

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

July 29, 2010

---

---

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, 2010

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)

(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.

Large accelerated filer [  ]

Accelerated filer [  ]

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

Non-accelerated filer   
(Do not check if a smaller reporting company)

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 July 27, 2010, the Registrant had 62,138,151 shares outstanding of its \$.01 par value common stock.

---

---

Quarterly Report on FORM 10-Q For The Period Ended

June 30, 2010

Table of Contents

Chembio Diagnostics, Inc.

	Page
<b>Part I. FINANCIAL INFORMATION:</b>	
<b>Item 1. Financial Statements:</b>	
Condensed Consolidated Balance Sheets as of June 30, 2010 (unaudited) and December 31, 2009.	2
Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2010 and 2009.	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2010 and 2009.	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5 to 15
<b>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</b>	<b>16</b>
<b>Item 4. Controls and Procedures</b>	<b>28</b>
<b>Part II. OTHER INFORMATION:</b>	
Exhibits	29
<b>SIGNATURES</b>	<b>30</b>
<b>EXHIBITS</b>	

## PART I

## Item 1. FINANCIAL STATEMENTS

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

	- ASSETS -	
	June 30, 2010 (UNAUDITED)	December 31, 2009
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 746,848	\$ 1,068,235
Accounts receivable, net of allowance for doubtful accounts of \$20,000 for 2010 and 2009	1,817,284	1,776,327
Inventories	1,849,708	1,555,903
Prepaid expenses and other current assets	300,790	266,637
<b>TOTAL CURRENT ASSETS</b>	<b>4,714,630</b>	<b>4,667,102</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>853,181</b>	<b>580,213</b>
<b>OTHER ASSETS:</b>		
License agreements, net of current portion	650,000	700,000
Deposits on manufacturing equipment	52,824	338,375
Deposits and other assets	36,226	29,560
<b>TOTAL ASSETS</b>	<b>\$ 6,306,861</b>	<b>\$ 6,315,250</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 1,310,745	\$ 1,906,163
Current portion of loans payable	54,852	9,600
Deferred research and development revenue	115,006	360,833
License fee payable	875,000	875,000
Current portion of obligations under capital leases	23,062	21,536
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,378,665</b>	<b>3,173,132</b>
<b>OTHER LIABILITIES:</b>		
Loans payable - net of current portion	214,113	14,931
Obligations under capital leases - net of current portion	27,347	39,273
<b>TOTAL LIABILITIES</b>	<b>2,620,125</b>	<b>3,227,336</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		

**STOCKHOLDERS' EQUITY:**

Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 62,138,151 and 61,979,901 shares issued and outstanding for 2010 and 2009, respectively	621,382	619,799
Additional paid-in capital	39,586,170	39,453,522
Accumulated deficit	(36,520,816 )	(36,985,407 )
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>3,686,736</b>	<b>3,087,914</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 6,306,861</b>	<b>\$ 6,315,250</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, 2010	June 30, 2009	June 30, 2010	June 30, 2009
<b>REVENUES:</b>				
Net product sales	\$ 2,335,665	\$ 3,051,385	\$ 4,550,562	\$ 5,320,801
License and royalty income	717,472	52,322	738,968	52,322
R&D contracts and grants	696,305	269,817	1,243,328	545,999
<b>TOTAL REVENUES</b>	<b>3,749,442</b>	<b>3,373,524</b>	<b>6,532,858</b>	<b>5,919,122</b>
Cost of product sales	1,654,476	2,011,579	3,131,518	3,558,488
<b>GROSS MARGIN</b>	<b>2,094,966</b>	<b>1,361,945</b>	<b>3,401,340</b>	<b>2,360,634</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	791,596	702,986	1,592,354	1,350,358
Selling, general and administrative expenses	680,014	542,449	1,341,862	1,218,262
	1,471,610	1,245,435	2,934,216	2,568,620
<b>INCOME (LOSS) FROM OPERATIONS</b>	<b>623,356</b>	<b>116,510</b>	<b>467,124</b>	<b>(207,986 )</b>
<b>OTHER INCOME (EXPENSES):</b>				
Other expense	-	(6,696 )	-	(6,696 )
Interest income	618	1,531	1,729	4,915
Interest expense	(2,057 )	(1,406 )	(4,262 )	(5,527 )
	(1,439 )	(6,571 )	(2,533 )	(7,308 )
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>621,917</b>	<b>109,939</b>	<b>464,591</b>	<b>(215,294 )</b>
Provision for income taxes	-	-	-	-
<b>NET INCOME (LOSS)</b>	<b>\$ 621,917</b>	<b>\$ 109,939</b>	<b>\$ 464,591</b>	<b>\$ (215,294 )</b>
Basic earnings (loss) per share	\$ 0.01	\$ 0.00	\$ 0.01	\$ (0.00 )

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

Diluted earnings (loss) per share	\$ 0.01	\$ 0.00	\$ 0.01	\$ (0.00 )
Weighted average number of shares outstanding, basic	62,070,736	61,944,901	62,028,450	61,944,901
Weighted average number of shares outstanding, diluted	70,614,048	74,814,205	71,340,820	61,944,901

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, 2010	June 30, 2009
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers	\$ 6,491,901	\$ 6,088,328
Cash paid to suppliers and employees	(6,922,455 )	(5,239,948 )
Interest received	1,110	4,915
Interest paid	(2,204 )	(5,527 )
Net cash (used in) provided by operating activities	(431,648 )	847,768
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from sale of fixed assets	-	13,750
Acquisition of fixed assets	(144,345 )	(234,830 )
Net cash used in investing activities	(144,345 )	(221,080 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option exercises	20,572	-
Proceeds from loan	250,000	29,228
Payment of loan obligation	(5,566 )	-
Payment of capital lease obligation	(10,400 )	(9,069 )
Net cash provided by financing activities	254,606	20,159
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>		
	(321,387 )	646,847
Cash and cash equivalents - beginning of the period	1,068,235	1,212,222
Cash and cash equivalents - end of the period	\$ 746,848	\$ 1,859,069
<b>RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 464,591	\$ (215,294 )
Adjustments:		
Depreciation and amortization	148,052	191,999



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

Loss on sale of fixed asset	-	6,696
Share based compensation	113,659	91,850
Changes in assets and liabilities:		
Accounts receivable	(40,957 )	198,434
Inventories	(293,805 )	166,187
Prepaid expenses and other current assets	(34,153 )	(23,178 )
Deposits and other assets	52,210	74,510
Accounts payable and accrued liabilities	(595,418 )	(138,184 )
Deferred research and development revenue	(245,827 )	494,748
Net cash (used in) provided by operating activities	\$ (431,648 )	\$ 847,768

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  
JUNE 30, 2010  
(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. Rapid HIV tests represented nearly 91% of the Company’s product revenues in the six months ended June 30, 2010. The Company also has other rapid tests that together represented approximately 9% of sales in the first six months of 2010. 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 owned by Alere North America, Inc. (“Alere”, formerly Inverness Medical Innovations, Inc.), which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company’s products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2008, 2009 and the first six months of 2010, the Company completed development of its first four 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 consolidated interim financial information as of June 30, 2010 and for the three and six-month periods ended June 30, 2010 and 2009 have been prepared without audit, 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, 2009, 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 consolidated financial position as of June 30, 2010, its consolidated results of operations for the three and six-month periods ended June 30, 2010 and 2009 and its cash flows for the six-month periods ended June 30, 2010 and 2009, 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 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 R&D contracts and grants when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

For certain collaborative research projects the Company recognizes revenue by defining milestones at the inception of the agreement and determining when it may be appropriate to apply the milestone method of revenue recognition.

Any projects or grants funded in advance are deferred until earned. As of June 30, 2010, an aggregate of \$115,000 of advanced revenues was unearned.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2010  
(UNAUDITED)

## (c) Inventories:

Inventories consists of the following at:

	(Audited)	
	December 31,	
June 30, 2010	2009	
Raw materials	\$ 869,670	\$ 1,031,567
Work in process	273,909	184,081
Finished goods	706,129	340,255
	\$ 1,849,708	\$ 1,555,903

## (d) Earnings (Loss) Per Share:

The following weighted average number of shares was used for the computation of basic and diluted earnings (loss) per share:

	For the three months ended		For the six months ended	
	June 30, 2010	June 30, 2009	June 30, 2010	June 30, 2009
Basic	62,070,736	61,944,901	62,028,450	61,944,901
Diluted	70,614,048	74,814,205	71,340,820	61,944,901

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted income (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 six-month period ended June 30, 2009 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 that period. The following securities, presented on a common share equivalent basis for the three-month periods ended June 30, 2010 and 2009 and the six-month period ended June 30, 2010, were included in computing diluted earnings per share; for the six month period ending June 30, 2009, these were excluded from the diluted loss per share computation:

	For the three months ended		For the six months ended	
	June 30, 2010	June 30, 2009	June 30, 2010	June 30, 2009
1999 and 2008 Plan				
Stock Options	5,704,933	4,140,554	5,683,602	3,264,033
Other Stock Options	124,625	124,625	124,625	124,625
Warrants	2,713,754	8,604,125	3,504,143	9,383,684
	8,543,312	12,869,304	9,312,370	12,772,342

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

## (e) Employee Stock Option Plan:

The Company has a 1999 Stock Option Plan (“SOP”) that originally covered the potential issuance of options to purchase 1,500,000 shares of Common Stock. Under the terms of the SOP, the Compensation Committee of the Company’s Board is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and other key individuals. The options become exercisable at such times and under such conditions as determined by the Compensation Committee. The SOP was amended at the Company’s 2005 stockholders’ meeting. The number of options under the SOP was increased to 3,000,000 shares of Common Stock. It was also amended to allow independent directors to be eligible for grants under the portion of the SOP concerning non-qualified options.

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.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six-month periods ended June 30, 2010 and 2009 was \$.22 and \$.09 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		For the six months ended	
	June 30, 2010	June 30, 2009	June 30, 2010	June 30, 2009
Expected term (in years)	n/a	4	5	4
Expected volatility	n/a	123.81%	116.82%	123.81%
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	n/a	2.98%	1.43%	1.81-1.95%

The Company's results for the six-month periods ended June 30, 2010 and 2009 include share-based compensation expense totaling \$114,000 and \$92,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$13,000 and \$9,000, respectively), research and development (\$60,000 and \$36,000, respectively) and selling, general and administrative expenses (\$41,000 and \$47,000, 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.

Stock option compensation expense for the six-month periods ended June 30, 2010 and 2009 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.



## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

The following table provides stock option activity for the six months ended June 30, 2010:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2009	2,416,650	\$ 0.36	3.23 years	\$ -
Impact of re-price (for accounting purposes treated as a cancellation and re-issue):				
effect as if cancelled	(1,252,750 )	\$ 0.48		
effect as if re-issued	1,252,750	\$ 0.13		
Granted	3,459,000	\$ 0.13		
Exercised	(35,000 )	\$ 0.13		
Forfeited/expired /cancelled	(253,750 )	\$ 0.17		
Outstanding at December 31, 2009	5,586,900	\$ 0.15	3.59 years	\$ 756,990
Granted	300,000	\$ 0.27		
Exercised	(158,250 )	\$ 0.13		
Forfeited/expired/cancelled	(97,250 )	\$ 0.26		
Outstanding at June 30, 2010	5,631,400	\$ 0.16	3.29 years	\$ 734,925
Exercisable at June 30, 2010	3,064,725	\$ 0.13	2.75 years	\$ 377,924

As of June 30, 2010, there was \$158,000 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted average period of approximately 1.33 years. The total fair value of stock options vested during the six-month periods ended June 30, 2010 and 2009, was approximately \$125,000 and \$107,000, 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, 2010	June 30, 2009	June 30, 2010	June 30, 2009
Africa	\$ 820,980	\$ 999,048	\$ 1,317,871	\$ 1,458,785
Asia	33,457	72,458	84,511	94,599
Europe	28,178	27,087	60,632	45,772
Middle East	76,192	60,949	103,135	92,996

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

North America	1,344,134	1,252,338	2,867,771	2,171,365
South America	32,724	639,505	116,642	1,457,284
	\$ 2,335,665	\$ 3,051,385	\$ 4,550,562	\$ 5,320,801



## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

## (g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

		(Audited)	
	June 30, 2010	December 31, 2009	
Accounts payable – suppliers	\$ 448,125	\$ 662,739	
Accrued royalties / license fees	521,335	612,709	
Accrued payroll	84,566	114,234	
Accrued vacation	144,045	99,057	
Accrued bonuses	-	238,600	
Accrued expenses – other	112,674	178,824	
<b>TOTAL</b>	<b>\$ 1,310,745</b>	<b>\$ 1,906,163</b>	

## (h) Recent Accounting Pronouncements Affecting the Company

## Revenue Arrangements with Multiple Deliverables

In October 2009, the Financial Accounting Standards Board (“FASB”) issued authoritative guidance (“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 is effective for fiscal years beginning on or after June 15, 2010. The Company is evaluating the impact this guidance may have on its condensed consolidated financial statements.

## Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades

In April 2010, the FASB issued guidance which clarified that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity’s equity shares trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. The Company is evaluating the impact that this guidance will have on its condensed consolidated financial statements, if any.

## Milestone Method of Revenue Recognition

In April 2010, the FASB issued guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and nonsubstantive milestones, and each milestone should be evaluated individually to determine if it is substantive. This guidance is effective on a prospective basis for milestones achieved in fiscal years,

and interim periods within those years, beginning on or after June 15, 2010, with early adoption permitted. This guidance was adopted by the Company and was effective as of January 1, 2010. The provisions of this guidance have been applied to all research and development agreements prospectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

Disclosures about the Credit Quality of Financing Receivables and the Allowance for Credit Losses

In July 2010, the FASB issued guidance that requires more information about the credit quality of financing receivables in the disclosures to financial statements, such as aging information and credit quality indicators. Both new and existing disclosures must be disaggregated by portfolio segment or class. The disaggregation of information is based on how a company develops its allowance for credit losses and how it manages its credit exposure. Financing receivables include loans and trade accounts receivable. However, short-term trade accounts receivable, receivables measured at fair value or lower of cost or fair value, and debt securities are exempt from these disclosure amendments. This guidance is effective for periods ending on or after December 15, 2010. The amendments that require disclosures about activity that occurs during a reporting period are effective for periods beginning on or after December 15, 2010. The Company is evaluating the impact that this guidance will have on its condensed consolidated financial statements, if any.

NOTE 3—COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a. Oswaldo Cruz Foundation/Fiocruz:

On September 26, 2008, the Company signed an Agreement (“FIOCRUZ Agreement”), with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil (“FIOCRUZ”) for the transfer of technology from the Company to FIOCRUZ, for patents applied in Brazil or other Mercosur countries for the term of the patents and the transfer of all technical information related to DPP® HIV 1/2 rapid test (“DPP® technology”) and the process to obtain rapid test for the detection of HIV1/2 by the DPP® technology. This Agreement contemplates the scientific and technological co-operation between the Company and FIOCRUZ for such activities so that FIOCRUZ will be able to manufacture the DPP® technology in Brazil.

Based on the following events, in accordance with guidance, management has concluded the FIOCRUZ event recorded this quarter meets the definition of a milestone event:

- a) The company had a specific outcome through achieving registration of the DPP® technology by ANVISA.
- b) There was substantive uncertainty at the date the arrangement was entered into on September 2008, as there was no guarantee that the product under the FIOCRUZ agreement would receive approval by ANVISA.
- c) This event results in additional payments being due to the Company in the future.

As required in guidance, management evaluated the substantive uncertainty existed as follows:

- a) The consideration is commensurate with the Company’s performance to achieve the milestone (ANVISA approval).
- b) The consideration of \$400,000 relates solely to past performance from the initiation of the agreement through June 30, 2010 (the payment consideration date), as the company provided R&D type activities to enable the product to be approved by ANVISA, already owned the DPP® technology and is non-refundable.
- c) It is reasonable relative to all of the deliverables and payment terms within the arrangement as the bulk of the revenue will be provided through additional future royalties and purchase commitments due to the Company. Under the FIOCRUZ Agreement, after the Product registration by ANVISA, the Company will supply product and FIOCRUZ will do their best efforts to purchase each year for a period of three years from the Company the amount of 833,333 units of product at a product transfer price of \$3.00 per unit for a minimum aggregate purchase obligation equal to \$7.5M. Following the purchase of \$7.5 million, during each of the succeeding two years, FIOCRUZ will

purchase test components as specified by FIOCRUZ at an aggregate purchase price of \$1.25 million in each of the fourth and fifth year.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

b. Bio-Rad:

On April 16, 2008, the Company announced a development agreement (“Bio-Rad Agreement”) with Bio-Rad Laboratories, N.A. (“Bio-Rad”). The Agreement with Bio-Rad is for the development of a new multiplex product (“product”) that would be developed on DPP® and which would be marketed exclusively by Bio-Rad under an exclusive limited DPP® license from Chembio to Bio-Rad limited to the field of application of this product. The agreement with Bio-Rad contemplated that the Company would enter into a license agreement subject to the satisfaction of certain development and other conditions. On January 19, 2009, Chembio granted, effective December 31, 2008, a limited exclusive license (“License Agreement”) within a defined field of application for Chembio’s DPP® technology to Bio-Rad. The license was granted following development milestones as set forth in the agreement mentioned above.

Based on the following events, in accordance with guidance, management has concluded the Bio-Rad events recorded this quarter meet the definition of a single milestone event:

- a) The company had a specific outcome completing Phase 2 “End of the Development Phase” as listed in the Work Schedule and Flow Chart where Bio-Rad has made the decision to transfer the product to Chembio’s manufacturing process.
- b) There was substantive uncertainty at the date the arrangement was entered into on April 2008, as there was no guarantee that any Phase of the development program would be achieved.
- c) This event results in additional payments being due to the Company in the future.

As required in guidance, management evaluated the substantive uncertainty existed as follows:

- a) The consideration is commensurate with the Company’s performance to achieve the milestone, Phase 2 in accordance with work schedule as provided in the Bio-Rad agreement.
- b) The consideration of \$465,000 relates solely to past performance from the initiation of the agreement through June 29, 2010 (the payment consideration date), as the company provided R&D type activities to enable the product to be available to transfer to manufacturing.
- c) It is reasonable relative to all of the deliverables and payment terms within the arrangement as there are additional royalties and purchase commitments due to the Company to be executed in the future which will result in a larger revenue stream. Under the Bio-Rad Agreement, after the execution of the transfer of manufacturing, the Company will be due an additional \$75,000 upon Bio-Rad’s written decision to validate the Effective Transfer of Manufacturing to Bio-Rad, an additional \$75,000 payable one year after the Bio-Rad’s written decision to validate the Effective Transfer of Manufacturing to Bio-Rad. Under the Bio-Rad Agreement, the Company granted to Bio-Rad a royalty free license when the Company manufactures the product, and when Bio-Rad manufactures the product a seven percent royalty payment on net sales in those countries and other jurisdictions where Chembio has filed the relevant patent.

c. 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. In addition, the Company has several development contracts with third parties related to its DPP® technology. These development projects are funded in advance and are presented as deferred revenue until earned.



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

d. Battelle/CDC DPP® Influenza Immunity Test:

In December 2009, Chembio entered into a development agreement for up to approximately \$900,000 in connection with the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplates a period of approximately nine months in which the development activity is to be completed. Chembio entered this agreement with Battelle Memorial Institute, which has a master contract with the United States Centers for Disease Control and Prevention ("CDC"), to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of CDC. As of June 30, 2010, the Company earned \$521,777 in research and development revenues from this agreement.

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 of the Term Note is five years, expiring June, 2015. The Term Note 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. (CMLTD is 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, 2010. 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 June 30, 2010 was \$250,000 and nothing was drawn down on the Demand Note as of June 30, 2010.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
 NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
 JUNE 30, 2010  
 (UNAUDITED)

Future minimum payments under the Term Note, excluding interest, as of June 30, 2010 were as follows:

Year ending June 30,	
2011	\$44,668
2012	47,188
2013	49,850
2014	52,662
2015	55,632
	250,000.00
Less: current maturities	(44,668 )
	\$205,332

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 June 30, 2010 was \$18,965.

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 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 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 shall be 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.

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

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

NOTE 6 — 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 As of June 30, 2010
	June 30, 2010		June 30, 2009		June 30, 2010		June 30, 2009		
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	
Customer 1	1,288,038	55	1,160,765	38	2,449,965	54	2,004,872	38	-
Customer 2	474,564	20	728,640	24	474,564	10	728,640	14	575,400
Customer 3	*	*	556,600	18	*	*	1,349,800	25	*

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 six months ended				Accounts Payable As of June 30, 2010
	June 30, 2010		June 30, 2009		June 30, 2010		June 30, 2009		
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	
Vendor 1	76,400	15	134,526	20	184,063	14	259,588	22	8,160

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.

14

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

(c) Agreement with Alere:

On June 25, 2009, the Company and Alere North America, Inc. (“Alere”, formerly Inverness Medical Innovations, Inc.) entered into a letter agreement whereby certain obligations aggregating approximately \$1,010,000 as of December 31, 2008 were agreed to be paid from future revenues. The obligations include the Company’s share under its agreements with Alere for the amount of HIV-2 royalties that Alere paid when Alere entered into an HIV-2 license agreement with Bio-Rad Laboratories, Inc. of approximately \$485,000 and royalties owed by Chembio on lateral flow licenses to Alere of approximately \$525,000 as of December 31, 2008. Under the agreement, Alere will retain an additional 10% of Clearview® HIV 1/2 STAT-PAK® net sales and 5% of Clearview® Complete HIV 1/2 net sales until these obligations are extinguished. As of June 30, 2010, the full amount was extinguished.

(d) 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.

(e) Equipment Purchase Commitment:

In June and November of 2009, the Company entered into agreements with a tooling manufacturer to design and build a tool for cassettes that house its tests. The estimated cost of \$62,800 is being paid in installments. As of June 30, 2010, an aggregate of \$38,800 has been paid for this tooling and is included in other assets on the Company’s balance sheet. In addition, \$14,025 of progress payments on leasehold improvements has been paid and is included in other assets on the Company’s balance sheet.

## 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 have not changed significantly from December 31, 2009.

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "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 half of 2010, the Company had a total of \$1,592,000 of research and development expenses, which were comprised of \$356,000 of clinical and regulatory expenses and \$1,236,000 of research and development expenses. The research and development expenses include the costs of personnel to assist both in the transfer of newly developed products into the Company's manufacturing operation and also to provide technical support to the Company's manufacturing operation. During the first half of 2010, the Company realized revenue in respect of research and development agreements and grants in the amount of \$1,243,000 versus revenue of \$546,000 for the six-month period ended June 30, 2009.

16

---

Therefore, while the Company increased its research and development expenses in the first half of 2010 versus the first half of 2009, it has more than offset these increased research and development expenses with income from research and development agreements and grants. The Company has been able to utilize these funded development programs to enhance its proprietary capabilities.

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&2. We have completed development of all of these products. During the second quarter we received notification from FIOCRUZ that our DPP® HIV screening test was approved by Brazil's National Health Surveillance Agency (ANVISA). Two of the other three products HIV confirmatory and Canine Leishmaniasis, have already been submitted for regulatory approval. During the second quarter there was additional evaluation materials and documentation that was requested of us by FIOCRUZ related to the HIV confirmatory and leishmaniasis tests, which request we believe has been satisfied. We are in the process of validating the manufacture of the Leptospirosis product so that we can provide evaluation lots and documentation to FIOCRUZ for their regulatory approval submission of this product to ANVISA during the third quarter. Although there can be no assurance, we believe that the three remaining products will receive Brazilian regulatory approval (ANVISA for the HIV Confirmatory and Leptospirosis tests and MAPA for the canine leishmaniasis test) during 2010.

**Bio-Rad Laboratories OEM DPP® Agreement**- On April 6, 2008, we entered a development agreement with Bio-Rad Laboratories N.A., a division of Bio-Rad Laboratories Inc. (NYSE:BIO), a leading in-vitro diagnostic and life science company. The agreement with Bio-Rad is for the development of a six band multiplex product on our DPP®. On June 25, 2010, the Company received a letter from Bio-Rad, confirming the completion of Phase 2 (the Development Phase) of the Agreement. In addition, Bio-Rad exercised its option right for the transfer to Bio-Rad of exclusive manufacturing rights for the Product.

**Battelle/CDC DPP® Influenza Immunity Test** – In December 2009, Chembio entered into a development agreement for up to approximately \$900,000 in connection with the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplates a period of approximately nine months in which the development activity is to be completed. Chembio entered this agreement with Battelle Memorial Institute, an organization that has a master contract with the United States Centers for Disease Control and Prevention ("CDC") to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of the CDC. This development program is proceeding on schedule and we plan to send the first prototypes of this product to CDC during the third quarter for their evaluation.

**DPP® Hepatitis C and DPP® Hepatitis C/HIV Oral Fluid Antibody Tests** - Prototypes of these products have been developed and were evaluated in 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 some of the results of the study and have been advised that the data and analysis will be available to all manufacturers that participated with products in the study during the third quarter of 2010. The data and analysis should be useful in helping us to ascertain the performance characteristics of our products in comparison to other products that were also in this evaluation.

**DPP® Influenza** –We have developed a prototype multiplex test for FLU A/B Antigen Detection and have started design work in order to consider further modifications and optimization. We are in the process of obtaining samples that we can use in order to accurately assess development progress. This product will be our first commercial antigen detection test on DPP®, and we believe that this has independent value to demonstrate the capabilities of our

technology to access large markets beyond serological antibody detection markets. Our current plan is still for development to be completed and for our clinical studies to be initiated during 2010.

DPP® Leptospirosis – In June 2010, we completed the first year of 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 Cornell 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, Weill Medical College, Cornell University in New York and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America.



Other Research & Development Activities - Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts & 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.

In April 2009, we entered into a Services Agreement with the Infectious Disease Research Institute to develop DPP® products for Leishmaniasis and Leprosy for which we have received \$250,000 and which, subject to attainment of certain results, is expected to provide us with approximately \$75,000 within the next six months. Under this agreement, we would receive an additional \$75,000 during the second year, subject to the attainment of certain results.

In May 2010, we completed work on a Phase I NIH grant for development of a DPP® serological test for the qualitative detection of active pulmonary tuberculosis in humans. In the final Phase I report submitted to NIH we reported that the minimum sensitivity goal of 75-80% had been achieved. Based on this result, we submitted also in May 2010, a request for \$2.7 million in Phase II funding over a three-year period in order for Chembio and its collaborating organizations to optimize the assay, determine diagnostic test performance, and validate test production protocols in preparation for regulatory approval. On July 9, 2010, we were informed that the application was evaluated such that, based on historical grant approval criteria, we believe that there is a substantial likelihood of Phase II funding being awarded beginning in 2011.

In July 2010, we submitted several applications for grants that we believe are eligible Qualifying Therapeutic Discovery Projects, as part of the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148). This program is targeted to projects that show a reasonable potential to (for diagnostic products) prevent or detect chronic or acute diseases and conditions or reduce the long-term growth of health care costs in the United States, and that have the greatest potential to create and sustain high-quality, high-paying U.S. jobs and to advance U.S. competitiveness in life, biological and medical sciences. The grants are only available to companies with no more than 250 employees. The program covers up to 50 percent of a qualified investment made or to be made in 2009 and 2010, limited to a maximum of \$5 million per company.

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.

Platform Enhancements - In addition to the specific products we plan to commercialize, we also are pursuing enhancements to our DPP® technology platform during 2010 and 2011. These enhancements include enabling a simplified test procedure, lowering the overall manufacturing costs, enabling development of combination antibody and antigen assays, and integrating molecular sample amplification systems with our detection system. We are active in each of these areas subject to available resources, and also are pursuing patent protection where applicable.

During the second quarter, we began validation of certain automated assembly equipment we received delivery of in the first quarter, which we believe, if successfully validated, may result in savings to our lateral flow and DPP® assembly operation. Our plan is to complete this validation during the third quarter of 2010, although there can be no assurance of this.

Patents - During the first quarter of 2010, the Company's Dual Path Immuno-Assay device, which was granted a United States patent in 2007, received patent protection in the United Kingdom. During the first quarter of 2010, the

Company received broader protection of its DPP technology in the U.S. through the issuance of a U.S. method patent for its DPP technology. The DPP technology has also been afforded patent protection in certain other foreign jurisdictions over the last year (Malaysia, Singapore and Eur-Asia), and patent protection is being actively prosecuted in all major markets globally. We have also filed additional provisional patent applications that we believe will strengthen our intellectual property portfolio.

#### Regulatory Activities

CE Mark for FDA approved HIV tests –Based on the most recent dialog we have had with our Notified Body, we now believe we will be able to meet the CE Marking requirements for our two FDA approved rapid HIV tests, and we have developed an initial budget for this of \$76,000, though we believe additional savings can be achieved to bring this cost down further. We are in contact with certain organizations in Europe regarding our acquiring blood donor repository samples, which is the main component of this cost.

Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – We received notification from FIOCRUZ that our DPP® HIV screening test was approved by ANVISA for sale by FIOCRUZ in Brazil. We anticipate that FIOCRUZ will receive the required approvals from its regulatory agencies during the third quarter of 2010 for the DPP® Leishmaniasis test and the DPP® HIV Confirmatory test, although there can be no assurance of this.

FDA Approval for DPP® HIV 1/2 Screening Assay for Oral Fluid - We have commenced the clinical trials and they have proceeded slowly. We anticipate completing the clinical trials and submitting the PMA application during 2010, and receiving approval of the PMA before the end of 2011, although there can be no assurance of this. The pace of the clinical trials will depend upon operating cash flow or other financing sources we may pursue, the availability of which there can be no assurance.

DPP® Syphilis Screen & Confirm - We were preparing to commence clinical trials in connection with our planned 510(k) submission for this product during the third quarter of 2010, however we have had some delays in validating the manufacture of lots we need to produce for use in such clinical trials. This delay is due to inconsistency of one of the components used in the product. We believe we have identified a solution for this. We have also received some evaluation results from the retrospective international study organized by the WHO. These results require further analysis before we commence US clinical trials as the data we received from the WHO suggested some variability of results on low titer non-treponemal samples. We are trying to ascertain the reasons for this variability, and whether this variability was related to different product lots, operator training, and/or other factors. Notwithstanding this, the product was recommended for the prospective phase of the WHO study.

#### Recent Events

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 of the Term Note is five years, expiring June, 2015. The Term Note 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, and 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. (CMLTD is 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, 2010. 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 June 30, 2010 was \$250,000 and nothing was drawn down on the Demand Note as of June 30, 2010.

On June 25, 2010, the Company received a letter from Bio-Rad, confirming the completion of Phase 2 (the Development Phase) of the Agreement. In addition, Bio-Rad exercised its option right for the transfer to Bio-Rad of exclusive manufacturing rights for the Product.

As a result of the Company's receipt of confirmation of completion of Phase 2 the Company recorded revenue of \$465,000 which included a milestone fee payment of \$340,000, received in January of 2009 pursuant to the License Agreement, and an additional \$125,000 earned in June 2010 as a result of the completion of the milestone.

The exercise of the option to manufacture has triggered potential aggregate maximum payments to the Company of \$275,000. The first payment of \$125,000 is due 30 days from the date the option is exercised, the second payment, in the amount of \$75,000, is due upon Bio-Rad's making the test available for clinical evaluations, and the final payment, in the amount of \$75,000, is due one year after Bio-Rad has made the test available for clinical evaluations.

Also in accordance with the License Agreement, upon commercialization of the Product, Chembio will receive a royalty in the amount of 7% of net product sales in those countries and other jurisdictions where Chembio has filed the relevant patent.

On June 28, 2010, Bio-Manguinhos, a division of FIOCRUZ, notified the Company that it had received regulatory approval from Brazil's National Health Surveillance Agency (ANVISA) to market Chembio's DPP® HIV 1/2 rapid test. The approval triggers \$400,000 in milestone revenues, which were received by Chembio in July 2010, less withholdings of 15% from the Brazilian government for taxes, which is reflected as an expense in the quarter ended June 30, 2010.

Under the agreement with FIOCRUZ for the DPP® HIV test, Chembio is expected to transfer to FIOCRUZ the technology related to this product over a five-year period. Thereafter, assuming the technology transfer process is completed, a five-year royalty phase will begin, with royalties equal to 4% of Net Sales, as defined in the applicable agreement.

In July 2010, the Company received a purchase order from the Pharmaceuticals Fund and Supply Agency of the government of Ethiopia in the amount of \$2,056,320 for its HIV 1/2 STAT PAK® rapid HIV test. This product is a designated test in the national testing algorithm of Ethiopia. The purchase order is secured by a letter of credit containing terms acceptable to the Company. Deliveries are anticipated to be made pursuant to this purchase order during the third and fourth quarters of 2010.

#### Critical Accounting Policies and Estimates

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets, accounting for complex financial instruments and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2009, see our annual report on Form 10-K for the twelve months ended December 31, 2009, which was filed with the SEC on March 5, 2010.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2010 AS COMPARED WITH THE THREE MONTHS ENDED JUNE 30, 2009

## Revenues:

Selected Product Categories:	For the three months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
HIV	\$ 2,135,711	\$ 2,799,644	\$ (663,933 )	-23.71 %
DPP	5,601	35	5,566	15902.86 %
Other	194,353	251,706	(57,353 )	-22.79 %
Net Product Sales	2,335,665	3,051,385	(715,720 )	-23.46 %
License and royalty income	717,472	52,322	665,150	1271.26 %
R&D contracts and grants	696,305	269,817	426,488	158.07 %
Total Revenues	\$ 3,749,442	\$ 3,373,524	\$ 375,918	11.14 %

Revenues for our HIV tests and related components during the three months ended June 30, 2010 decreased by approximately \$664,000 over the same period in 2009. This was primarily attributable to decreased sales to Brazil of \$557,000 and Ethiopia of \$254,000, partially offset by increased sales in North America, primarily from sales to Alere of our HIV products, which increased by \$127,000 to \$1,288,000. The increase in R&D contracts and grants was due to revenue generated from grants and development contracts that are related to potential new products utilizing our patented DPP® technology and in addition \$125,000 earned in June 2010 as a result of the completion of the milestone in our Bio-Rad agreement. This included funds from our recent grants from NIH for Leptospirosis, which was effective as of June 1, 2009 and from Battelle for an influenza immunity test. License and royalty income includes milestone fee payments of \$340,000 from Bio-Rad pursuant to the License Agreement we signed in January 2009 and \$400,000 in a milestone fee payment from FIOCRUZ on the approval of the Company's DPP® HIV 1/2 rapid test, and for 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			
	June 30, 2010	June 30, 2009	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 2,094,966	\$ 1,361,945	\$ 733,021	53.82 %
Less: R&D contracts and grants, license and royalties	1,413,777	322,139	1,091,638	338.87 %
Gross Margin from Net Product Sales	\$ 681,189	\$ 1,039,806	\$ (358,617 )	-34.49 %
Gross Margin %	29.16 %	34.08 %		

The increase in our gross margin was primarily due to the increase in non-product revenues (see revenues above). The decrease in our product gross margin resulted primarily from \$92,000 worth of kits that were scrapped when they failed acceptance testing, lower production in the second quarter of 2010 compared to the second quarter of 2009 consumed less of our fixed overheads and decreased sales to Brazil, which were at higher average unit prices.



## Research and Development:

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

Selected expense lines:	For the three months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$ 88,580	\$ 65,480	\$ 23,100	35.28 %
Share-based compensation	2,970	3,582	(612 )	-17.09 %
Clinical trials	77,018	15,000	62,018	413.45 %
Other	20,419	2,195	18,224	830.25 %
<b>Total Regulatory</b>	<b>188,987</b>	<b>86,257</b>	<b>102,730</b>	<b>119.10 %</b>
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	404,098	344,005	60,093	17.47 %
Consulting	5,156	32,538	(27,382 )	-84.15 %
Share-based compensation	13,496	30,554	(17,058 )	-55.83 %
Materials and supplies	127,279	143,710	(16,431 )	-11.43 %
Other	52,580	65,922	(13,342 )	-20.24 %
<b>Total other than Regulatory</b>	<b>602,609</b>	<b>616,729</b>	<b>(14,120 )</b>	<b>-2.29 %</b>
<b>Total Research and Development</b>	<b>\$ 791,596</b>	<b>\$ 702,986</b>	<b>\$ 88,610</b>	<b>12.60 %</b>

Expenses for Clinical & Regulatory Affairs for the three months ended June 30, 2010 increased by \$103,000 as compared to the same period in 2009. This was primarily due to expenses we incurred in 2010 for clinical trials conducted for our DPP HIV Screen Assay. In addition, increases in wages and related costs also contributed to the increase.

R&D expenses other than Clinical & Regulatory Affairs decreased by \$14,000 in the three months ended June 30, 2010 as compared with the same period in 2009 and were primarily related to decreases in all categories, except for an increase in personnel required to perform the work related to the funded research and development contracts and grants all related to our patented DPP® technology.

Research and development expenses net of revenues from R&D contracts and grants (see sub-heading Revenues above) was \$95,000 for the three months ended June 30, 2010 (\$791,000 less \$696,000) compared to \$433,000 (\$703,000 less \$270,000) for the same period in 2009.

## Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
Wages and related costs	\$ 238,658	\$ 200,171	\$ 38,487	19.23 %
Consulting	41,745	46,129	(4,384 )	-9.50 %
Commissions	16,020	82,333	(66,313 )	-80.54 %
Share-based compensation	17,015	36,563	(19,548 )	-53.46 %



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

Marketing materials	8,422	3,505	4,917	140.29	%
Investor relations	61,949	4,276	57,673	1348.76	%
Legal, accounting and SOX 404 compliance	96,893	61,658	35,235	57.15	%
Travel, entertainment and trade shows	14,804	7,808	6,996	89.60	%
Other	184,508	100,006	84,502	84.50	%
Total S, G &A	\$ 680,014	\$ 542,449	\$ 137,565	25.36	%

Selling, general and administrative expenses for the three months ended June 30, 2010 increased by 25% as compared with the same period in 2009. This was primarily due to the recording of \$60,000 in Brazilian tax withholdings on the milestone payment, an increase in investor relations, an increase in wages and related expenses and an increase in legal, accounting and SOX 404 compliance expenses, partially offset by a decrease in commissions as a result of lower sales in Brazil.

## Other Income and (Expense):

	For the three months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
Other income	\$ -	\$ (6,696 )	\$ 6,696	-100.00 %
Interest income	618	1,531	(913 )	-59.63 %
Interest expense	(2,057 )	(1,406 )	(651 )	46.30 %
Total Other Income and (Expense)	\$ (1,439 )	\$ (6,571 )	\$ 5,132	-78.10 %

Other income and (expense) for the three months ended June 30, 2010 decreased approximately \$5,000 as compared with the same period in 2009, primarily as a result of a loss on the sale of an asset in 2009 wasn't repeated and was partially offset by an increase in interest expense and a decrease in interest income due to a decrease in interest rates in interest-bearing accounts.

## RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2010 AS COMPARED WITH THE SIX MONTHS ENDED JUNE 30, 2009

## Revenues:

Selected Product Categories:	For the six months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
HIV	\$ 4,143,044	\$ 4,396,439	\$ (253,395 )	-5.76 %
DPP	5,601	619,530	(613,929 )	-99.10 %
Other	401,917	304,832	97,085	31.85 %
Net Product Sales	4,550,562	5,320,801	(770,239 )	-14.48 %
License and royalty income	738,968	52,322	686,646	1312.35 %
R&D contracts and grants	1,243,328	545,999	697,329	127.72 %
Total Revenues	\$ 6,532,858	\$ 5,919,122	\$ 613,736	10.37 %

Revenues for our HIV tests and related components during the six months ended June 30, 2010 decreased by approximately \$253,000 over the same period in 2009. This was primarily attributable to decreased sales to Brazil of \$815,000 and Ethiopia of \$254,000, partially offset by increased sales in North America, primarily from sales to Alere of our HIV products, which increased by \$445,000 to \$2,450,000 as well as sales to Mexico of \$275,000. The increase in R&D contracts and grants was due to revenue generated from grants and development contracts that are related to potential new products utilizing our patented DPP® technology and in addition \$125,000 earned in June 2010 as a result of the completion of the milestone in our Bio-Rad agreement. This included funds from our recent grants from NIH for Leptospirosis, which was effective as of June 1, 2009, and from Battelle for an influenza immunity test. License and royalty income includes milestone fee payments of \$340,000 from Bio-Rad pursuant to the License Agreement we signed with them in January 2009 and \$400,000 in a milestone payment from FIOCRUZ on the approval of the Company's DPP® HIV 1/2 rapid test and for royalties from Brazil under our 2004 technology transfer and license agreement.

## Gross Margin:

Gross Margin related to Net Product Sales:	For the six months ended		\$ Change	% Change	
	June 30, 2010	June 30, 2009			
Gross Margin per Statement of Operations	\$ 3,401,340	\$ 2,360,634	\$ 1,040,706	44.09	%
Less: R&D contracts and grants, license and royalties	1,982,296	598,321	1,383,975	231.31	%
Gross Margin from Net Product Sales	\$ 1,419,044	\$ 1,762,313	\$ (343,269 )	-19.48	%
Gross Margin %	31.18 %	33.12 %			

The increase in our gross margin was primarily due to the increase in non-product revenues (see revenues above). The decrease in our product gross margin resulted primarily from \$92,000 worth of product that were scrapped when they failed acceptance testing, lower production in the six months of 2010 compared to the six months of 2009 consumed less of our fixed overheads and decreased sales to Brazil, which were at higher average unit prices.

## Research and Development:

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

Selected expense lines:	For the six months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
<b>Clinical and Regulatory Affairs:</b>				
Wages and related costs	\$ 170,051	\$ 131,029	\$ 39,022	29.78 %
Consulting	14,805	15,181	(376 )	-2.48 %
Share-based compensation	7,638	3,582	4,056	113.23 %
Clinical trials	133,768	16,780	116,988	697.19 %
Other	29,693	9,455	20,238	214.05 %
<b>Total Regulatory</b>	<b>\$ 355,955</b>	<b>\$ 176,027</b>	<b>\$ 179,928</b>	<b>102.22 %</b>
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	\$ 828,691	\$ 698,720	\$ 129,971	18.60 %
Consulting	15,139	49,970	(34,831 )	-69.70 %
Share-based compensation	51,756	37,736	14,020	37.15 %
Materials and supplies	234,538	254,492	(19,954 )	-7.84 %
Other	106,275	133,413	(27,138 )	-20.34 %
<b>Total other than Regulatory</b>	<b>\$ 1,236,399</b>	<b>\$ 1,174,331</b>	<b>\$ 62,068</b>	<b>5.29 %</b>
<b>Total Research and Development</b>	<b>\$ 1,592,354</b>	<b>\$ 1,350,358</b>	<b>\$ 241,996</b>	<b>17.92 %</b>

Expenses for Clinical & Regulatory Affairs for the six months ended June 30, 2010 increased by \$180,000 as compared to the same period in 2009. This was primarily due to expenses we incurred in 2010 for clinical trials conducted for our DPP HIV Screen Assay. In addition, increases in wages and related costs also contributed to the increase.

R&D expenses other than Clinical & Regulatory Affairs increased by \$62,000 in the six months ended June 30, 2010 as compared with the same period in 2009 and were primarily related to an increase in personnel required to perform the work related to the funded research and development contracts and grants all related to our patented DPP® technology and an increase in the cost of share-based compensation related to the value of employee stock options issued and amortized. These increases were partially offset by a decrease in consulting and other costs.

Research and development expenses net of revenues from R&D contracts and grants (see sub-heading Revenues above) was \$349,000 for the six months ended June 30, 2010 (\$1,592,000 less \$1,243,000) compared to \$804,000 (\$1,350,000 less \$546,000) for the same period in 2009.

## Selling, General and Administrative Expenses:

Selected expense lines:	For the six months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
Wages and related costs	\$ 479,113	\$ 437,253	\$ 41,860	9.57 %
Consulting	97,621	107,871	(10,250 )	-9.50 %
Commissions	33,569	166,296	(132,727 )	-79.81 %

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

Share-based compensation	41,338	46,564	(5,226 )	-11.22	%
Marketing materials	9,768	9,938	(170 )	-1.71	%
Investor relations	99,352	7,315	92,037	1258.20	%
Legal, accounting and SOX 404 compliance	272,521	222,018	50,503	22.75	%
Travel, entertainment and trade shows	30,291	24,756	5,535	22.36	%
Other	278,289	196,251	82,038	41.80	%
Total S, G &A	\$ 1,341,862	\$ 1,218,262	\$ 123,600	10.15	%

Selling, general and administrative expenses for the six months ended June 30, 2010 increased by 10% as compared with the same period in 2009. This was primarily due to the recording of \$60,000 in Brazilian tax withholdings on the milestone payment, an increase in investor relations, an increase in wages and related expenses and an increase in legal, accounting and SOX 404 compliance expenses, partially offset by a decrease in commissions as a result of lower sales in Brazil.

## Other Income and (Expense):

	For the six months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
Other income (expense)	\$ -	\$ (6,696 )	\$ 6,696	-100.00 %
Interest income	1,729	4,915	(3,186 )	-64.82 %
Interest expense	(4,262 )	(5,527 )	1,265	-22.89 %
Total Other Income and (Expense)	\$ (2,533 )	\$ (7,308 )	\$ 4,775	-65.34 %

Other income and (expense) for the three months ended June 30, 2010 improved by approximately \$5,000 as compared with the same period in 2009, primarily as a result of a loss on the sale of an asset in 2009 wasn't repeated and partially because of a decrease in interest expense, both of which were partially offset by a decrease in interest income due to a decrease in interest rates in interest-bearing accounts.

## LIQUIDITY AND CAPITAL RESOURCES

	For the six months ended			
	June 30, 2010	June 30, 2009	\$ Change	% Change
Net cash (used in) provided by operating activities	\$ (431,648 )	\$ 847,768	\$ (1,279,416 )	-150.92 %
Net cash used in investing activities	(144,345 )	(221,080 )	76,735	-34.71 %
Net cash provided by financing activities	254,606	20,159	234,447	1162.99 %
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	\$ (321,387 )	\$ 646,847	\$ (968,234 )	-149.69 %

The Company had a decrease in cash for the six months ended June 30, 2010 as compared to an increase in cash for the same period in 2009. The decrease during the 2010 period is primarily attributable to cash used in operations. The increase in the 2009 period is primarily attributable to the cash provided by operations, including cash received of \$340,000 as deferred revenue. The decreased cash from operations in 2010 was primarily attributable to the increase in inventories of \$294,000, a decrease in deferred revenue of \$246,000 and a decrease in accounts payable of \$635,000. The increase in inventories was in response to an anticipated order resulting from anticipated approval in Brazil for one of our products, while the approval has not yet been received it is expected during the third quarter of 2010 and will result in the shipment of this inventory. The decrease in deferred revenue was due to the achievement of a milestone for which payment was received in January 2009 and for which there was no counterpart in 2010. The Company's non-cash expenses totaled \$416,000, which consisted of \$148,000 from depreciation expense, \$114,000 in share based compensation expense and \$154,000 in the amortization of licenses.

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

The milestones Chembio achieved during the second quarter of 2010 provided strong validation of our DPP® technology as further progress was made toward commercializing this patented technology in a variety of point-of-care applications. These milestones included the completion of the product development phase of our six band multiplex product pursuant to our April 2008 agreement with Bio-Rad Laboratories, Inc. and the approval granted to our Brazilian customer FIOCRUZ by its regulatory body ANVISA to sell our DPP® HIV screening assay for use with oral fluid or blood samples. Additionally, in July 2010, the CDC Mozambique study results were published showing that Chembio's DPP® HIV 1/2 oral fluid screening assay yielded superior results in comparison to the other oral fluid test, as well as the two blood tests that are in the Mozambique national algorithm.

Based on the ANVISA product approval in Brazil, we anticipate that we will receive during the third quarter of 2010 an initial order from FIOCRUZ for this product, although there can be no assurance of this. Under the agreement, a technology transfer to FIOCRUZ for this product is anticipated to occur over a five-year period, with anticipated aggregate minimum sales by Chembio to FIOCRUZ of this product and related components of \$10 million over the period. Thereafter, it is anticipated that the technology transfer process will be complete and a five-year royalty phase will occur, with royalties of 4% of Net Sales as defined in the applicable agreement. In 2004, Chembio and FIOCRUZ entered a similar agreement for Chembio's HIV 1/2 STAT-PAK and components from which Chembio has realized approximately \$7.8 million of revenues from 2004-2009. Since 2009 royalty payments have averaged approximately \$24,000 per quarter for that product.

Although there can be no assurance, we are optimistic that additional approvals will be forthcoming from Brazil for the other two products that have been pending regulatory approval. We have been thoroughly briefed on the status of these submissions and believe we will receive approval, although there can be no assurance of this.

We believe the completion of the product development phase in our development contract with Bio-Rad demonstrates our capability of developing highly accurate multiplex (in this case 6 parameters) diagnostic devices, including tests that could be used for confirmation or differentiation of disease status. In fact the development project we have with Battelle/CDC for the influenza immunity test also is capitalizing on this capability, and we have other potential projects that would also leverage this unique capability of DPP® .

Bio-Rad has exercised its right to manufacture this product, triggering fees due to Chembio associated with such transfer. Thereafter, we anticipate Bio-Rad will prepare regulatory submissions for the product globally. Under Bio-Rad's limited exclusive DPP® license for this field of products, Chembio will be due royalties in the amount of 7% of Bio-Rad's Net Sales (as defined in the applicable agreement) from all jurisdictions where the DPP® patent is issued or being pursued.

The 1,266% increase in license revenue and 158% increase in R&D and grant revenue during the second quarter of 2010 as compared with the same period in 2009 more than offset the 23.7% decrease in net product sales during the second quarter of 2010. The increase is attributable to the combined occurrence of several R&D contracts and grants as described above.

The 23.7% decrease in product sales was almost entirely attributable to the fact that in the second quarter of 2009 we realized the final sales to FIOCRUZ related to our 2004 agreement, which agreement is now in the royalty phase. We believe that the new product approval in Brazil described above will replace the business we enjoyed from 2004 through 2009.

Based on the current forecast from Alere, we believe our sales to Alere for the balance of the year will be level with the amount achieved during the first half, and decreased from the level of the second half of 2009. This is based on higher inventory levels from product shipped during the fourth quarter of 2009 that have been utilized this year. We

believe that the longer term outlook for the U.S. rapid HIV test market remains strong based on increased adoption of CDC routine HIV testing recommendations in some jurisdictions, the new national HIV strategy announced by the Obama administration in July, new marketing initiatives by Alere, continued strong customer satisfaction with our rapid HIV tests in the U.S. market, and possible state budgetary constraints that may be making the use of our competitors' tests less justifiable, particularly where use of finger-stick whole blood is sufficiently convenient.

During June 2010, we received two significant orders from customers in Africa which we believe will result in our substantially increasing our sales to this region in 2010 as compared with 2009. In 2009, we realized net sales to this region of \$3,351,000. Based on our current backlog we anticipate that we will realize at least a 25% increase in sales to Africa in 2010, or at least approximately \$900,000 to \$4,250,000. This is the case notwithstanding the 9.6% decrease we have experienced during the first six months of 2010.



Our operating results during the second quarter of 2010 include approximately \$100,000 of finished product written off due to cosmetic defects attributable to inconsistencies in a supplier's component which we did not adequately pre-screen prior to introduction into our manufacturing process. We have since developed a pre-qualification regime for this component that we believe will prevent this from recurring, though there can be no assurance of this. As a result, our gross margin was negatively impacted by approximately 4%.

Our business plan in general is to manage our expenditures related to our development, regulatory approval, and commercialization of our new DPP® products based on our current operating cash flow from our base business, and as supplemented by fees and contract development income we receive from our OEM, contract development agreements and grants. For the remainder of 2010, we anticipate additional approvals in Brazil and initial products sales there, continued strong R&D contract and grant revenues as compared to 2009, modest growth in sales to Alere, and increased sales to the Africa region based upon confirmed orders we have received. The extent to which these objectives, among others, are achieved will determine to what extent 2010 is a successful year.

We believe that our cash flow from these sources will enable us to move our development programs forward, as it did during the first half of the year, although there can be no assurance of this.

Our ability to fully fund the commercialization of our new HIV, Syphilis and Influenza products, which will cost approximately \$3 million, will depend on our generating positive cash flow from our business or if deemed to be in the Company's interest, other financing sources. We have considered the issuance of common stock as one alternative way toward supplementing and/or insuring our ability to fully fund our business plan. The Company is considering other financing alternatives, such as the bank financing that we closed during the second quarter, although there can be no assurance that any of these possibilities will occur or result in an outcome that is more or less favorable to the Company and/or its stockholders.

#### Equipment Purchase Commitment:

In June and November of 2009, the Company entered into agreements with a tooling manufacturer to design and build a tool for cassettes that house its tests. The estimated cost of \$62,800 is being paid in installments. As of June 30, 2010, an aggregate of \$38,800 has been paid for this tooling and is included in other assets on the Company's balance sheet. In addition \$14,025 of progress payments on leasehold improvements has been paid and is included in other assets on the Company's balance sheet.

#### 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 second 2010 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.
3.2	Amended and Restated Bylaws. (1)
10.13	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA
10.14	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA
10.15	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA
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 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.

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: July 28, 2010      By: /s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer  
(Principal Executive Officer)

Date: July 28, 2010      By: /s/ Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

30

---

---