQUIVALENTS	<u>\$ 1,379,087</u>	<u>\$ 2,978</u>	<u>\$ 1,376,109</u>	<u>46209.17%</u>

The Company's cash increased for the six months ended June 30, 2012 by \$1,379,000 as compared to an increase in cash for the same period in 2011 of \$3,000. The increase in the 2012 period is enumerated above under Material Changes in Financial Condition. The increase during the 2011 period are primarily attributable to the change in receivables of \$2.32 million, along with non-cash expenses aggregating \$258,000 partially offset by a decrease in accruals and payables of \$60,000, decrease in deferred revenue of \$65,000, decrease in other assets of \$10,000 and an increase in inventories of \$1,568,000. The increase in the 2012 period includes non-cash items from the change in deferred tax assets of \$440,000. The Company's other non-cash expenses totaled \$449,000, which consisted of \$270,000 from depreciation and amortization expense and \$179,000 in share-based compensation expense.

### Fixed Asset Commitments

As of June 30, 2012, the Company had paid deposits on various pieces of equipment aggregating \$285,495, which is reflected in Other Assets on the balance sheet. The Company is further committed to additional equipment-purchase obligation of \$95,685 as various milestones are achieved by the various vendors.



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

In the quarter ended June 30, 2012, Chembio experienced strong growth in revenues, and operating income. As compared to the comparable period in 2011, revenues increased 68.3% to \$6.08MM, and operating income increased 159.9% to \$.51MM. The increased product revenues were based on strong shipments of the DPP® products being supplied to Ministry of Health programs in Brazil by our partner in Brazil, FIOCRUZ, as well as on substantial growth in our product revenues from Alere. We had strong cash flows, increasing our cash balance to nearly \$4.4MM, a \$1.38MM year-to-date increase. Gross margin was negatively impacted by some manufacturing inefficiencies and scrap.

As we announced during the second quarter, the 3,000 patient study we commenced in 2010 in support of a Pre-Marketing Application approval for our DPP® HIV Screening Assay for use with oral fluid or blood samples was completed in April, and in June we submitted the third and final module of the PMA to the FDA. We anticipate an approved PMA application by the end of the year.

The Company has a number of new product opportunities in addition to the aforementioned oral fluid HIV test that is pending before the FDA. These new products, if successfully developed and commercialized, could result in new revenue streams in future periods. These new products include our proprietary Sure Check HIV 1/2 test that is already approved in the United States professional market, and for which we are submitting an Investigational Device Exemption this year to pursue FDA approval for home use. Furthermore we are making good progress with our point-of-care tests for Syphilis and Hepatitis-C. Finally we are working on a number of new potential projects based on our patented DPP® point-of-care technology and in some cases conducting feasibility studies. These include potential products with application to the areas of women's health, veterinary diagnostics, and blood viruses. We believe that these projects can ultimately result in potential new revenue streams in future periods, although there can be no assurance of this.

In the meantime, based on substantially increased revenues that are anticipated this year from our DPP® OEM products with FIOCRUZ in Brazil, combined with even modest growth in the U.S. rapid HIV test market and/or our market share with our FDA-approved rapid HIV tests marketed by Alere, as well as possible gains from existing and/or new international distributors for our lateral flow and DPP® products, we anticipate strong improvements to our revenues, net income and cash flows in 2012.

## ITEM 4. CONTROLS AND PROCEDURES

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

## PART II. OTHER INFORMATION

## ITEM 6. EXHIBITS

## EXHIBITS INDEX

Number	Description
3.1	Articles of Incorporation, as amended. (1)
3.2	Amended and Restated Bylaws. (2)
4.1*	Form of Employee Option Agreement. (3)
4.2	1999 Equity Incentive Plan. (4)
4.3	2008 Stock Incentive Plan. (5)
4.4	Rights Agreement, dated March 8, 2010 (6)
4.5	Form of Warrant (to be filed by amendment) [to be revised]
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (7)
10.2*	Employment Agreement dated March 5, 2010 with Javan Esfandiari. (8)
10.3	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (9)
10.4	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9)
10.5	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9)
10.6	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (9)
10.7	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.8	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.9	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.10	Revolving Term Note, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
10.11	Loan and Security Agreement, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
14.1	Ethics Policy (12)
21	List of Subsidiaries
23.1	Consent of BDO USA, LLP, Independent Registered Public Accountants.
23.2	Consent of ParenteBeard LLC, Independent Registered Public Accountants.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document
1	Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.
2	Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
3	Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
4	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
5	Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
6	Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
7	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
8	Incorporated by reference to the Registrant's registration statement on Form S-1/A filed with the Commission on March 11, 2010.
9	Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
10	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
11	Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 3, 2011.
12	Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 30, 2006.
(*)	An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this document.

## SIGNATURES

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

Chembio Diagnostics, Inc.

Date: August 9, 2012      By: /s/ Lawrence A. Siebert  
\_\_\_\_\_  
Lawrence A. Siebert  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 9, 2012      By: /s / Richard J. Larkin  
\_\_\_\_\_  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)

**CERTIFICATION**

I, Lawrence A. Siebert, certify that:

1. I have reviewed this Form 10-Q of Chembio Diagnostics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2012      /s/ Lawrence A. Siebert  
Lawrence A. Siebert, Chief Executive Officer

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**CERTIFICATION**

I, Richard J. Larkin, certify that:

1. I have reviewed this Form 10-Q of Chembio Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2012

/s/ Richard J. Larkin

Richard J. Larkin, Chief Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q (the "Report") of Chembio Diagnostics, Inc. (the "Company") for the quarter ended June 30, 2012, each of the undersigned Lawrence A. Siebert, the Chief Executive Officer of the Company, and Richard J. Larkin, the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of the undersigned's knowledge and belief:

(1) This Form 10-Q for the quarter ended June 30, 2012 fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Form 10-Q for the quarter ended June 30, 2012 fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the periods presented therein.

Dated: August 9, 2012

/s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer

Dated: August 9, 2012

/s/ Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer

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