

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

May 05, 2011

---

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 March 31, 2011

OR

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

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

000-30379

(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

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

3661 Horseblock Road  
Medford, New York 11763

(Address of principal executive offices including zip code)

(631) 924-1135

(Registrant's telephone number, including area code)

\_\_\_\_N/A\_\_\_\_

(Former Name or Former Address, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

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

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

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 May 4, 2010, the Registrant had 63,178,763 shares outstanding of its \$.01 par value common stock.

---

---

Quarterly Report on FORM 10-Q For The Period Ended

March 31, 2011

Table of Contents

Chembio Diagnostics, Inc.

	Page
Part I. FINANCIAL INFORMATION:	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of March 31, 2011 (unaudited) and December 31, 2010.	2
Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2011 and 2010.	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2011 and 2010.	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5 to 12
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 4. Controls and Procedures	19
Part II. OTHER INFORMATION:	
Exhibits	20
SIGNATURES	21
EXHIBITS	

## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	March 31, 2011 (UNAUDITED)	December 31, 2010
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 2,797,103	\$ 2,136,351
Accounts receivable, net of allowance for doubtful accounts of \$20,000 and \$35,000 for 2011 and 2010, respectively	1,726,517	3,946,398
Inventories	1,592,070	1,349,161
Prepaid expenses and other current assets	175,814	204,824
<b>TOTAL CURRENT ASSETS</b>	<b>6,291,504</b>	<b>7,636,734</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>		
	772,290	813,214
<b>OTHER ASSETS:</b>		
License agreements, net of current portion	575,000	600,000
Deposits and other assets	36,226	36,226
<b>TOTAL ASSETS</b>	<b>\$ 7,675,020</b>	<b>\$ 9,086,174</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 1,612,540	\$ 2,055,943
Current portion of loans payable	56,523	55,817
Deferred research and development revenue	65,000	65,000
License fee payable	-	875,000
Current portion of obligations under capital leases	25,557	24,697
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,759,620</b>	<b>3,076,457</b>
<b>OTHER LIABILITIES:</b>		
Loans payable - net of current portion	171,799	186,197
Obligations under capital leases - net of current portion	7,855	14,576

TOTAL LIABILITIES	1,939,274	3,277,230
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 62,550,065 and 61,996,151 shares issued and outstanding for 2011 and 2010, respectively	625,501	622,390
Additional paid-in capital	39,724,605	39,658,617
Accumulated deficit	(34,614,360 )	(34,472,063 )
TOTAL STOCKHOLDERS' EQUITY	5,735,746	5,808,944
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 7,675,020	\$ 9,086,174
See accompanying notes to condensed consolidated financial statements		

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE THREE MONTHS ENDED  
(UNAUDITED)

	March 31, 2011	March 31, 2010
<b>REVENUES:</b>		
Net product sales	\$ 3,015,063	\$ 2,214,897
License and royalty revenue	28,854	21,496
R&D, milestone and grant revenue	591,764	547,022
<b>TOTAL REVENUES</b>	<b>3,635,681</b>	<b>2,783,415</b>
 Cost of product sales	 1,709,339	 1,477,041
 <b>GROSS MARGIN</b>	 <b>1,926,342</b>	 <b>1,306,374</b>
<b>OPERATING EXPENSES:</b>		
Research and development expenses	1,290,142	800,758
Selling, general and administrative expenses	775,371	661,848
	2,065,513	1,462,606
<b>LOSS FROM OPERATIONS</b>	<b>(139,171 )</b>	<b>(156,232 )</b>
<b>OTHER INCOME (EXPENSES):</b>		
Interest income	1,310	1,110
Interest expense	(4,436 )	(2,204 )
	(3,126 )	(1,094 )
<b>LOSS BEFORE INCOME TAXES</b>	<b>(142,297 )</b>	<b>(157,326 )</b>
Provision for income taxes	-	-
<b>NET LOSS</b>	<b>\$ (142,297 )</b>	<b>\$ (157,326 )</b>
Basic and diluted loss per share	\$ (0.00 )	\$ (0.00 )
Weighted average number of shares outstanding, basic and diluted	62,284,772	61,986,165

See accompanying notes to condensed consolidated financial statements

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

March 31, 2011

March 31, 2010

INCREASE (DECREASE) IN  
CASH AND CASH  
EQUIVALENTS:

CASH FLOWS FROM  
OPERATING ACTIVITIES:

Cash received from customers	\$	5,855,562	\$	3,381,234
Cash paid to suppliers and employees		(4,292,294 )		(3,572,214 )
Interest received		1,310		1,110
Interest paid		(4,436 )		(2,204 )
Net cash provided by (used in) operating activities		1,560,142		(192,074 )

CASH FLOWS FROM INVESTING  
ACTIVITIES:

Acquisition of fixed assets		(46,358 )		(72,866 )
Net cash used in investing activities		(46,358 )		(72,866 )

CASH FLOWS FROM  
FINANCING ACTIVITIES:

Proceeds from option exercises		41,521		2,112
Payment of loan and license obligation		(888,692 )		(2,373 )
Payment of capital lease obligation		(5,861 )		(5,111 )
Net cash used in financing activities		(853,032 )		(5,372 )

INCREASE (DECREASE) IN  
CASH AND CASH  
EQUIVALENTS

		660,752		(270,312 )
Cash and cash equivalents - beginning of the period		2,136,351		1,068,235

Cash and cash equivalents - end of  
the period

	\$	2,797,103	\$	797,923
--	----	-----------	----	---------

RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY  
OPERATING ACTIVITIES:

Net loss	\$	(142,297 )	\$	(157,326 )
Adjustments:				
Depreciation and amortization		87,282		79,628
Provision for doubtful accounts		(15,000 )		-

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Share based compensation	27,578	75,150
Changes in assets and liabilities:		
Accounts receivable	2,234,881	597,819
Inventories	(242,909 )	(423,658 )
Prepaid expenses and other current assets	29,010	(18,293 )
Deposits and other assets	25,000	18,334
Accounts payable and accrued liabilities	(443,403 )	(382,895 )
Deferred research and development revenue	-	19,167
Net cash provided by (used in) operating activities	\$ 1,560,142	\$ (192,074 )
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	\$ -	\$ 300,000
See accompanying notes to condensed consolidated financial statements		



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2011  
(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 primary 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. Rapid HIV tests represented nearly 96% of the Company’s net product sales in the three months ended March 31, 2011 compared with nearly 91% for the three months ended March 31, 2010. The Company also has other rapid tests that together represented approximately 4% and 9% of net product sales in the first three months of 2011 and 2010, respectively. The Company’s products are sold, directly and through distributors, to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, and medical professionals 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 owned by Alere North America, Inc. (“Alere”), which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company’s new products and all of those that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2009, 2010 and 2011 to date, the Company has completed development of its first five products that employ the DPP®, and the Company has a number of additional products under development that employ the DPP®.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The following (a) condensed balance sheet as of December 31, 2010, which has been derived from audited financial statements, and (b) the unaudited interim condensed financial statements as of March 31, 2011 and for the three-month periods ended March 31, 2011 and 2010 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, 2010, previously filed with the SEC.

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 March 31, 2011, its condensed consolidated results of operations for the three-month periods ended March 31, 2011 and 2010 and its cash flows for the three-month periods ended March 31, 2011 and 2010, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

(b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition” (“SAB 104”). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is

determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, the Company recognizes revenue from non-milestone contracts and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

For the recognition of revenues for certain collaborative research projects defining milestones at the inception of the agreement, the Company applies the milestone method of revenue recognition. Revenues from milestones funded in advance are deferred until the milestone is completed.

As of March 31, 2011 an aggregate of \$65,000 of advanced revenues was unearned and is reflected as deferred revenue on the balance sheet.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2011  
(UNAUDITED)

## (c) Inventories:

Inventories consist of the following at:

	March 31, 2011	December 31, 2010
Raw materials	\$ 868,795	\$ 785,693
Work in process	432,501	235,548
Finished goods	290,774	327,920
	\$ 1,592,070	\$ 1,349,161

## (d) Earnings Per Share:

Basic earnings per share is computed by dividing net income or loss attributable to common stockholders 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. Diluted loss per share for the three-month periods ended March 31, 2011 and 2010 is the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for those periods. The following securities, presented on a common share equivalent basis for the three-month periods ended March 31, 2011 and 2010, have been excluded from the per share computations:

	For the three months ended March 31, 2011	March 31, 2010
1999 and 2008 Plan		
Stock Options	5,491,003	5,662,033
Other Stock Options	100,625	124,625
Warrants	2,545,005	4,294,531
	8,136,633	10,081,189

## (e) Employee Stock Option Plan:

The Company had a 1999 Stock Option Plan ("SOP"). The number of options available under the SOP was 3,000,000 shares of Common Stock. As of March 31, 2011, there were 1,811,500 outstanding options under this SOP.

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), with 5,000,000 shares of Common Stock. 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. 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 March 31, 2011, there were 56,664 options exercised, 3,348,652 outstanding options under this SIP and 1,594,684 options still available to be issued.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month periods ended March 31, 2011 and 2010 was none and \$.22 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:

	For the three months ended	
	March 31, 2011	March 31, 2010
Expected term (in years)	n/a	5
Expected volatility	n/a	116.82%
Expected dividend yield	n/a	n/a
Risk-free interest rate	n/a	1.43%

The Company's results for the three-month periods ended March 31, 2011 and 2010 include share-based compensation expense totaling \$28,000 and \$75,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$4,000 and \$8,000, respectively), research and development (\$12,000 and \$43,000, respectively) and selling, general and administrative expenses (\$12,000 and \$24,000, respectively). No income tax benefit has been recognized in the statement of operations for share-based compensation arrangements due to the history of operating losses.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2011  
(UNAUDITED)

Stock option compensation expense for the three-month periods ended March 31, 2011 and 2010 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The following table provides stock option activity for the three months ended March 31, 2011:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2010	5,586,900	\$ 0.15	3.59 years	\$ 756,990
Granted	300,000	\$ 0.27		
Exercised	(259,082 )	\$ 0.15		
Forfeited/expired /cancelled	(97,250 )	\$ 0.26		
Outstanding at December 31, 2010	5,530,568	\$ 0.16	2.82 years	\$ 1,497,063
Granted	-			
Exercised	(311,082 )	\$ 0.13		
Forfeited/expired/cancelled	(59,334 )	\$ 0.34		
Outstanding at March 31, 2011	5,160,152	\$ 0.16	2.72 years	\$ 1,599,736
Exercisable at March 31, 2011	2,616,811	\$ 0.13	2.28 years	\$ 775,717

As of March 31, 2011, there was \$75,000 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 .75 years. The total fair value of stock options vested during the three-month periods ended March 31, 2011 and 2010, was approximately none and \$47,000, 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	
	March 31, 2011	March 31, 2010
Africa	\$ 553,383	\$ 496,891
Asia	28,955	51,054
Europe	38,060	32,454
Middle East	7,163	26,943
North America	2,333,600	1,523,637

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

South America	53,902	83,918
	\$ 3,015,063	\$ 2,214,897

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2011  
(UNAUDITED)

(g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	March 31, 2011	December 31, 2010
Accounts payable – suppliers	\$ 862,636	\$ 883,719
Accrued commissions	37,755	114,451
Accrued royalties / license fees	362,544	352,285
Accrued payroll	92,089	162,740
Accrued vacation	141,586	129,732
Accrued bonuses	-	140,325
Accrued expenses – other	115,930	272,691
<b>TOTAL</b>	<b>\$ 1,612,540</b>	<b>\$ 2,055,943</b>

(h) Recent Accounting Pronouncements Affecting the Company

Revenue Arrangements with Multiple Deliverables

In October 2009, the FASB issued authoritative guidance that amends existing guidance for identifying separate deliverables in a revenue-generating transaction where multiple deliverables exist, and provides guidance for allocating and recognizing revenue based on those separate deliverables. The guidance is expected to result in more multiple-deliverable arrangements being separable than under current guidance. This guidance became effective for the Company on January 1, 2011. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Intangibles – Goodwill and Other

In December 2010, the FASB amended the existing guidance to modify Step 1 of the goodwill impairment test for a reporting unit with a zero or negative carrying amount. Upon adoption of the amendment, an entity with a reporting unit that has a carrying amount that is zero or negative is required to assess whether it is more likely than not that the reporting unit's goodwill is impaired. If the entity determines that it is more likely than not that the goodwill of the reporting unit is impaired, the entity should perform Step 2 of the goodwill impairment test for the reporting unit. Any resulting goodwill impairment should be recorded as a cumulative-effect adjustment to beginning retained earnings in the period of adoption. Any goodwill impairments occurring after the initial adoption of the amendment should be included in earnings. This guidance became effective for the Company on January 1, 2011. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Broad Transactions – Business Combination

In December 2010, the FASB amended the existing guidance to require a public entity, which presents comparative financial statements, to disclose revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only.

The amendment also expanded the required supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination, which are included in the reported pro forma revenue and earnings. The amendments became effective for the Company on January 1, 2011. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a. Oswaldo Cruz Foundation/Fiocruz:

During 2008, the Company signed four Agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil ("FIOCRUZ") for the supply, license and transfer of certain products and related technologies from the Company to FIOCRUZ. The agreements are for the following rapid test products: i) DPP® HIV 1/2 Screen, ii) DPP® HIV 1/2 Confirmatory, iii) DPP® Leptospirosis and iv) DPP® Leishmaniasis. These Agreements provide for a staged technology transfer collaboration pursuant to which FIOCRUZ will ultimately be able to fully manufacture the applicable product for supply in Brazil provided certain minimum purchases of products and related components have occurred.



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2011  
(UNAUDITED)

In accordance with guidance, management has concluded the FIOCRUZ events recorded this quarter for Leishmaniasis meet the definition of milestone events. The Company earned \$305,000 for the three months ended March 31, 2011. Future milestone revenues expected from the agreements are \$100,000.

Under the Leishmaniasis contract, there are additional royalties and purchase commitments due to the Company over the remaining life of the Agreement which will result in a larger revenue stream.

b. Infectious Disease Research Institute (IDRI) Agreement:

In April 2009, Chembio entered into a development agreement for up to approximately \$400,000 in connection with the development and initial supply of a low-cost, rapid point-of-care ("POC") test for infectious diseases. The agreement contemplated a period of approximately two years in which the development activity is to be completed.

As of March 31, 2011, the Company received an aggregate of \$390,000 in research and development payments from this agreement of which \$65,000 is reflected in deferred revenue. Future milestone payments of \$10,000 are expected over the next two quarters and will be recognized when the milestones are met.

c. National Institutes of Health (NIH) Grant:

In June 2009, the Company received a \$3 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 an aggregate of \$1,548,000 from this grant from inception through March 31, 2011, of which \$446,000 was paid to sub-contractors.

In March 2010, the Company received a \$3 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 \$48,000 from this grant from inception through March 31, 2011.

NOTE 4 — TERM NOTE, REVOLVING DEMAND NOTE, VEHICLE FINANCING AND LICENSE FEE PAYABLE:

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

The Term Note is payable at \$4,775.29 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 a 30-day clean-up, during which there can be no amounts outstanding.

The Security Agreement contains covenants that place annual 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 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 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 March 31, 2011. The Security Agreement requires that the Demand Note has an annual 30-day clean-up, during which there can be no amounts outstanding.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of March 31, 2011 was \$217,000 and nothing was drawn down on the Demand Note as of March 31, 2011.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2011  
(UNAUDITED)

Future minimum payments under the Term Note, excluding interest, as of March 31, 2011 were as follows for the periods ending March 31,

2012	\$46,545
2013	49,171
2014	51,944
2015	54,874
2016	14,119
	216,653
Less: current maturities	(46,545 )
	\$ 170,108

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. The balance due on this loan as of March 31, 2011 was \$11,669 and is reflected with the Term Note above on the balance sheet as current portion of loans payable of \$9,978 and loans payable – net of current portion of \$1,691.

In February 2008, the Company entered into a sublicense agreement (the “Agreement”) with Bio-Rad Laboratories, Inc. and Bio-Rad Pasteur (collectively, “Bio-Rad”). Bio-Rad is the exclusive licensee of the HIV-2 patent portfolio held by Institute Pasteur of Paris, France. Pursuant to the terms of the Agreement, Bio-Rad sublicensed to the Company patents related to the manufacture, use or sale of screening assays that detect HIV-2. In exchange for global non-exclusive rights to these patents, the Agreement initially provided that the Company pay Bio-Rad a \$1,000,000 sublicense fee; \$500,000 payable during 2008, of which \$125,000 was paid and \$375,000 was payable by December 31, 2008, with the remaining \$500,000 being payable by December 31, 2009. On January 29, 2009, the Company and Bio-Rad agreed to amend the Agreement so as to defer the remaining \$875,000 of payments due under the Agreement to one payment due in December 2010. The Company paid the \$875,000 on January 3, 2011. The Company will also pay Bio-Rad a royalty on net sales in the United States and Canada, if any, of Licensed Products sold under the Company’s brands as defined in the Agreement. The Agreement will continue until the expiration of the last-to-expire (in 2017) of the sublicensed patents, unless otherwise terminated at an earlier date by the Company or Bio-Rad.

**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").

For a more complete description of the material terms of the Rights Agreement and the rights to be issued pursuant thereto, please refer to Item 3.03 of the Company's Form 8-K Current Report filed with the SEC on March 11, 2010.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2011

(UNAUDITED)

NOTE6—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 three months ended		Accounts Receivable
	March 31, 2011	% of	March 31, 2010	% of	As of
	Sales	Sales	Sales	Sales	March 31, 2011
Customer 1	\$ 2,055,210	68	\$ 1,161,927	52	\$ 715,747
Customer 2	\$ 459,697	15	*	*	\$ 469,872

In the table above, the asterisk (\*) indicates that sales to the customer did not exceed 10% for the period indicated.

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

	For the three months ended		For the three months ended		Accounts Payable
	March 31, 2011	% of	March 31, 2010	% of	As of
	Purchases	Purc.	Purchases	Purc.	March 31, 2011
Vendor 1	\$ 108,456	13	\$ 107,663	14	\$ 10,567

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 \$510,000 per year. One contract expires in May 2012 and one contract expires in March 2013. In connection with the contract that expires March 2013, the Company issued 300,000 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.

11

---

NOTE7—SUBSEQUENT EVENTS:

On April 26, 2011, warrants to purchase 513,698 shares of common stock were exercised at \$.40 per share. The Company received \$205,479 for this exercise.

In November 2010, the Company signed an Agreement with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil (“FIOCRUZ”) for the supply, license and transfer of certain products and related technologies from the Company to FIOCRUZ. The agreements are for the following rapid test products: i) DPP® Syphilis Screen, and ii) DPP® Syphilis Screen and Confirm. This Agreement provides for a staged technology transfer collaboration pursuant to which FIOCRUZ will ultimately be able to fully manufacture the applicable product for supply in Brazil provided certain minimum purchases of products and related components have occurred.

In April 2011, FIOCRUZ informed the Company that ANVISA (the Brazilian regulatory agency) had approved the DPP® Syphilis Screen assay for use in Brazil. This approval triggered a milestone event of \$100,000 to the Company. In accordance with guidance, management has concluded the FIOCRUZ event is to be recorded for the second quarter of 2011 for Syphilis Screen as it meets the definition of milestone event. The Company earned \$100,000 for this milestone event.

Under the Syphilis contract, there are additional royalties and purchase commitments due to the Company over the remaining life of the Agreement, starting in 2011, which will result in a larger revenue stream

## 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 and 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 were 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 stated in Note 2 (b), have not changed significantly from December 31, 2010.

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 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 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 three months of 2011, the Company had a total of \$1,290,000 of research and development expenses as compared with \$801,000 during the first three months of 2010. Approximately \$395,000 of this \$489,000 increase, or 81% of the increase, is attributable to expenses for clinical trials for its DPP® HIV Screen. Because of the Company's strong operating cash flow during 2010 and 2011 year to date, including but not limited to its receipt of \$1.467 million of Qualified Therapeutic Discovery Project grants ("QTDP") under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010), the Company has been able to accelerate the pace of these clinical trials, which are now over two-thirds completed.

The Company has a number of additional products under development that employ the DPP® technology. These product development activities are further described below.

Oswaldo Cruz Foundation OEM DPP® Agreements - During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ), which is affiliated with the Ministry of Health in Brazil, relating to products based on our DPP® technology for Leptospirosis, Canine Leishmaniasis, screening for HIV 1/2 with oral fluid and blood samples, and a 5-band multiplex point-of-care confirmation test for HIV 1 and 2. In addition, in 2010 we signed a fifth agreement with FIOCRUZ relating to two DPP® Syphilis rapid tests. We have completed development of all of these products and four products have been approved and two are pending regulatory approval (See REGULATORY ACTIVITIES below).

Bio-Rad Laboratories OEM DPP® Agreement – During 2010 we completed work on a two-year development contract with Bio-Rad Laboratories, Inc. of a six band multiplex product on our DPP® platform after a two-year development phase, which was then followed by a technology transfer phase. After the product development was successfully completed in 2010, Chembio earned a license fee from Bio-Rad and Bio-Rad exercised its option to have the manufacture of the product transferred to Bio-Rad. Chembio will therefore participate in the commercialization of this product through the license agreement that it executed with Bio-Rad, which agreement provides for royalties payable to Chembio at the rate of 7% of Net Sales of licensed products as defined in that agreement. We believe the regulatory submissions by Bio-Rad will commence as soon as practicable. There can be no assurance that Bio-Rad will submit this product for regulatory approval, that the product if submitted will be approved, and if approved will be successfully commercialized and produce royalty income to Chembio.

Battelle/CDC DPP® Influenza Immunity Test – We have completed the development work associated with this project our initial prototypes are being evaluated by Battelle/CDC and recently we were requested by Battelle/CDC to manufacture and supply a larger number of prototypes.

DPP® Hepatitis C and DPP® Hepatitis C/HIV Tests – Various prototypes of these products are being developed and evaluated internally and externally, including a study that was organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the CDC. We have received the confidential results of the study which CDC has submitted for journal publication

DPP® Influenza – We have made significant progress on our multiplex test for FLU A/B Antigen Detection and we are verifying the performance of our prototype in order to begin full validation and commencement of regulatory activities for this product. Our current plan is still for product verification and validation to be completed during the second quarter of 2011 and for our clinical studies to be initiated during the balance of 2011.

DPP® Leptospirosis – We are about halfway through the three-year \$3 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. Our work pursuant to this grant is progressing on schedule. The test will be developed with our DPP® technology and will utilize proprietary reagents developed by Yale University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will be 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.

DPP® Tuberculosis – As reported 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 development of a simple, rapid, accurate, and cost-effective serological test for active tuberculosis that can be utilized in resource-limited settings.

Other Research & Development Activities - Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts and grant funding for development projects. These programs have subsidized the Company's development expenses while expanding the applications for and know-how related to DPP®, and have also served in creating important collaborative relationships.

On November 1, 2010, the Company was notified by the IRS that it received awards in the total amount of \$1.467 million relating to six "Qualifying Therapeutic Discovery Projects" under the U.S. Patient Protection and Affordable Care Act of 2010 (P.L. 111-148), a program that was created as part of the major United States federal health care reform legislation enacted earlier this year.

Under the award guidelines, qualified therapeutic discovery projects had to show a reasonable potential to result in new therapies to treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions,

reduce the long-term growth of health care costs in the United States, or significantly advance the goal of curing cancer within 30 years. Chembio's projects that received awards include products based on the Company's patented DPP® point-of-care diagnostic platform that are in various stages of its development pipeline such as its products for the rapid diagnosis of HIV, Hepatitis-C, and Syphilis.

We also have some smaller research and development agreements and grants in place, and applications for others that are pending.

There can be no assurance that any of these grant applications will result in any funding awards to the Company, nor that any of the existing research and development contracts or grants will continue 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.

## Regulatory Activities

CE Mark for FDA approved HIV tests – The final studies for the CE Marking requirements are underway for our two FDA-approved rapid HIV tests, although we have continued to experience delays. Our revised plan is to collect the remaining data required in order for the study to be submitted during the second quarter of 2011. Submission of the final data will occur shortly thereafter.

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – During 2010 we received notification from FIOCRUZ that our DPP® HIV 1/2 screening test and our DPP® HIV confirmatory test were each approved by Brazil's National Health Surveillance Agency (ANVISA). During the first quarter, as recently reported, our DPP® visceral canine leishmania ("VL") rapid test was approved by Brazil's Ministry of Agriculture, Livestock and Food Supply ("MAPA"). This is the first diagnostic product that FIOCRUZ has successfully submitted for approval to MAPA in Brazil. In addition, we were just notified (see Subsequent Events in the financial statement footnotes above and Recent Events below) that FIOCRUZ has now also received the required approval from ANVISA for the DPP® Syphilis-Treponemal test; we believe the remaining DPP® product approval that FIOCRUZ has pending with ANVISA, which is for the DPP® Leptospirosis test, will be granted soon, although there can be no assurance of this.

FDA Approval for DPP® HIV 1/2 Screening Assay for Oral Fluid - We have collected over 2/3 of the clinical data required for submission to the FDA. As recently reported, we began submitting the PMA (Pre-Marketing Approval) application using the Modular PMA option, and we have thus far submitted the module containing manufacturing information. We anticipate filing the remaining modules during the balance of 2011, although there can be no assurance of this.

DPP® Syphilis Screen & Confirm - We are engaged in a number of activities oriented to commercializing this product. We anticipate commencing clinical trials and other activities in support of a planned 510(K) clearance during the second quarter of 2011.

## Recent Events

On April 26, 2011, warrants to purchase 513,698 shares of common stock were exercised at \$.40 per share. The Company received \$205,479 for this exercise.

In April 2011, FIOCRUZ informed the Company that ANVISA (the Brazilian regulatory agency) had approved the DPP® Syphilis Screen assay for use in Brazil. This approval triggered a milestone event of \$100,000 to the Company.

## 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 other than stated in Note 2 (b), have not changed from December 31, 2010, see our Annual Report on Form 10-K for the twelve months ended December 31, 2010, which was filed with the SEC on March 3, 2011.

# RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2011 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2010

## Revenues:

### Selected Product Categories:

	For the three months ended				
	March 31, 2011	March 31, 2010	\$ Change	% Change	
HIV	\$ 2,891,079	\$ 2,007,333	\$ 883,746	44.03	%
DPP	51,000	-	51,000	100.00	%
Other	72,984	207,564	(134,580)	-64.84	%
Net Product Sales	3,015,063	2,214,897	800,166	36.13	%
License and royalty revenue	28,854	21,496	7,358	34.23	%
R&D, milestone and grant revenue	591,764	547,022	44,742	8.18	%
Total Revenues	\$ 3,635,681	\$ 2,783,415	\$ 852,266	30.62	%

Revenues for our HIV tests and related components during the three months ended March 31, 2011 increased by approximately \$884,000 over the same period in 2010. This was primarily attributable to increased sales to Alere from \$1,162,000 during the first three months of 2010 to \$2,055,000 during the three months ended March 31, 2011, an increase of \$893,000, or 77%. The increase in R&D, milestone and grant revenue was due to revenue generated from grants and development contracts that are related to potential new products utilizing our patented DPP® technology and a milestone event of \$305,000 from FIOCRUZ on the approval of the Company's DPP® Leishmaniasis rapid test. R&D, milestone and grant revenue also includes funds from our recent grants from NIH for Human Tuberculosis, which was effective as of March 1, 2011. License and royalty revenue primarily includes royalties from Brazil under our 2004 technology transfer and license agreement.

## Gross Margin:

### Gross Margin related to Net Product Sales:

	For the three months ended				
	March 31, 2011	March 31, 2010	\$ Change	% Change	
Gross Margin per Statement of Operations	\$ 1,926,342	\$ 1,306,374	\$ 619,968	47.46	%
Less: R&D, milestone, grant, license and royalties	620,618	568,518	52,100	9.16	%
Gross Margin from Net Product Sales	\$ 1,305,724	\$ 737,856	\$ 567,868	76.96	%
Gross Margin %	43.31	33.31			%

The increase in our gross margin percentage was primarily due to an increase in our sales to Alere which are at higher margin than products sold in Africa. This gross margin increase was after approximately \$120,000 in an unusually

high scrap expense that was incurred as a result of a product non-conformance detected during quality control in a production batch. Alere sales represented approximately 52% of sales in the three months ended March 31, 2010 as compared to approximately 68% in the three months ended March 31, 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				
	March 31, 2011	March 31, 2010	\$ Change	% Change	
Clinical and Regulatory Affairs:					
Wages and related costs	\$ 113,020	\$ 81,471	\$ 31,549	38.72	%
Consulting	-	14,805	(14,805)	-100.00	%
Share-based compensation	2,122	4,667	(2,545)	-54.53	%
Clinical trials	452,064	56,750	395,314	696.59	%
Other	18,896	9,274	9,622	103.75	%
Total Regulatory	586,102	166,967	419,135	251.03	%
R&D Other than Regulatory:					
Wages and related costs	475,277	424,593	50,684	11.94	%
Consulting	500	9,982	(9,482)	-94.99	%
Share-based compensation	10,318	38,260	(27,942)	-73.03	%
Materials and supplies	158,848	107,260	51,588	48.10	%
Other	59,097	53,696	5,401	10.06	%
Total other than Regulatory	\$ 704,040	633,791	70,249	11.08	%
Total Research and Development	\$ 1,290,142	\$ 800,758	\$ 489,384	61.12	%

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2011 increased by \$419,000 as compared to the same period in 2010. This was primarily due to expenses we incurred in 2011 for clinical trials conducted for our DPP® HIV Screen Assay which increased approximately \$395,000 over the 2010 period.

R&D expenses other than Clinical & Regulatory Affairs increased by \$70,000 in the three months ended March 31, 2011 as compared with the same period in 2010 and were primarily related to an increase in material and supplies along with an increase in wages and related costs due to new hires, both related to additional products being developed utilizing our patented DPP® technology, offset by decreases in share-based compensation.

## Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended				
	March 31, 2011	March 31, 2010	\$ Change	% Change	
Wages and related costs	\$ 269,398	\$ 240,455	\$ 28,943	12.04	%
Consulting	37,571	55,876	(18,305)	-32.76	%
Commissions	65,652	17,549	48,103	274.11	%
Share-based compensation	11,549	24,322	(12,773)	-52.52	%

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10-Q

Marketing materials	734	1,346	(612 )	-45.47	%
Investor relations/investment bankers	51,029	37,403	13,626	36.43	%
Legal, accounting and SOX 404 compliance	182,900	175,628	7,272	4.14	%
Travel, entertainment and trade shows	12,444	15,486	(3,042 )	-19.64	%
Bad Debt Allowance	(15,000 )	-	(15,000 )	100.00	%
Other	159,094	93,783	65,311	69.64	%
Total S, G &A	\$ 775,371	\$ 661,848	\$ 113,523	17.15	%

Selling, general and administrative expenses for the three months ended March 31, 2011 increased by 17% as compared with the same period in 2010. This was primarily due to expenses incurred for the recording of \$46,000 in Brazilian tax withholdings (included in the Other Expenses category above) on the milestone payment, an increase in commissions as a result of the milestone payment, an increase in investor relations expenses and an increase in wage and related expenses, partially offset by a decrease in consulting and share-based compensation expenses.



## Other Income and (Expense):

	For the three months ended			
	March 31, 2011	March 31, 2010	\$ Change	% Change
Interest income	\$ 1,310	\$ 1,110	\$ 200	18.02 %
Interest expense	(4,436 )	(2,204 )	(2,232 )	101.27 %
Total Other Income and (Expense)	\$ (3,126 )	\$ (1,094 )	\$ (2,032 )	185.74 %

Other income and (expense) for the three months ended March 31, 2011 decreased approximately \$2,000 as compared with the same period in 2010, primarily as a result of an increase in interest expense due to the term loan with HSBC, and partially offset by an increase in interest income due to an increase in cash in interest-bearing accounts.

## MATERIAL CHANGES IN FINANCIAL CONDITION

Selected Changes in Financial Condition	March 31, 2011	As of December 31, 2010	\$ Change	% Change
Cash and cash equivalents	\$ 2,797,103	\$ 2,136,351	\$ 660,752	30.93 %
Accounts receivable, net of allowance for doubtful accounts of \$20,000 and \$35,000 for 2011 and 2010, respectively	1,726,517	3,946,398	(2,219,881 )	-56.25 %
Inventories	1,592,070	1,349,161	242,909	18.00 %
Accounts payable and accrued liabilities	1,612,540	2,055,943	(443,403 )	-21.57 %
License fee payable	-	875,000	(875,000 )	-100.00 %
Obligations under capital leases - net of current portion	7,855	14,576	(6,721 )	-46.11 %

Cash increased by \$661,000 from December 31, 2010, primarily due to the collection of accounts receivable which decreased by \$2.22 million, which was partially offset by the payment to Bio-Rad of \$875,000 (see reduction in license fee payable), an increase in inventory of \$243,000 and a \$443,000 reduction of accounts payable.

## LIQUIDITY AND CAPITAL RESOURCES

	For the three months ended			
	March 31, 2011	March 31, 2010	\$ Change	% Change
Net cash provided by (used in) operating activities	\$ 1,560,142	\$ (192,074 )	\$ 1,752,216	-912.26 %
Net cash used in investing activities	(46,358 )	(72,866 )	26,508	-36.38 %
Net cash used in financing activities	(853,032 )	(5,372 )	(847,660 )	15779.23 %

NET INCREASE  
(DECREASE) IN CASH  
AND CASH

EQUIVALENTS	\$	660,752	\$	(270,312	) \$	931,064	-344.44	%
-------------	----	---------	----	----------	------	---------	---------	---

The Company's cash increased for the three months ended March 31, 2011 as compared to a decrease in cash for the same period in 2010. The decrease during the 2010 period is primarily attributable to cash used in operations. The increase in the 2011 period is primarily attributable to the cash provided by operations, including cash received from the change in receivables of \$2.23 million. The increased cash from operations in 2011 was primarily attributable to the change in receivables, along with non-cash expenses aggregating \$125,000 and a decrease in other assets of \$29,000 partially offset by an increase in accruals and payables of \$443,000 and an increase in inventories of \$268,000. The Company's non-cash expenses totaled \$125,000, which consisted of \$87,000 from depreciation expense, \$28,000 in share-based compensation expense, and \$25,000 in the amortization of licenses, offset by a decrease in accounts receivable allowance of \$15,000.

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

Based on the purchase orders and forecasts we have from Alere, FIOCRUZ, and other key current and potential new customers, and also based upon our existing contract development and grant revenues, we believe that Chembio can achieve significant total revenue growth and gross margin improvements during 2011. We believe this total revenue growth, if achieved, will primarily be from increased sales to Alere, which are at higher average selling prices, and from FIOCRUZ, which is at higher average prices than our other international sales. We believe that we will realize sales to FIOCRUZ this year at least from the four DPP® products approved in Brazil (which now also includes DPP® Syphilis), although there can be no assurance of this. We believe this growth in product revenues in 2011 is likely to more than offset an anticipated reduction in our 2011 non-product revenues as compared to our 2010 non-product revenues, although there can be no assurance of this.

We believe that the anticipated increased product revenues, if realized, and of which there can be no assurance, together with the cash on hand, will enable us to fund all of our budgeted clinical and development programs for our Chembio-branded DPP® products. The extent of our revenue and gross margin growth, and the cost and timing of our research and development, regulatory and clinical programs, will be the primary determinants of whether, and to what extent, we will generate profits after these expenses. We do believe these expenses will be significantly increased as compared with the comparable periods in 2010, as was evident in our first quarter 2011 results.

In addition to the reduced non-product revenue we anticipate in 2011, we also anticipate the non-recurrence of the QTDP grants which, notwithstanding the use of the word “grant” by this program, was recognized under GAAP in our 2010 audited financial statements as a \$1.467 million reduction in our 2010 research and development expenses. Accordingly, our comparisons of our 2011 results to the results of 2010 will be after adjusting for the \$1.467 million of QTDP “grants” recognized in (the fourth quarter) 2010. On the other hand, our comparisons will also be after accounting for \$275,000 in non-recurring expenses (which we assume will not recur in 2011 or the foreseeable future, although there can be no assurance of this) that we incurred during the second half of 2010 related to potential strategic opportunities.

We believe that our investment in clinical and regulatory expenses during 2011 will be approximately \$2 million, as compared with approximately \$654,000 in 2010, although there can be no assurance of this. Notwithstanding this significant investment in the commercialization of our product pipeline, which will be disproportionate during the first half of 2011, based on the current and anticipated orders from Alere and FIOCRUZ, and other customers, we believe we will produce strong profitability in 2011, although there can be no assurance of this. We look forward to providing an update on our anticipated shipments to FIOCRUZ.

Our 2011 non-cash expenses (share-based compensation, depreciation and amortization expenses) are anticipated to be approximately \$560,000, or approximately \$140,000 per quarter as compared with approximately \$700,000, or approximately \$175,000 per quarter, for 2010.

We are beginning to recruit personnel in order to establish our commercial organization, initially to expand our licensing and contract development activities, and increase international distribution of our growing portfolio of products, and then, in 2012 establish a U.S.-based direct selling organization as our new products are approved or cleared for marketing. We believe that this is a sound business strategy that is balanced, by participating in global and domestic market opportunities and by developing both OEM collaborations and a branded business which we believe will not conflict. We will do this while leveraging our intellectual property and expertise in developing and scaling up manufacturing of high quality point of care diagnostic products in a regulated global market. We believe this is the way to build sustainable and long-term shareholder value.

#### 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 2011 fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

## EXHIBITS INDEX

Number	Description
3.1	Articles of Incorporation, as amended. (1)
3.2	Amended and Restated Bylaws. (2)
4.1	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (3)
4.2	Registration Rights Agreement, dated June 29, 2006. (4)
4.3	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
4.4	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (5).
4.5	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (5)
4.6	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (6)
4.7*	Form of Employee Option Agreement. (6)
4.8	1999 Equity Incentive Plan. (7)
4.9	2008 Stock Incentive Plan. (8)
4.1	Rights Agreement, dated March 8, 2010 (9)
4.11	Form of Warrant (to be filed by amendment)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (10)
10.2*	Employment Agreement dated March 5, 2010 with Javan Esfandiari. (11)
10.3	Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
10.4	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.5	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.6	Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (5)
10.7	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (5)
10.8	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (5)
10.9	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (5)
10.1	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (5)
10.11	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
10.12	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
10.13	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (12)
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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

- 1 Incorporated by reference to the Registrant's 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 Current Report on Form 8-K filed with the Commission on January 31, 2005.
  - 4 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.
  - 5 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
  - 6 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
  - 7 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
  - 8 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
  - 9 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
  - 10 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
  - 11 Incorporated by reference to the Registrant's registration statement on Form S-1/A filed with the Commission on March 11, 2010.
  - 12 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
- (\*) 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 registration statement.

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: May 5, By: /s/ Lawrence A. Siebert  
2011

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

Date: May 5, By: /s/ Richard J. Larkin  
2011

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