

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

November 04, 2010

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

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FORM 10 - Q

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

For the quarterly period ended September 30, 2010

000-30379

(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of  
incorporation)

88-0425691

(IRS Employer Identification  
Number)

3661 Horseblock Road  
Medford, New York 11763

(Address of principal executive offices including zip code)

(631) 924-1135

(Registrant's telephone number, including area code)

(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 ☐

Non-accelerated filer ☐

Smaller reporting company ☒

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(Do not check if a smaller reporting company)

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

Yes ☐ No ☒

As of November 2, 2010, the Registrant had 62,188,151 shares outstanding of its \$.01 par value common stock.

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Quarterly Report on FORM 10-Q For The Period Ended

September 30, 2010

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## PART I

## Item 1. FINANCIAL STATEMENTS

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

## - ASSETS -

	September 30, 2010 (UNAUDITED)	December 31, 2009
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,335,983	\$ 1,068,235
Accounts receivable, net of allowance for doubtful accounts of \$20,000 for 2010 and 2009	2,634,956	1,776,327
Inventories	1,883,441	1,555,903
Prepaid expenses and other current assets	190,515	266,637
<b>TOTAL CURRENT ASSETS</b>	<b>6,044,895</b>	<b>4,667,102</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>828,320</b>	<b>580,213</b>
<b>OTHER ASSETS:</b>		
License agreements, net of current portion	625,000	700,000
Deposits on manufacturing equipment	28,800	338,375
Deposits and other assets	36,226	29,560
<b>TOTAL ASSETS</b>	<b>\$ 7,563,241</b>	<b>\$ 6,315,250</b>

## - LIABILITIES AND STOCKHOLDERS' EQUITY -

<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,416,672	\$ 1,906,163
Current portion of loans payable	55,470	9,600
Deferred research and development revenue	81,673	360,833
License fee payable	875,000	875,000
Current portion of obligations under capital leases	23,865	21,536
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,452,680</b>	<b>3,173,132</b>
<b>OTHER LIABILITIES:</b>		
Loans payable - net of current portion	200,071	14,931
Obligations under capital leases - net of current portion	21,071	39,273
<b>TOTAL LIABILITIES</b>	<b>3,673,822</b>	<b>3,227,336</b>

COMMITMENTS AND  
CONTINGENCIES

STOCKHOLDERS' EQUITY:

Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 62,188,151 and 61,979,901 shares issued and outstanding for 2010 and 2009, respectively	621,882	619,799
Additional paid-in capital	39,620,376	39,453,522
Accumulated deficit	(36,352,839 )	(36,985,407 )
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>3,889,419</b>	<b>3,087,914</b>

<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 7,563,241</b>	<b>\$ 6,315,250</b>
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See accompanying notes to condensed consolidated financial statements

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

	For the three months ended		For the nine months ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
<b>REVENUES:</b>				
Net product sales	\$ 3,786,572	\$ 3,924,237	\$ 8,337,133	\$ 9,245,039
License and royalty revenue	61,789	31,388	400,758	83,710
R&D, milestone and grant revenue	656,642	408,060	2,299,970	954,058
<b>TOTAL REVENUES</b>	<b>4,505,003</b>	<b>4,363,685</b>	<b>11,037,861</b>	<b>10,282,807</b>
 Cost of product sales	 2,296,502	 2,494,719	 5,428,020	 6,053,207
<b>GROSS MARGIN</b>	<b>2,208,501</b>	<b>1,868,966</b>	<b>5,609,841</b>	<b>4,229,600</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	1,230,100	777,502	2,822,455	2,127,859
Selling, general and administrative expenses	801,854	783,810	2,143,715	2,002,073
	2,031,954	1,561,312	4,966,170	4,129,932
<b>INCOME FROM OPERATIONS</b>	<b>176,547</b>	<b>307,654</b>	<b>643,671</b>	<b>99,668</b>
<b>OTHER INCOME (EXPENSES):</b>				
Other expense	(3,923 )	-	(3,923 )	(6,696 )
Interest income	1,018	2,168	2,747	7,083
Interest expense	(5,666 )	(2,682 )	(9,927 )	(8,210 )
	(8,571 )	(514 )	(11,103 )	(7,823 )
<b>INCOME BEFORE INCOME TAXES</b>	<b>167,976</b>	<b>307,140</b>	<b>632,568</b>	<b>91,845</b>
 Provision for income taxes	 -	 -	 -	 -
<b>NET INCOME</b>	<b>\$ 167,976</b>	<b>\$ 307,140</b>	<b>\$ 632,568</b>	<b>\$ 91,845</b>
 Basic earnings per share	 \$ 0.00	 \$ 0.00	 \$ 0.01	 \$ 0.00

Diluted earnings per share	\$ 0.00	\$ 0.00	\$ 0.01	\$ 0.00
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Weighted average number of shares outstanding, basic	62,146,847	61,944,901	62,068,204	61,944,901
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Weighted average number of shares outstanding, diluted	70,547,231	75,365,577	71,074,284	74,937,831
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See accompanying notes to condensed consolidated financial statements

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

	September 30, 2010	September 30, 2009
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers	\$ 10,179,232	\$ 9,959,812
Cash paid to suppliers and employees	(9,964,407 )	(9,010,860 )
Interest received	1,110	7,083
Interest paid	(2,204 )	(8,210 )
Net cash provided by operating activities	213,731	947,825
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	-	13,750
Acquisition of fixed assets	(188,193 )	(310,035 )
Net cash used in investing activities	(188,193 )	(296,285 )
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	27,073	-
Proceeds from loan	250,000	29,228
Payment of loan obligation	(18,990 )	(2,340 )
Payment of capital lease obligation	(15,873 )	(13,841 )
Net cash provided by financing activities	242,210	13,047
NET INCREASE IN CASH AND CASH EQUIVALENTS	267,748	664,587
Cash and cash equivalents - beginning of the period	1,068,235	1,212,222
Cash and cash equivalents - end of the period	\$ 1,335,983	\$ 1,876,809
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net income	\$ 632,568	\$ 91,845
Adjustments:		



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Depreciation and amortization	212,838	278,568
Provision for doubtful accounts	-	9,699
Loss on retirement/sale of fixed asset	3,923	6,696
Share based compensation	141,864	140,517
Changes in assets and liabilities:		
Accounts receivable	(858,629 )	(335,034 )
Inventories	(327,538 )	445,053
Prepaid expenses and other current assets	76,122	(85,722 )
Deposits and other assets	101,234	213,260
Accounts payable and accrued liabilities	510,509	(176,057 )
Deferred research and development revenue	(279,160 )	359,000
Net cash provided by operating activities	\$ 213,731	\$ 947,825
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  
SEPTEMBER 30, 2010  
(UNAUDITED)

NOTE	1	—	DESCRIPTION OF BUSINESS:
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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 95% of the Company’s product revenues in the nine months ended September 30, 2010 compared with nearly 85% for the nine months ended September 30, 2009. The Company also has other rapid tests that together represented approximately 5% and 15% of sales in the first nine months of 2010 and 2009, respectively. The Company’s products are sold, directly and through distributors, to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, and medical professionals both domestically and internationally. Chembio’s products are sold under the Company’s STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Alere North America, Inc. (“Alere”, 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. Although these products employ lateral flow technologies that are proprietary and/or licensed to the Company, all of the Company’s new products that are currently being developed are based on its patented Dual Path Platform (DPP®), a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2008, 2009 and the first nine months of 2010, the Company completed development of its first four products that employ the DPP® technology, two of which attained regulatory approvals since June 2010. The Company has a number of additional products under development that employ the DPP® technology.

NOTE	2	—	SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:
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(a) Basis of Presentation:

The consolidated interim financial information as of September 30, 2010 and for the three and nine-month periods ended September 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 September 30, 2010, its consolidated results of operations for the three and nine-month periods ended September 30, 2010 and 2009 and its cash flows for the nine-month periods ended September 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.

Certain reclassifications have been made to the 2010 nine month results to conform to the third quarter 2010 presentation.

(b) Revenue Recognition

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

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

For certain collaborative research projects, the Company recognizes revenue by defining milestones at the inception of the agreement and applies the milestone method of revenue recognition for relevant contracts.

Any projects or grants funded in advance are deferred until earned. As of September 30, 2010, an aggregate of \$82,000 of advanced revenues was unearned.

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

(c) Inventories:

Inventories consists of the following at:

	September 30, 2010	(Audited) December 31, 2009
Raw materials	\$ 924,544	\$ 1,031,567
Work in process	367,492	184,081
Finished goods	591,405	340,255
	\$ 1,883,441	\$ 1,555,903

(d) Earnings Per Share:

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

	For the three months ended September 30, 2010	September 30, 2009	For the nine months ended September 30, 2010	September 30, 2009
Basic	62,146,847	61,944,901	62,068,204	61,944,901
Diluted	70,547,231	75,365,577	71,074,284	74,937,831

Basic earnings per share is computed by dividing net income attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted income per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. The following securities, presented on a common share equivalent basis for the three-month periods ended September 30, 2010 and 2009, and the nine-month periods ended September 30, 2010 and 2009 were included in computing diluted earnings per share:

	For the three months ended September 30, 2010	September 30, 2009	For the nine months ended September 30, 2010	September 30, 2009
1999 and 2008 Plan Stock Options	5,622,704	5,621,927	5,663,079	4,058,634
Other Stock Options	124,625	124,625	124,625	124,625
Warrants	2,653,055	7,674,124	3,218,376	8,809,671
	8,400,384	13,420,676	9,006,080	12,992,930

(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.

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

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the nine-month periods ended September 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 nine months ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Expected term (in years)	n/a	n/a	5	4
Expected volatility	n/a	n/a	116.82%	123.81%
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	n/a	n/a	1.43%	1.81-1.95%

The Company's results for the nine-month periods ended September 30, 2010 and 2009 include share-based compensation expense totaling \$142,000 and \$183,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$17,000 and \$25,000, respectively), research and development (\$72,000 and \$75,000, respectively) and selling, general and administrative expenses (\$53,000 and \$83,000, 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 nine-month periods ended September 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.

The following table provides stock option activity for the nine months ended September 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		

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Outstanding at December 31, 2009	5,586,900	\$ 0.15	3.59 years	\$ 756,990
Granted	300,000	\$ 0.27		
Exercised	(208,250 )	\$ 0.13		
Forfeited/expired/cancelled	(97,250 )	\$ 0.26		
Outstanding at September 30, 2010	5,581,400	\$ 0.16	3.06 years	\$ 521,369
Exercisable at September 30, 2010	3,014,725	\$ 0.13	2.54 years	\$ 261,035

As of September 30, 2010, there was \$131,000 of net unrecognized compensation cost related to stock options that have not vested, which is expected to be recognized over a weighted average period of approximately 1.11 years. The total fair value of stock options vested during the nine-month periods ended September 30, 2010 and 2009, was approximately \$125,000 and \$60,000, respectively.

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

## (f) Geographic Information:

U.S. GAAP establishes standards for the manner in which business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about products and services, geographic areas, and major customers.

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

	For the three months ended		For the nine months ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Africa	\$ 2,273,872	\$ 963,025	\$ 3,591,743	\$ 2,421,810
Asia	9,958	30,994	94,469	125,593
Europe	23,804	18,830	84,436	64,602
Middle East	18,354	57,997	121,489	150,993
North America	1,326,186	1,918,765	4,193,957	4,090,130
South America	134,398	934,626	251,039	2,391,911
	\$ 3,786,572	\$ 3,924,237	\$ 8,337,133	\$ 9,245,039

## (g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	September 30, 2010	(Audited) December 31, 2009
Accounts payable – suppliers	\$ 1,076,173	\$ 662,739
Accrued commissions	371,929	43,931
Accrued royalties / license fees	541,840	612,709
Accrued payroll	97,072	114,234
Accrued vacation	137,207	99,057
Accrued bonuses	100,000	238,600
Accrued expenses – other	92,451	134,893
TOTAL	\$ 2,416,672	\$ 1,906,163

## (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.

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

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

a. Bio-Rad:

On April 16, 2008, the Company entered into a development agreement (“Bio-Rad Agreement”) with Bio-Rad Laboratories, N.A. (“Bio-Rad”). The Bio-Rad Agreement 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 initial development milestones. On January 19, 2009, following attainment of the agreed-upon initial milestones, Chembio granted, effective December 31, 2008, a limited exclusive license (“License Agreement”) to Bio-Rad as contemplated.

In accordance with guidance, management has concluded that there were no Bio-Rad events that would meet the definition of a single milestone event during the three month period ended September 30, 2010.

There are additional royalties and purchase commitments due to the Company which may result in a larger revenue stream. Also under the Bio-Rad Agreement, after the completion of the transfer of manufacturing is confirmed, the Company will be due an additional \$75,000, and an additional \$75,000 on the first anniversary of such confirmation. Under the License Agreement, the Company will be due a seven percent royalty payment on Bio-Rad’s net sales in those countries and other jurisdictions where Chembio has filed the relevant patent.

b. Oswaldo Cruz Foundation/Fiocruz:

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

In accordance with guidance, management has concluded that the regulatory approval in Brazil of the DPP® HIV 1/2 Confirmatory product which triggered a milestone payment by FIOCRUZ to the Company under the applicable agreement (the “Confirmatory Milestone”) during the three-month period ended September 30, 2010 meets the definition of a milestone event:

- a) The Company had a specific outcome, regulatory approval in Brazil, as defined in the Agreement.
- b) There was substantive uncertainty when the Agreement was entered into in 2008, as there was no guarantee that the product under this would receive regulatory approval in Brazil.
- 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 provide the technology and support of FIOCRUZ to attain the milestone (regulatory approval in Brazil).
- b) The consideration of \$225,000 relates solely to past performance from the initiation of the agreement through September 21, 2010 (the payment consideration date), as the Company provided R&D-type activities to enable the

product to be granted regulatory approval in Brazil, already owned the DPP® technology, and the consideration 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 future purchases of the product and related components and technology. Under this FIOCRUZ agreement, after the Product is granted regulatory approval, the Company will supply product and FIOCRUZ will use its best efforts to purchase, for a period of eighteen months, 300,000 units of product at a product transfer price of \$8.00 per unit for a minimum aggregate purchase obligation equal to \$2.40 million. Following the purchase of \$2.4 million, during the succeeding eighteen months, FIOCRUZ will purchase test components as specified by FIOCRUZ at an aggregate purchase price of \$2.32 million.

As of September 30, 2010 the total milestone revenues from these agreements (including the DPP HIV 1/2 Screen which was granted regulatory approval in Brazil during the quarter ended June 30, 2010) are \$625,000. Future milestone revenues expected from the remaining two agreements are \$405,000.

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

c. Infectious Disease Research Institute (IDRI) Agreement:

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

As of September 30, 2010, the Company received \$75,000 in research and development payments from this agreement and is reflected in deferred revenue. Future milestone payments of \$75,000 are expected over the next two quarters and will be recognized when the milestones are met.

d. National Institutes of Health (NIH) Grant:

In June 2009, the Company received a \$3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred.

e. 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.

Based on the following events, in accordance with guidance, management has concluded the Battelle milestones recorded this quarter meet the definition of milestone events:

- a) The contract is a fixed price contract with a specific outcome with certain objectives to be met at specified intervals.
- b) There was substantive uncertainty at the date the arrangement was entered into in December 2009, as there was no guarantee that any milestones in the development program would be achieved.
- c) There is an expectation of future revenues from achieving these milestones.

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, in accordance with work schedule as provided in the Battelle agreement.
- b) The consideration for each milestone relates solely to past performance from the initiation of the agreement through September 30, 2010, as the Company provided R&D type activities to enable continuation of the development process.
- c) It is reasonable relative to all of the deliverables and payment terms within the arrangement as there is an expectation of purchase commitments due to the Company to be executed in the future.

As of September 30, 2010, the Company earned \$772,700 in research and development revenues from this agreement. Additional milestone payments of \$125,000 are expected over the next two quarters.



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

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

The Term Note is payable at \$4,775.29 per month in arrears. The payment was calculated by amortizing the \$250,000 note over 60 months at an interest rate of 5.5% per annum. The Term Note matures June, 2015 and is secured under the terms of the Security Agreement.

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

The Security Agreement contains covenants that place annual restrictions on the Company’s operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, restrictions on fundamental changes. The Security Agreement also requires that the Company maintain a minimum tangible net worth at all times of greater than \$3,000,000 and EBITDA to CMLTD plus interest cannot be less than 1.25 to 1.00 for any fiscal year. (CMLTD is defined as any one-year period, the current scheduled principal payments required to be paid for the applicable period.). The Company was in compliance with all required financial covenants at September 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 September 30, 2010 was \$239,000 and nothing was drawn down on the Demand Note as of September 30, 2010.

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

Periods ending September 30,

2011	\$45,286
2012	47,843
2013	50,540
2014	53,390
2015	41,926
	238,985
Less: current maturities	(45,286 )

\$193,699

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 September 30, 2010 was \$16,556.

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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:
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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.

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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 three months ended		For the nine months ended		For the nine months ended		Accounts Receivable
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009	September 30, 2009	September 30, 2010	As of September 30, 2010
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	
Customer 1	1,090,599	29	1,402,902	36	3,540,525	42	3,449,775	37	277,425
Customer 2	1,289,184	34	564,000	14	1,763,895	21	1,292,640	14	507,714
Customer 3	*	*	912,970	23	*	*	2,262,770	24	336,257
Customer 4	735,750	19	*	*	*	*	*	*	810,874
Customer 5	*	*	406,702	10	*	*	*	*	72,500

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

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

	For the three months ended		For the three months ended		For the nine months ended		For the nine months ended		Accounts Payable
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009	September 30, 2009	September 30, 2010	As of September 30, 2010
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	
Vendor 1	250,754	23	170,152	20	434,817	18	429,740	21	89,370

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

(b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration, United States Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

(c) 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 to Bio-Rad Laboratories, Inc. (Bio-Rad) when Alere entered into an HIV-2 license agreement with Bio-Rad of approximately \$485,000 as well as royalties owed by Chembio on lateral flow licenses to Alere of approximately \$525,000 as of December 31, 2008. Under the agreement, Alere retained 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.

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(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 September 30, 2010, an aggregate of \$28,800 has been paid for this tooling and is included in other assets on the Company's balance sheet.

NOTE

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SUBSEQUENT EVENTS:

On November 1, 2010, the Company was notified by the Internal Revenue Service (IRS) that it was awarded grants under the Qualifying Therapeutic Discovery Projects ("QTDP"), as part of the U.S. Patient Protection And Affordable Care Act of 2010 (P.L. 111-148). The grants are for \$1,467,000 in the aggregate covering six different projects. The grants include \$620,000 relating to qualified expenditures made in 2009, for which payment will be made immediately, and \$846,000 for qualified expenditures made or that will have been made during 2010, which amount is to be paid at the end of January 2011. Except for approximately \$100,000, the \$846,000 in grants awarded for 2010 are for expenditures already made or incurred by the Company this year to date; the Company anticipates qualifying for the full \$846,000 as a result of expenditures planned during the fourth quarter of 2010. The effect of these grants will be reflected in the fourth quarter of 2010.

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

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

### Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an ongoing basis we review our estimates and assumptions. Our estimates were based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and other than stated in Note 2 (b), have not changed significantly from December 31, 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 nine months of 2010, the Company had a total of \$2,822,000 of research and development expenses, which were comprised of \$788,000 of clinical and regulatory expenses, of which \$393,000 was for clinical trials, and \$2,034,000 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 nine months of 2010, the Company realized revenue in respect of research and development milestones and grants in the amount of \$2,300,000 versus revenue of \$954,000 for the nine-month period ended September 30, 2009.

Therefore, while the Company increased its research and development expenses in the first nine months of 2010 versus the first nine months of 2009, it has offset some of 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). During the third quarter we received notification from FIOCRUZ that our DPP® HIV confirmatory test was approved by Brazil's National Health Surveillance Agency (ANVISA). We anticipate receiving initial orders for either or both of these products in the near term, although there can be no assurance of this.

During the third quarter we were informed by FIOCRUZ that additional data was necessary to complete the Leishmania approval, and we believe that FIOCRUZ will submit this during November. We now anticipate approval of this product either late in the fourth quarter of 2010 or in the first quarter of 2011 although there can be no assurance of this. We are completing 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 fourth quarter. We believe that these products will also receive Brazilian regulatory approval in the fourth quarter of 2010 or in the first quarter of 2011 although there can be no assurance of this.

**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. The exercise of this option therefore means that Chembio will participate in the commercialization of this product through the license agreement that it executed with Bio-Rad, which agreement provides for royalties payable to Chembio at the rate of 7% of Net Sales of licensed products as defined in that agreement. During the third quarter we substantially completed the transfer of the manufacturing data to Bio Rad so that it can begin to submit this product for regulatory approval in those markets it intends to address with this product as the manufacturer of the product. We believe the regulatory submissions by Bio-Rad will commence as soon as practicable. There can be no assurance that Bio-Rad will submit this product for regulatory approval, that the product if submitted will be approved, and if approved will be successfully commercialized and produce royalty income to Chembio.

**Battelle/CDC DPP® Influenza Immunity Test** – 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. We have substantially completed the development work associated with this project and are in the process of producing prototypes for an evaluation that will take place over the next several months.

**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 the confidential results of the study which CDC is submitting for publication. This data will help 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 1Q-2011.

DPP® Leptospirosis – We are nearing the halfway point 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 Yale University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will be in collaboration with the Division of Infectious Diseases, Yale University in New Haven, CT and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America.



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 three months. Under this agreement, we would receive an additional \$75,000 during the second year, subject to the attainment of certain results.

As previously reported in July 2010, we were informed that the grant application we submitted to the NIH for \$2.7 million relating to the development of a DPP® serological test for the qualitative detection of active pulmonary tuberculosis in humans was evaluated such that, based on historical grant approval criteria and funding levels, we believe that there is a substantial likelihood of Phase II funding being awarded in the beginning of 2011.

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

Under the award guidelines, qualified therapeutic discovery projects had to show a reasonable potential to result in new therapies to treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions, reduce the long-term growth of health care costs in the United States, or significantly advance the goal of curing cancer within 30 years. Chembio's projects that received awards include products based on the Company's patented DPP® point-of-care diagnostic platform that are in various stages of its development pipeline such as its products for the rapid diagnosis of HIV, Hepatitis-C, and Syphilis.

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

There can be no assurance that any of these grant applications will result in any funding awards to the Company, nor that any of the existing research and development contracts or grants will continue or that they will meet regulatory or any other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if they are successfully completed, can or will be successfully commercialized.

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 third quarter we completed the validation of certain automated assembly equipment we received delivery of in the first quarter, which we believe should result in savings to our lateral flow and DPP® assembly operation, although there can be no assurance of this.

Patents - During the third quarter we were notified that the Company's Dual Path Immuno-Assay technology, which was granted a United States patent in 2007, is being allowed for patent protection in China and Mexico. The DPP technology has also been afforded patent protection in certain other foreign jurisdictions over the last year (United Kingdom, Malaysia, Singapore and Euro-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 –** We anticipate meeting the CE Marking requirements for our two FDA approved rapid HIV tests, though we have continued to experience delays. Our revised plan is to collect the remaining data required in order for it to be submitted during the first quarter of 2011.

**Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) –** In June and September we received notifications from FIOCRUZ that our DPP® HIV screening test and our DPP® HIV confirmatory test were each approved by ANVISA for sale by FIOCRUZ in Brazil. We anticipate that FIOCRUZ will receive the required approvals from its regulatory agencies during the fourth quarter of 2010 or the first quarter of 2011 for the DPP® Leishmaniasis test and the DPP® Leptospirosis test, although there can be no assurance of this.

**FDA Approval for DPP® HIV 1/2 Screening Assay for Oral Fluid -** We have collected approximately 25% of the clinical data required for submission to the FDA. We anticipate completing the clinical trials and submitting the PMA application during the first quarter of 2011, and receiving approval of the PMA in the beginning of 2012, 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 have completed R&D work for this product and we are now completing the full manufacturing validation of this product in anticipation of clinical trials and other activities in support of a planned 510(K) clearance commencing in the second quarter of 2011.

## 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 Note matures June, 2015 and is secured under the terms of the Security Agreement.

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

The Security Agreement contains covenants that place annual restrictions on the Company’s operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, 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 defined as any one-year period, the current scheduled principal payments required to be paid for the applicable period.). The Company was in compliance with all required financial covenants at September 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 September 30, 2010 was \$238,985 and nothing was drawn down on the Demand Note as of September 30, 2010

In September 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 Confirmatory rapid test. The approval triggers \$225,000 in milestone revenues, which is expected to be received by Chembio in the fourth quarter of 2010, less withholdings of 15% from the Brazilian government for taxes, which is reflected as an expense in the quarter ended September 30, 2010.

Under this agreement with FIOCRUZ for the DPP® HIV 1/2 Confirmatory test, Chembio is expected to transfer to FIOCRUZ the technology related to this product over a three-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. The Company shipped \$1,289,184 in the third quarter of 2010 and expects to ship the balance in the fourth quarter of 2010.

On November 1, 2010, the Company was notified by the IRS that it received awards in the total amount of \$1.467 million relating to six “Qualifying Therapeutic Discovery Projects” under the U.S. Patient Protection and Affordable Care Act of 2010 (P.L. 111-148), a program that was created as part of the major United States federal health care reform legislation enacted earlier this year. Please see discussion under “Recent Developments And Chembio’s Plan Of Operations For The Next Twelve Months” regarding QTDP for more information.

#### 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 other than stated in Note 2 (b), 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 SEPTEMBER 30, 2010 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2009

Revenues:

Selected Product  
Categories:

	For the three months ended			
	September 30, 2010	September 30, 2009	\$ Change	% Change
HIV	\$ 3,589,417	\$ 3,432,837	\$ 156,580	4.56 %
DPP	920	203,695	(202,775 )	-99.55 %
Other	196,235	287,705	(91,470 )	-31.79 %
Net Product Sales	3,786,572	3,924,237	(137,665 )	-3.51 %
License and royalty revenue	61,789	31,388	30,401	96.86 %
R&D, milestone and grant revenue	656,642	408,060	248,582	60.92 %
Total Revenues	\$ 4,505,003	\$ 4,363,685	\$ 141,318	3.24 %

Revenues for our HIV tests and related components during the three months ended September 30, 2010 increased by approximately \$157,000 over the same period in 2009. This was primarily attributable to increased sales to Ethiopia of \$1,289,000, partially offset by decreased sales of our HIV products to Brazil of \$710,000 and to Alere of \$312,000. The increase in R&D, milestone and grant revenue was due to revenue generated from grants and development contracts that are related to potential new products utilizing our patented DPP® technology and a milestone fee payment of \$225,000 from FIOCRUZ on the approval of the Company's DPP® HIV Confirmatory rapid test. This also includes 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 revenue includes royalties from Brazil under our 2004 technology transfer and license agreement.

Gross Margin:

Gross Margin related to  
Net Product Sales:

	For the three months ended			
	September 30, 2010	September 30, 2009	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 2,208,501	\$ 1,868,966	\$ 339,535	18.17 %
Less: R&D, milestone, grants, license and royalties	718,431	439,448	278,983	63.48 %
Gross Margin from Net Product Sales	\$ 1,490,070	\$ 1,429,518	\$ 60,552	4.24 %
Gross Margin %	39.35 %	36.43 %		

The increase in our gross margin was primarily due to the increase in non-product revenues (see revenues above). The increase in our product gross margin resulted primarily from an increase in our production of tests for the 2010 period

over the 2009 period which consumed more of our fixed overheads in the three months ended September 30, 2010.

## Research and Development:

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

Selected expense lines:	For the three months ended				
	September 30, 2010		September 30, 2009		
			\$ Change	% Change	
Clinical and Regulatory Affairs:					
Wages and related costs	\$ 108,722	\$ 94,517	\$ 14,205	15.03	%
Consulting	23,170	14,769	8,401	56.88	%
Share-based compensation	2,122	4,667	(2,545 )	-54.53	%
Clinical trials	259,574	29,271	230,303	786.80	%
Other	38,716	14,750	23,966	162.48	%
Total Regulatory	432,304	157,974	274,330	173.66	%
R&D Other than Regulatory:					
Wages and related costs	477,726	422,486	55,240	13.07	%
Consulting	4,052	13,577	(9,525 )	-70.16	%
Share-based compensation	10,950	14,722	(3,772 )	-25.62	%
Materials and supplies	243,332	105,824	137,508	129.94	%
Other	61,736	62,919	(1,183 )	-1.88	%
Total other than Regulatory	797,796	619,528	178,268	28.77	%
Total Research and Development					
	\$ 1,230,100	\$ 777,502	\$ 452,598	58.21	%

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2010 increased by \$274,000 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.

R&D expenses other than Clinical & Regulatory Affairs increased by \$178,000 in the three months ended September 30, 2010 as compared with the same period in 2009 and were primarily related to an increase in material and supplies along with an increase in wages and related costs due to new hires, both related to additional products being developed utilizing our patented DPP® technology, offset by decreases in all other categories.

Research and development expenses net of revenues from R&D, milestone and grant revenue (see sub-heading Revenues above) was \$573,000 for the three months ended September 30, 2010 (\$1,230,000 less \$657,000, this includes clinical trials of \$260,000) compared to \$370,000 (\$778,000 less \$408,000, this includes clinical trials of \$30,000) for the same period in 2009.

## Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended		\$ Change	% Change



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	September 30, 2010	September 30, 2009			
Wages and related costs	\$ 264,509	\$ 314,148	\$ (49,639 )	-15.80	%
Consulting	74,393	35,250	39,143	111.04	%
Commissions	32,653	120,268	(87,615 )	-72.85	%
Share-based compensation	11,543	21,378	(9,835 )	-46.01	%
Marketing materials	3,942	7,423	(3,481 )	-46.89	%
Investor relations/investment bankers	61,420	29,735	31,685	106.56	%
Legal, accounting and SOX 404 compliance	167,708	125,325	42,383	33.82	%
Travel, entertainment and trade shows	19,036	22,712	(3,676 )	-16.19	%
Other	166,650	107,571	59,079	54.92	%
Total S, G &A	\$ 801,854	\$ 783,810	\$ 18,044	2.30	%

Selling, general and administrative expenses for the three months ended September 30, 2010 increased by 2% as compared with the same period in 2009. This was primarily due to expenses incurred for strategic opportunities of approximately \$143,000 in the 2010 period, which did not occur in the 2009 period, the recording of \$34,000 in Brazilian tax withholdings on the milestone payment, an increase in consulting expenses, an increase in investor relations 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 and a decrease in wages and related expenses .

## Other Income and (Expense):

	For the three months ended				
	September 30, 2010	September 30, 2009	\$ Change	% Change	
Other income	\$ (3,923 )	\$ -	\$ (3,923 )	100.00	%
Interest income	1,018	2,168	(1,150 )	-53.04	%
Interest expense	(5,666 )	(2,682 )	(2,984 )	111.26	%
Total Other Income and (Expense)	\$ (8,571 )	\$ (514 )	\$ (8,057 )	1567.51	%

Other income and (expense) for the three months ended September 30, 2010 increased approximately \$8,000 as compared with the same period in 2009, primarily as a result of a retirement of an asset in 2010, an increase in interest expense due to the term loan with HSBC, and partially offset by a decrease in interest income due to a decrease in interest rates in interest-bearing accounts.

## RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2010 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2009

## Revenues:

Selected Product  
Categories:

	For the nine months ended				
	September 30, 2010	September 30, 2009	\$ Change	% Change	
HIV	\$ 7,732,462	\$ 7,829,276	\$ (96,814 )	-1.24	%
DPP	6,521	619,530	(613,009 )	-98.95	%
Other	598,150	796,233	(198,083 )	-24.88	%
Net Product Sales	8,337,133	9,245,039	(907,906 )	-9.82	%
License and royalty revenue	400,758	83,710	317,048	378.75	%
R&D, milestone and grant revenue	2,299,970	954,058	1,345,912	141.07	%
Total Revenues	\$ 11,037,861	\$ 10,282,807	\$ 755,054	7.34	%

Revenues for our HIV tests and related components during the nine months ended September 30, 2010 decreased by approximately \$97,000 over the same period in 2009. This was primarily attributable to decreased sales to Brazil of \$1,643,000, partially offset by increased sales Ethiopia of \$471,000 as well as sales to Nigeria of \$871,000. Sales in North America, primarily from sales to Alere of our HIV products, increased for the nine-month period by \$91,000 to \$3,541,000. The increase in R&D, milestone and grant revenue was due to revenue generated from grants and development contracts that are related to potential new products utilizing our patented DPP® technology and was also due to \$125,000 earned in June 2010 as a result of the completion of the milestone in our Bio-Rad agreement and milestone fees of \$400,000 and \$225,000 from FIOCRUZ that were triggered upon the approval of the Company's DPP® HIV 1/2 Screening Assay and DPP® HIV 1/2 Confirmatory rapid tests, respectively. R&D revenues also include funds realized from Phase II NIH grant for Leptospirosis, which was effective as of June 1, 2009, and funds realized from Battelle for an influenza immunity test. License and royalty revenue includes milestone fee payments of \$340,000 from Bio-Rad pursuant to the License Agreement we signed with them in January 2009 and for royalties

from Brazil under our 2004 technology transfer and license agreement.

# Gross Margin:

Gross Margin related to  
Net Product Sales:

	For the nine months ended			
	September 30, 2010	September 30, 2009	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 5,609,841	\$ 4,229,600	\$ 1,380,241	32.63 %
Less: R&D, milestone, grants, license and royalties	2,700,728	1,037,768	1,662,960	160.24 %
Gross Margin from Net Product Sales	\$ 2,909,113	\$ 3,191,832	\$ (282,719 )	-8.86 %
Gross Margin %	34.89 %	34.52 %		

The increase in our gross margin was primarily due to the increase in non-product revenues (see revenues above). The increase in our product gross margin resulted primarily from reduced royalty expense due to product sold in 2010 to countries where a lower rate applies than in 2009 as well as increased allocation of overhead to inventory. For the 2010 period we were applying 375% vs. 300% during the 2009 period.

## Research and Development:

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

Selected expense lines:	For the nine months ended				
	September 30, 2010	September 30, 2009	\$ Change	% Change	
Clinical and Regulatory Affairs:					
Wages and related costs	\$ 278,773	\$ 225,546	\$ 53,227	23.60	%
Consulting	37,975	29,950	8,025	26.79	%
Share-based compensation	9,759	8,249	1,510	18.31	%
Clinical trials	393,342	46,051	347,291	754.14	%
Other	68,409	24,204	44,205	182.64	%
Total Regulatory	\$ 788,258	\$ 334,000	\$ 454,258	136.01	%
R&D Other than Regulatory:					
Wages and related costs	\$ 1,306,417	\$ 1,121,206	\$ 185,211	16.52	%
Consulting	19,190	63,548	(44,358 )	-69.80	%
Share-based compensation	62,706	52,458	10,248	19.54	%
Materials and supplies	477,870	360,316	117,554	32.63	%
Other	168,014	196,331	(28,317 )	-14.42	%
Total other than Regulatory	\$ 2,034,197	\$ 1,793,859	\$ 240,338	13.40	%
Total Research and Development					
	\$ 2,822,455	\$ 2,127,859	\$ 694,596	32.64	%

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2010 increased by \$454,000 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 \$240,000 in the nine months ended September 30, 2010 as compared with the same period in 2009 and were primarily related to an increase in personnel and materials 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, milestones and grants (see sub-heading Revenues above) was \$522,000 for the nine months ended September 30, 2010 (\$2,822,000 less \$2,300,000, this includes clinical trials of \$393,000) compared to \$1,174,000 (\$2,128,000 less \$954,000, this includes clinical trials of \$46,000) for the same period in 2009.

In addition please see discussion under “Recent Developments And Chembio’s Plan Of Operations For The Next Twelve Months” regarding QTDP.

## Selling, General and Administrative Expenses:

Selected expense lines:	For the nine months ended		\$ Change	% Change	
	September 30, 2010	September 30, 2009			
Wages and related costs	\$ 743,623	\$ 751,401	\$ (7,778 )	-1.04	%
Consulting	172,014	143,121	28,893	20.19	%
Commissions	100,236	286,564	(186,328 )	-65.02	%
Share-based compensation	52,881	67,942	(15,061 )	-22.17	%
Marketing materials	13,710	17,360	(3,650 )	-21.03	%
Investor relations/investment bankers	160,771	37,049	123,722	333.94	%
Legal, accounting and SOX 404 compliance	440,229	347,343	92,886	26.74	%
Travel, entertainment and trade shows	49,327	47,467	1,860	3.92	%
Other	410,924	303,826	107,098	35.25	%
Total S, G &A	\$ 2,143,715	\$ 2,002,073	\$ 141,642	7.07	%

Selling, general and administrative expenses for the nine months ended September 30, 2010 increased by 7% as compared with the same period in 2009. This was primarily due to the recording of \$94,000 in Brazilian tax withholdings on the milestone payments, an increase in investor relations and an increase in legal, accounting and SOX 404 expenses for compliance and for pursuing possible strategic opportunities, partially offset by a decrease in commissions as a result of lower sales in Brazil and a decrease in wages and related expenses.

## Other Income and (Expense):

	For the nine months ended				
	September 30, 2010	September 30, 2009	\$ Change	% Change	
Other income (expense)	\$ (3,923 )	\$ (6,696 )	\$ 2,773	-41.41	%
Interest income	2,747	7,083	(4,336 )	-61.22	%
Interest expense	(9,927 )	(8,210 )	(1,717 )	20.91	%
Total Other Income and (Expense)	\$ (11,103 )	\$ (7,823 )	\$ (3,280 )	41.93	%

Other income and (expense) for the three months ended September 30, 2010 was lower by approximately \$3,000 as compared with the same period in 2009, primarily as a result of an increase in interest expense due to the term loan with HSBC and a decrease in interest income due to a decrease in interest rates in interest-bearing accounts, both of which were partially offset by a lower loss on the sale of an asset in 2009 compared to a retirement of an asset in 2010.

## LIQUIDITY AND CAPITAL RESOURCES

	For the nine months ended				
	September 30, 2010	September 30, 2009	\$ Change	% Change	
Net cash provided by operating activities	\$ 213,731	\$ 947,825	\$ (734,094 )	-77.45	%
Net cash used in investing activities	(188,193 )	(296,285 )	108,092	-36.48	%
Net cash provided by financing activities	242,210	13,047	229,163	1756.44	%
NET INCREASE IN CASH AND CASH EQUIVALENTS	\$ 267,748	\$ 664,587	\$ (396,839 )	-59.71	%

The Company had an increase in cash for the nine months ended September 30, 2010 which was less than the increase in cash for the same period in 2009. The increase during the 2010 period is primarily attributable to cash provided by financing activities (\$250,000 term loan from HSBC) and cash provided by 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 increased cash from operations in 2010 was primarily attributable to net income along with non-cash expenses aggregating \$992,000, the increase in accruals and payables of \$510,000 and a decrease in other assets of \$177,000 partially offset by an increase in receivables of \$859,000, a decrease in deferred revenue of \$279,000 and an increase in inventories of \$328,000. The increase in inventories was in response to anticipated approval in Brazil for one of our products which would result in an order. Although the approval has not yet been received, it is expected during the fourth quarter of 2010 and would 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 \$430,000, which consisted of \$213,000 from depreciation expense, \$142,000 in share-based compensation expense and \$75,000 in the amortization of licenses.



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

Chembio is positioned to achieve its seventh straight year of double digit revenue growth and its second consecutive year of profitability. This revenue growth and resulting profitability has come from our entry into the U.S. market with our two FDA-approved rapid HIV tests, as well as significantly increased revenue streams from contract development agreements, grants, milestone payments, and license fees, and also from a resurgence in our sales to Africa, particularly during the second half of 2010. We believe that the non-product revenues are strong evidence of the opportunities that lie ahead for our robust pipeline of products incorporating our patented DPP® point-of-care technology.

The first meaningful product revenues from DPP®-based products should be realized during the current fourth quarter as we produce against an initial \$500,000 order from the Oswaldo Cruz Foundation for our DPP® HIV Screening Assay for use with oral fluid and blood samples. (In 2009 we had DPP® product revenues, but all were related to registrations and evaluations). We anticipate significant additional purchase orders for the HIV screening product for delivery during 2011, although there can be no assurance of this.

Based on the purchase orders we have in hand from Alere, we believe our sales to Alere for the fourth quarter will be at least \$1.8 million. We believe that Alere's sales to the market in calendar year 2010 will have increased by at least 18% over 2009 even though our sales to Alere may only be level to a slight increase over 2009. This difference is due to the fact that Alere started the year with higher inventory levels from product shipped during the fourth quarter of 2009 (when we had a 148% increase in sales to Alere) and because there was some slowdown in the market during the first half of this year. We believed then, as we do now, and as now evidenced by a strong resurgence in demand from Alere, that the longer term outlook for the U.S. rapid HIV test market remains strong. This is based partially on the increased adoption of CDC routine HIV testing recommendations, the new national HIV strategy announced by the Obama administration in July of 2010, new participants in the U.S. health care system as a result of the health care reform, new marketing initiatives by Alere, continued strong customer satisfaction with our rapid HIV tests in the U.S. market, and possibly due to state budgetary constraints that may be making the use of our competitors' tests less justifiable. We also believe that we will see additional growth in these sales of at least 15% in 2011, although there can be no assurance of this.

Based on our current backlog, we anticipate that we will realize at least a 75% increase in sales to Africa in 2010 over 2009. Combining the fourth quarter shipments anticipated to Alere, Brazil and Africa, we believe that our fourth quarter product sales should be 50% more than 2009, thereby having 2010 total revenues exceeding 2009 total revenue by more than 15%, although there can be no assurance of this. Also, as a result of our completing the validation of our new assembly equipment during the third quarter of 2010, we believe that we should be able to realize improved efficiencies in the assembly of our DPP® products, as well as of our lateral flow products, going forward, although there can be no assurance of this. We also believe that other manufacturing improvements that we have made, as well as other improvements that are ongoing, will further contribute to improved margins.

During the third quarter of 2010 the Company incurred approximately \$190,000 in professional expenses in connection with pursuing a potential acquisition of Chembio. Discussions concerning a potential sale opportunity have continued into the current quarter. The Company has and will continue to consider strategic opportunities that it believes warrant consideration. Currently there is no such opportunity that has progressed sufficiently for specific disclosure. There can be no assurance that any acquisition or other strategic transaction will occur.

On November 1 the Company was notified that it received grant awards in the total amount of \$1.467 million relating to six "Qualifying Therapeutic Discovery Projects" under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010, the United States federal health care reform legislation enacted earlier this year. The program established criteria by which small businesses could apply to be certified for either a tax credit or grant up to specified limits for tax years 2009 and 2010. Under the award guidelines, qualified



therapeutic discovery projects had to show a reasonable potential to detect or treat chronic or acute diseases and conditions, reduce the long-term growth of health care costs in the United States, result in new therapies to treat areas of unmet medical need or prevent, or significantly advance the goal of curing cancer within 30 years. The projects also needed to show a reasonable potential to create or sustain high quality jobs and to advance United States competitiveness in the fields of life sciences, biological and medical sciences. Chembio's six projects, that received awards, include products based on the Company's patented DPP® point-of-care diagnostic platform that are in various stages of its development pipeline. These projects include products such as the rapid diagnosis of HIV, Hepatitis-C, and Syphilis. The grants include \$620,000 relating to qualified expenditures made in 2009, for which payment will be made immediately, and grants of \$846,000 for qualified expenditures made or that will have been made during 2010, which amount is to be paid at the end of January 2011. Except for approximately \$100,000, the \$846,000 in grants awarded for 2010 are for expenditures already made or incurred by the Company this year to date; the Company anticipates qualifying for the full \$846,000 as a result of expenditures planned during the fourth quarter of 2010.

Therefore, based upon this outlook, and excluding any additional costs incurred concerning a potential sale, and excluding the income effect of the QTDP grants, our operating income should also be significantly improved over the third quarter, although there can be no assurance of this. In addition, our 2010 D&A (non-cash Depreciation and Amortization expenses) will be approximately \$700,000, or approximately \$175,000 per quarter.

Our business plan in general is to support the current lateral flow products while leveraging the commercialization of our new DPP® products and managing our expenditures related to the development of these DPP® products and regulatory approvals. We also plan to strengthen our operating cash flow from our base business (sales of manufactured products), and as supplemented by fees and contract development income we receive from our OEM agreements, contract development agreements and grants, meeting our obligations when due in order to build the Company's value.

As stated above, our ability to fully fund the commercialization of our new HIV, Syphilis and Influenza products, which will cost approximately \$3 million (of which we have funded approximately \$390,000 for the first nine months of 2010), will depend on continued positive cash flow from operations. In addition, our recent award of \$1,467,000 of funds and commitments from the QTDP will facilitate these efforts significantly. We believe that our operating cash flow will enable us to move our development programs forward, as it did during the first nine months of 2010, as will the QTDP grant income, although there can be no assurance of this.

#### 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 September 30, 2010, an aggregate of \$28,800 has been paid for this tooling 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 (1)
3.2	Amended and Restated Bylaws. (2)
10.13	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (1)
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 (1)
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 (1)
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 Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
2	Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: November 4, 2010 By: /s/ Lawrence A. Siebert

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

Date: November 4, 2010 By: /s / Richard J. Larkin

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