CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
November 04, 2009

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

FORM 10 - Q

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

For the quarterly period ended September 30, 2009

000-30379
(Commission File Number)
Chembio Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

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

3661 Horseblock Road
Medford, New York 11763
(Address of principal executive offices including zip code)
(631) 924-1135
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes X No ___

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes___ No X

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 [X]

(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 X

As of November 4, 2009, the Registrant had 61,944,901 shares outstanding of its $.01 par value common stock.

Quarterly Report on FORM 10-Q For The Period Ended

September 30, 2009

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Chembio Diagnostics, Inc.

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PART I
Item 1. FINANCIAL STATEMENTS

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

	September 30, 2009 (UNAUDITED)	December 31, 2008
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,876,809	$ 1,212,222
Accounts receivable, net of allowance for doubtful accounts of $20,000 and $10,301 for 2009 and 2008, respectively	1,134,638	809,303
Inventories	1,373,984	1,819,037
Prepaid expenses and other current assets	309,627	225,153
TOTAL CURRENT ASSETS	4,695,058	4,065,715
FIXED ASSETS, net of accumulated depreciation	642,427	881,406
OTHER ASSETS:		
License agreements, net of current portion	725,000	940,000
Deposits and other assets	279,560	27,820
TOTAL ASSETS	$ 6,342,045	$ 5,914,941
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 2,206,964	$ 2,383,021
Deferred research and development revenue	359,000	-
Current portion of loan payable	10,184	-
Current portion of obligations under capital leases	20,811	18,780
TOTAL CURRENT LIABILITIES	2,596,959	2,401,801
OTHER LIABILITIES:		
Obligations under capital leases - net of current portion	44,936	60,808
Loan payable - net of current portion	16,704	-
License fee payable - net of current portion	875,000	875,000
TOTAL LIABILITIES	3,533,599	3,337,609

COMMITMENTS AND CONTINGENCIES				
STOCKHOLDERS' EQUITY:				
Preferred stock – 10,000,000 shares authorized, none outstanding		-		-
Common stock - $.01 par value; 100,000,000 shares authorized 61,944,901 shares issued and outstanding		619,449		619,449
Additional paid-in capital		39,391,619		39,252,350
Accumulated deficit		(37,202,622)		(37,294,467)
TOTAL STOCKHOLDERS' EQUITY		2,808,446		2,577,332
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$	6,342,045	$	5,914,941

See accompanying notes

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

	For the three months ended		For the nine months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
REVENUES:				
Net product sales	$ 3,924,237	$ 3,406,803	$ 9,245,039	$ 8,111,015
License and royalty income	31,388	-	83,710	-
Research grant income	408,060	109,361	954,058	487,661
TOTAL REVENUES	4,363,685	3,516,164	10,282,807	8,598,676
Cost of product sales	2,494,719	2,124,722	6,053,207	5,362,246
GROSS PROFIT	1,868,966	1,391,442	4,229,600	3,236,430
OPERATING EXPENSES:				
Research and development expenses	777,502	758,851	2,127,859	1,952,436
Selling, general and administrative expenses	783,810	868,120	2,002,073	2,696,351
	1,561,312	1,626,971	4,129,932	4,648,787
INCOME (LOSS) FROM OPERATIONS	307,654	(235,529)	99,668	(1,412,357)
OTHER INCOME (EXPENSES):				
Other expense	-	-	(6,696)	-
Interest income	2,168	3,587	7,083	29,958
Interest expense	(2,682)	(5,112)	(8,210)	(15,966)
	(514)	(1,525)	(7,823)	13,992
INCOME (LOSS) BEFORE INCOME TAXES	307,140	(237,054)	91,845	(1,398,365)
Provision for income taxes	-	-	-	-

NET INCOME (LOSS)	$ 307,140	$ (237,054)	$ 91,845	$ (1,398,365)
Basic earnings (loss) per share	$ 0.00	$ (0.00)	$ 0.00	$ (0.02)
Diluted earnings (loss) per share	$ 0.00	$ (0.00)	$ 0.00	$ (0.02)
Weighted average number of shares outstanding, basic	61,944,901	61,944,901	61,944,901	61,036,181
Weighted average number of shares outstanding, diluted	75,365,577	61,944,901	74,937,831	61,036,181

See accompanying notes

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

	September 30, 2009	September 30, 2008
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers	$ 9,959,812	$ 7,523,847
Cash paid to suppliers and employees	(9,010,860)	(8,982,976)
Interest received	7,083	29,958
Interest paid	(8,210)	(15,966)
Net cash provided by (used in) operating activities	947,825	(1,445,137)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	13,750	-
Acquisition of and deposits on fixed assets	(310,035)	(363,652)
Net cash used in investing activities	(296,285)	(363,652)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from loan	29,228	-
Payment of loan obligation	(2,340)	-
Payment of capital lease obligation	(13,841)	(19,151)
Net cash provided by (used in) financing activities	13,047	(19,151)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	664,587	(1,827,940)
Cash and cash equivalents - beginning of the period	1,212,222	2,827,369
Cash and cash equivalents - end of the period	$ 1,876,809	$ 999,429
RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:		
Net income (loss)	$ 91,845	$ (1,398,365)
Adjustments:		
Depreciation and amortization	278,568	239,222
Provision for doubtful accounts	9,699	256
Loss on sale of fixed asset	6,696	-

Common stock, options and warrants issued as compensation	140,517	268,159
Changes in assets and liabilities:		
Accounts receivable	(335,034)	(1,075,085)
Inventories	445,053	261,723
Prepaid expenses and other assets	(85,722)	(816,039)
Deposits and other assets	213,260	-
Deferred revenue	359,000	56,666
Accounts payable and accrued expenses	(176,057)	143,326
Licenses fee payable	-	875,000
Net cash provided by (used in) operating activities	$ 947,825	$ (1,445,137)
Supplemental disclosures for non-cash investing and financing activities:		
Value of common stock issued upon cashless warrant exercise	-	14,074

See accompanying notes

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2009
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiaries (referred to collectively as the "Company" or "Chembio") 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 approximately 85% of the Company's product revenues in the first nine months of 2009. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio's products are sold under the Company's STAT PAK® or SURE CHECK® registered trademarks or under the private labels of its marketing partners, for example the Clearview® label owned by Inverness Medical Innovations, Inc. ("Inverness"), which is the Company's exclusive marketing partner for its FDA approved rapid HIV test products in the United States. These products employ lateral flow technologies that are proprietary, and that incorporate lateral flow patents licensed to the Company by Inverness. All of the Company's new products 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 and 2009 to date, the Company has completed development of its first four products that employ the DPP®, and the Company has a number of additional products under development that employ the DPP®.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("US-GAAP"), which contemplate continuation of the Company as a going concern. Although revenues, gross margins and cash flow from operating activities increased in the nine months ended September 30, 2009 as compared to the same period in 2008 and the Company was profitable for the three and nine months ended September, 30, 2009, there can be no assurance that these trends will continue. At September 30, 2009, the Company had stockholders' equity of $2,808,000 and working capital of $2,098,000. The Company estimates that its resources are sufficient to fund its needs through the next twelve months or that, in the alternative, it could attempt to raise additional capital although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment (including production equipment of $323,500 of which the Company has paid $250,000 as of September 30, 2009) and the extent to which the Company increases net cash flow through operating efficiencies. There are no assurances that the Company will remain profitable or generate positive cash flow by the end of 2009 or, in the alternative, be successful in raising sufficient capital to fund its needs through September 30, 2010.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The consolidated interim financial information as of September 30, 2009 and for the three- and nine-month periods ended September 30, 2009 and 2008 have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures 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, 2008, 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, 2009, its consolidated results of operations for the three and nine-month periods ended September 30, 2009 and 2008 and its cash flows for the nine-month periods ended September 30, 2009 and 2008, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2009
(UNAUDITED)

(b) Inventories:

Inventory consists of the following at:

	September 30, 2009	December 31, 2008
Raw materials	$ 869,579	$ 836,446
Work in process	316,829	300,986
Finished goods	187,576	681,605
	$ 1,373,984	$ 1,819,037

(c) Earnings (Loss) Per Share:

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

	For the three months ended		For the nine months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Basic	61,944,901	61,944,901	61,944,901	61,036,181
Diluted	75,365,577	61,944,901	74,937,831	61,036,181

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings (loss) per share reflects the potential dilution from the exercise or conversion of other securities into Common Stock, but only if dilutive. Diluted loss per share for the three and nine-month periods ended September 30, 2008 are the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for those periods. Diluted earnings per share for the three and nine-month periods ended September 30, 2009, reflects certain common stock equivalents which are not anti-dilutive. The following securities, presented on a common share equivalent basis for the three and nine-month periods ended September 30, 2009 and 2008, except those presented for the three and nine-month periods ended September 30, 2009, have been excluded from the per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
1999 & 2008 Plan Stock Options	5,621,927	2,797,482	4,058,634	2,565,655
Other Stock Options	124,625	124,625	124,625	124,625
Warrants	7,674,124	10,163,244	8,809,671	16,183,547
	13,420,676	13,085,351	12,992,930	18,873,827

(d) Reclassifications:

Certain reclassifications have been made to conform to the 2009 presentation. For the three and nine-months ended September 30, 2008 the Company reclassified its royalty and license expenses to cost of product sales, from selling, general and administrative expenses (S,G&A).

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(e) Employee Stock Option Plan:

The Company has a 1999 Stock Option Plan ("SOP") that originally covered 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 cover 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"), which covers 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. Stock option compensation expense represents the estimated fair value, at their respective dates of grant, of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the nine-month periods ended September 30, 2009 and 2008 was $.09 and $.13 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 historical volatility of our stock. The expected term is determined using the simplified method as permitted by SAB 110, as the Company has no 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, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Expected term (in years)	n/a	n/a	4	1 to 4
Expected volatility	n/a	n/a	123.81%	109.33-112.33%
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	n/a	n/a	1.81-1.95%	1.91-2.98%

The Company's results for the three-month periods ended September 30, 2009 and 2008 include share-based compensation expense totaling $49,000 and $24,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold ($8,000 and none, respectively), research and development ($19,000 and $14,000, respectively) and S,G&A expenses ($22,000 and $10,000, respectively). The Company's results for the nine-month periods ended September 30, 2009 and 2008 include share-based compensation

expense totaling $139,000 and $268,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold ($10,000 and $19,000, respectively), research and development ($61,000 and $75,000, respectively) and S,G&A expenses ($68,000 and $174,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

On May 7, 2009, the Compensation Committee of the Company reduced, to $0.13 per share, the exercise price of each outstanding employee option that was issued under the 1999 Equity Incentive Plan (the "1999 Plan") for which the exercise price was greater than $0.44 per share of the Company's common stock. There was no other change made to the terms of the stock options other than the reduction in the exercise price. A total of 1,036,750 options were affected and the fair value difference of the options before and after the reduction was $31,660 and was expensed in the three months ended June 30, 2009.

In addition, on May 7, 2009 in accordance with the terms of the Company's 2008 Stock Incentive Plan, the Company granted certain employees of the Company, options to purchase an aggregate of 2,925,000 shares of the Company's common stock. The exercise price for these options is equal to $0.13 per share. The options become exercisable in thirds on the first, second and third anniversaries of the date of the grant. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant. The fair value of these options is being amortized over the vesting life of the options.

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On May 7, 2009, the Board of Directors of the Company revised the compensation of non-employee directors to increase the number of options to purchase the Company's common stock issued to directors once every five years from 180,000 to 375,000. To accommodate the transition, on June 3, 2009 at the annual meeting, non-employee directors that were re-elected were issued their five-year allotment of options and those options previously granted but not exercisable as of June 3, 2009 were cancelled. The number issued was 750,000 and the number cancelled was 216,000. The fair value of these options granted is being amortized over the vesting life of the options.

The following table provides stock option activity for the nine months ended September 30, 2009:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2008	2,201,500	$ 0.64		
Impact of re-price (for accounting purposes treated as a cancellation and re-issue):				
effect as if cancelled	(1,846,500)	$ 0.64		
effect as if re-issiued	1,846,500	$ 0.48		
Granted	967,650	$ 0.18		
Exercised	-	-		
Forfeited/expired /cancelled	(752,500)	$ 0.58		
Outstanding at December 31, 2008	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-issiued	1,252,750	$ 0.13		
Granted	3,459,000	$ 0.13		
Exercised	-	-		
Forfeited/expired/cancelled	(253,750)	$ 0.17		
Outstanding at September 30, 2009	5,621,900	$ 0.15	3.82 years	$ 267,506
Exercisable at September 30, 2009	2,096,900	$ 0.14	2.49 years	$ 26,756

As of September 30, 2009, there was $247,000 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted average period of approximately 1.68 years. The total fair value of stock options vested during the three-month periods ended September 30, 2009 and 2008, was approximately none and $10,000, respectively. The total fair value of stock options vested during the nine-month periods ended September 30, 2009 and 2008, was approximately $60,000 and $273,000, respectively

(f) Geographic Information:

US-GAAP establishes standards for the way that 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
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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, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Africa	$ 963,025	$ 1,397,297	$ 2,421,810	$ 3,698,178
Asia	30,994	80,300	125,593	211,040
Europe	18,830	49,215	64,602	130,935
Middle East	57,997	122,190	150,993	277,340
North America	1,918,765	645,124	4,090,130	1,688,874
South America	934,626	1,112,677	2,391,911	2,104,648
	$ 3,924,237	$ 3,406,803	$ 9,245,039	$ 8,111,015

(g) Accounts payable and accrued liabilities

Accounts payable and accrued liabilities consist of:

	September 30, 2009	December 31, 2008
Accounts payable – suppliers	$ 634,905	$ 634,083
Accrued commissions	45,391	67,857
Accrued royalties / license fees	993,581	1,400,941
Accrued payroll	67,590	95,135
Accrued vacation	126,614	91,895
Accrued bonuses	226,271	-
Accrued legal and accounting	30,000	18,000
Accrued expenses – other	82,612	75,110
TOTAL	$ 2,206,964	$ 2,383,021

(h) Recent Accounting Pronouncements affecting the Company

Codification

In July 2009, the Financial Accounting Standards Board’s (FASB) Accounting Standards Codification (ASC) became the single official source of authoritative, nongovernmental generally accepted accounting principles (“US-GAAP” or “GAAP”) in the United States. This guidance is contained in ASC Topic 105 “Generally Accepted Accounting

Principles." The historical GAAP hierarchy was eliminated and the ASC became the only level of authoritative GAAP, other than guidance issued by the Securities and Exchange Commission. This guidance is effective for interim and annual periods ending after September 15, 2009. The Company adopted the provisions of this guidance as of September 30, 2009. The Company's accounting policies were not affected by the conversion to the ASC. However, references to specific accounting standards have been changed to refer to the appropriate section of the ASC.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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Fair Value Measurements

In September 2006, the FASB issued guidance that defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This guidance is contained in ASC Topic 820 “Fair Value Measurements and Disclosures.” This guidance does not require any new fair value measurements, but applies under other accounting pronouncements that require or permit fair value measurements. The effective date of this guidance for financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis was January 1, 2008, and the Company did adopt the provisions of this guidance at that time as it related to financial assets and liabilities recognized or disclosed at fair value on a recurring basis. Effective January 1, 2009, pursuant to this guidance, the Company adopted the provisions of this guidance as it relates to non financial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. The adoption of this guidance had no impact on the Company’s financial statements.

In April 2009, the FASB issued guidance that extends the disclosure requirements regarding the fair value of financial instruments to interim financial statements of publicly traded companies. This guidance is primarily contained in ASC Topic 825 “Financial Instruments” and ASC Topic 270 “Interim Reporting.” This guidance is effective for interim periods ending after June 15, 2009. The adoption of this guidance had no impact on the Company’s financial statements.

Collaborative Arrangements

In December 2007, the FASB issued guidance to participants in a collaborative arrangement which is contained in ASC Topic 808. A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two (or more) parties who are both (a) active participants in the activity and (b) exposed to significant risks and rewards dependent on the commercial success of the activity. Many collaborative arrangements involve licenses of intellectual property, and the participants may exchange consideration related to the license at the inception of the arrangement. Participants in a collaborative arrangement shall report costs incurred and revenue generated from transactions with third parties (that is, parties that do not participate in the arrangement) in each entity's respective income statement pursuant to such guidance. An entity should not apply the equity method of accounting to activities of collaborative arrangements. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The adoption of this guidance had no impact on the Company’s financial statements.

Business Combinations

On January 1, 2009, we adopted the accounting pronouncements relating to business combinations (primarily contained in ASC Topic 805 “Business Combinations”), including assets acquired and liabilities assumed arising from contingencies. These pronouncements established principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree as well as provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. In addition, these pronouncements eliminate the distinction between contractual and non-contractual contingencies, including the initial recognition and measurement criteria and require an acquirer to develop a systematic and rational basis for subsequently measuring and accounting for acquired contingencies depending on their nature. Our adoption of these pronouncements will

have an impact on the manner in which we account for any future acquisitions.

Non-Controlling Interests in Consolidated Financial Statements

On January 1, 2009, we adopted the accounting pronouncement on non-controlling interests in consolidated financial statements, which establishes accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. This guidance is primarily contained in ASC Topic 810 “Consolidation”. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. The adoption of this standard has not had a material impact on our consolidated financial statements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
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(UNAUDITED)

Subsequent Events

In May 2009, the FASB issued guidance that is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or are available to be issued. This guidance is contained in ASC Topic 855 “Subsequent Events.” It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. This guidance is effective for interim and annual periods ending after June 15, 2009. The Company adopted the provisions of this guidance as of June 30, 2009. Management has evaluated events and transactions as of the date and time the financial statements were issued and filed with the Securities and Exchange Commission, that being November 4, 2009 (See Note 6 – Subsequent Events).

Accounting Standards Updates Not Yet Effective

In June 2009, an update was made to “Consolidation – Consolidation of Variable Interest Entities.” Among other things, the update replaces the calculation for determining which entities, if any, have a controlling financial interest in a variable interest entity (VIE) from a quantitative based risks and rewards calculation, to a qualitative approach that focuses on identifying which entities have the power to direct the activities that most significantly impact the VIE’s economic performance and the obligation to absorb losses of the VIE or the right to receive benefits from the VIE. The update also requires ongoing assessments as to whether an entity is the primary beneficiary of a VIE (previously, reconsideration was only required upon the occurrence of specific events), modifies the presentation of consolidated VIE assets and liabilities, and requires additional disclosures about a Company’s involvement in VIEs. This update will be effective for the Company beginning January 1, 2010. The Company is evaluating the impact that this guidance will have on its financial statements, if any.

In September 2009, an update was made to “Fair Value Measurements and Disclosures – Investments in Certain Entities that Calculate Net Asset Value per Share (or Its Equivalent).” This update permits entities to measure the fair value of certain investments, including those with fair values that are not readily determinable, on the basis of the net asset value per share of the investment (or its equivalent) if such net asset value is calculated in a manner consistent with the measurement principles in “Financial Services-Investment Companies” as of the reporting entity’s measurement date (measurement of all or substantially all of the underlying investments of the investee in accordance with the “Fair Value Measurements and Disclosures” guidance). The update also requires enhanced disclosures about the nature and risks of investments within its scope that are measured at fair value on a recurring or nonrecurring basis. This update will be effective for the Company beginning October 1, 2009. The Company does not believe that the adoption of this guidance will have an impact on its financial statements.

NOTE 3 — DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

In January 2009, the Company received a refundable license fee of $340,000 from Bio-Rad Laboratories, Inc., pursuant to a license agreement, related to a specific application of our DPP® technology which will become fully earned and non-refundable based upon certain future conditions being met and is currently deferred revenue. In addition the Company recognizes income from research projects and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of September 30, 2009, an aggregate of $359,000 of advanced revenues was unearned.

NOTE 4 — VEHICLE FINANCING AND LICENSE FEE PAYABLE:

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, 2009 was $26,888.

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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 HIV-2 in the Company's HIV screening assays. In exchange for global non-exclusive rights to these patents, the Agreement initially provided that the Company will 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 rapid test immunoassay tests sold under the Company's brands of Licensed Products 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.

NOTE5—COMMITMENTS AND CONTINGENCIES:

(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 nine months ended				
	September 30, 2009		September 30, 2008		September 30, 2009		September 30, 2008		Accounts Receivable As of
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	September 30, 2009
Customer 1	$ 1,402,902	36	$ 604,728	18	$ 3,449,775	37	$ 1,569,689	19	$ 235,895
Customer 2	564,000	14	*	*	1,292,640	14	*	*	41,783
Customer 3	912,970	23	1,077,400	32	2,262,770	24	2,060,280	25	144,783
Customer 4	*	*	1,138,941	33	*	*	2,638,062	33	-
Customer 5	406,702	10	*	*	*	*	*	*	150,452

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 vendors in excess of 10% of total purchases for the periods indicated:

	For the three months ended				For the nine months ended				
	September 30, 2009		September 30, 2008		September 30, 2009		September 30, 2008		Accounts Payable
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.	As of September 30, 2009
Vendor 1	$ 170,152	20	$ 148,540	20	$ 429,740	21	$ 366,550	18	$ 1,868

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.

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(b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration, U.S. 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 Inverness:

On June 25, 2009, the Company and Inverness Medical Innovations, Inc. (Inverness) 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 Inverness for the amount of HIV-2 royalties that Inverness paid when Inverness entered into an HIV-2 license agreement with Bio-Rad Laboratories, Inc. of approximately $485,000 and royalties owed by Chembio on lateral flow licenses to Inverness of approximately $525,000 as of December 31, 2008. Under the agreement Inverness will retain an additional 10% of Clearview® HIV 1/2 STAT-PAK® net sales and 5% of Clearview® Complete HIV 1/2 net sales until these obligations are extinguished. The approximate aggregate balance due is $515,000 as of September 30, 2009.

(d) Employment Agreement:

Effective May 11, 2009, the Company's Board of Directors approved the Company's extension of the June 15, 2006 employment agreement (the "Employment Agreement") with the Company's President and Chief Executive Officer. The Employment Agreement, which had been extended for an additional one-year term from May 11, 2008, provides that this officer will continue to serve as the Chief Executive Officer and President of the Company for an additional three-year term.

Other than the dates and salary amounts, the terms of the extended Employment Agreement are substantially similar to the June 15, 2006 Employment Agreement. Under the terms of the extended Employment Agreement this officer will (i) continue as the Company's Chief Executive Officer and President for an additional term of three years from May 11, 2009; (ii) will earn a salary of $265,000, which was reduced temporarily to $225,250 in connection with his agreement to a 15% salary reduction until the later to occur of July 1, 2009, or the date upon which other employees' salaries are restored to the levels that existed prior to January 14, 2009 when the Company implemented payroll reductions; (iii) will continue to be eligible for a bonus of up to 50% of his salary, consisting of (a) a bonus of up to 25% of his salary that is at the complete discretion and determination of the Board, and (b) a bonus of up to an additional 25% of his salary that will be determined based upon revenue and earnings performance criteria established by the Board. Effective July 1, 2009, the other employees' salaries were restored to the levels that existed prior to January 14, 2009, together with the salary of the Chief Financial Officer.

(e) Equipment Purchase Commitment:

In January of 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of $323,500 is being paid in installments. As of September 30, 2009, $250,000 has been paid and is included in deposits and other assets on the Company's balance sheet.

(f) Research and Development Projects and Grants:

In June 2009, the Company received a $3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. In addition the Company has several development contracts with third parties related to its DPP® technology. These development projects are funded in advance and are presented as deferred revenue until earned (see Note 3).

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NOTE6—SUBSEQUENT EVENTS:

The Company evaluated subsequent events for recognition and disclosure through November 4, 2009, the date the financial statements were available to be issued.

In October 2009, the Company entered into a letter agreement (“Agreement”) with the Trustee of Adaltis, Inc, a Canadian company that filed for bankruptcy in Canada in August 2009. Pursuant to a License and Supply Agreement (“L&S Agreement”) dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc., Adaltis licensed and supplied certain HIV 1&2 peptides that the Company used in certain HIV tests manufactured and sold by the Company. Under the terms of the Agreement, the Company purchased for a lump-sum amount a paid-up license to the patents through their expiration dates, thereby cancelling its obligation to pay any additional liabilities under the L&S Agreement. The Company also acquired the right to purchase the peptides from any supplier chosen by Chembio, including but not limited to the current supplier. The Agreement further provides for a full mutual release of all claims, including any and all obligations under the L&S Agreement.

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

Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. Our 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 accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an ongoing basis we review our estimates and assumptions. Our estimates were based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in ''Critical Accounting Policies,'' and have not changed significantly from December 31, 2008.

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," "anticipate "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 Management Discussion And Analysis relates to the business of the Company, including its subsidiaries, which develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, all of which employ lateral flow technology and two of which were approved by the FDA in 2006. In addition, we have a fourth rapid HIV test, more recently developed on our patented Dual Path Platform (DPP®) technology, for the detection of antibodies to HIV in oral fluid samples, as well as in whole blood, serum and plasma samples. The products which employ lateral flow technology are manufactured and sold under a non-exclusive license we have from Inverness Medical Innovations, Inc. ("Inverness"), which is also our exclusive marketing partner for the FDA-approved products that are sold in the United States (as well as Europe and

Asia for the product that is known as the “barrel” format product) under Inverness’ Clearview® brand. Inverness launched its marketing of these products in the United States in February 2007. Chembio’s two HIV STAT-PAK® rapid HIV tests (in cassette and dipstick formats) are marketed outside the United States through different partners and channels under our license from Inverness.

Rapid HIV tests represented nearly 87.5% of the Company’s product revenues in the quarter ended September 30, 2009, (and 84.7% of product revenues for the nine months ended September 30, 2009). The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio’s products are sold under the Company’s STAT PAK® or SURE CHECK ® registered trademarks or under the private labels of its marketing partners, for example the Clearview® label owned by Inverness Medical Innovations, Inc.

Research and Development Activities

All of the Company's current research & development activities are based on its patented Dual Path Platform (DPP®). The DPP® is a unique, simple, rapid diagnostic point-of-care platform that has certain advantages over lateral flow technology. For example a diagnostic test employing the DPP® technology can provide improved features that include higher sensitivity, earlier detection, improved performance with more challenging sample types (such as oral fluid), and the improved ability to detect multiple analytes (multiplexing) in one test device.

The Company has completed development of four 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 two that have been developed pursuant to private label agreements with The Oswaldo Cruz Foundation ("FIOCRUZ") for the Brazilian public health market, as explained below. The Company has a number of additional products under development that employ the DPP® technology. These product development activities are further described below.

- DPP® Hepatitis C and DPP® Hepatitis C/HIV Oral Fluid Antibody Tests - Prototypes of these products have been developed and are being evaluated in a study that has been organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department Of Health and Human Services. The evaluation will be completed during 2009 and the results should be useful in helping to ascertain the performance characteristics of these products in comparison to other products that will also be in this evaluation. Chembio's DPP® HIV 1/2 test is also being evaluated in this study.

- DPP® Influenza –Research & development efforts are ongoing with respect to the development of antigen (Flu A & B) detection and antibody detection (multiplexed strains to ascertain specific immune status in connection with vaccine programs) assays. We have developed a prototype of a Flu A & B antigen detection test that we believe performs substantially equivalently to seasonal Flu A & B detection tests that are cleared for marketing in the United States. However, given that all currently cleared tests were designed before the appearance this year of the novel H1N1 virus, we are pursuing using our unique multiplexing capability to also include antibodies against H1N1. This development work is in its initial stages. Also, during the third quarter, Chembio provided a 3-band prototype multiplex antibody test (that included various Flu antigens other than H1N1) pursuant to a $50,000 funded pilot program with the Influenza division of the CDC. Based on the results of this work, which we believe were satisfactory, additional contract development opportunities may become available for a larger multiplex test that would be used for surveillance and other purposes to assess exposure to various additional strains of influenza, including H1N1.

- DPP® Leptospirosis – In June, as we previously reported, we were awarded a three-year $3 million Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide, and our work is progressing on schedule. The test will be developed with DPP® and will utilize proprietary reagents developed by Cornell University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will be in collaboration with the Division of Infectious Diseases, Weill Medical College, Cornell University in New York and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America. In the Phase I work completed in 2008, which occurred with this same collaborative group, novel diagnostic targets were identified and evaluated in a prototype test in Chembio's patented DPP® format. The studies demonstrated that the test prototype had an overall sensitivity of 85% and a specificity of 90% using serum samples of Leptospirosis patients from Brazil and Thailand. Furthermore, the DPP® prototype had a sensitivity of 78% in identifying Leptospirosis in the first 7 days of illness, the "window-of-opportunity" during which initiation of antimicrobial therapy provides the greatest benefit.

- Other Research & Development Activities - Chembio continues to work with commercial, governmental and private organizations in order to obtain research grants and other 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 creating important collaborative relationships. In April 2008 we entered into a development agreement with Bio-Rad Laboratories, Inc. ("Bio-Rad"), to develop a multiplex test on our DPP®. In January of this year, based on our achievement of the initial milestones in 2008 that established product feasibility, we entered into a license agreement with Bio-Rad related to this specific application and we received a $340,000 refundable license fee which will become non-refundable only when the product development phase is completed. We believe that the product development phase of this project is likely to be completed during the fourth quarter, enabling us to recognize the license fee and to begin the process of transferring the product to manufacturing and to enable regulatory submissions to be made by Bio-Rad for this product. During the third quarter we recorded $42,000 in research & development income from Bio-Rad and we anticipate receiving, subject to the attainment of development milestones, approximately $145,000 more in development funds from Bio-Rad within the next seven months. 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 $125,000 and which, subject to attainment of development milestones, will additionally provide us with approximately $125,000 within the next six months. The second year provides for another $150,000, subject to the attainment of development milestones. During the first quarter we entered into a funded feasibility study agreement with the Foundation for Innovative and Novel Diagnostics (FIND), a non-profit organization funded by the Gates Foundation, related to development of serological tests for Tuberculosis and Malaria using our DPP®. The Company received $165,000 from FIND and as a result of our achievement of all milestones, we recognized revenue of $99,000 in the first and second quarters as well as $66,000 during the third quarter with further development activity pending a full evaluation and comparison of results.

There can be no assurance that any of these projects will continue, meet regulatory or other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if successfully completed, will be successfully commercialized.

Regulatory Activities

- CE Mark for FDA approved HIV tests – All testing and related documentation that was requested by our Notified Body during the second quarter has been completed and based on the results of the testing we believe that our CE Mark filing is now complete for our HIV 1/2 STAT PAK® and it has been submitted. We now expect to receive the CE Mark for this product in the beginning of 2010. Under our agreement with Inverness, we are to obtain a CE Marking for the Clearview® Complete HIV 1/2. However Inverness has a rapid HIV test product that is already CE marked in Europe and so they recently informed us that they have chosen to focus their marketing resources in Europe exclusively on that product. Accordingly we expect that we will reclaim marketing rights for this product in Europe, and will complete the CE mark filing for this product under the Chembio brand Sure Check® HIV 1/2. At that time, we intend to arrange for alternative distribution partners in Europe for this product.

- Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – We anticipate that FIOCRUZ will receive required approvals from its regulatory agencies during 2009 or early 2010 for the DPP® Leishmaniasis, HIV Confirmatory, and the DPP® HIV screening tests. This will trigger approximately $900,000 of technology transfer fees payable to the Company and, soon after these approvals are granted, is likely to result in receipt of orders from FIOCRUZ for these products. We initially believed that these approvals would be granted during 2009. Due to a variety of factors, none of which relate to the anticipated demand for the products or their performance, we believe these approvals will be granted either during the remainder of 2009 or during the first quarter of 2010.

- DPP® HIV 1/2 Screening Assay for Oral Fluid - During the third quarter we were notified that this product met the performance and other criteria established by the United States President's Emergency Plan for AIDS Relief (PEPFAR) for inclusion on the USAID waiver list, enabling procurement by countries and other beneficiaries of this US taxpayer-funded program. This evaluation was based on, among other criteria, sensitivity and specificity studies using serum panels and FDA approved reference tests that are approved for serum. We will be supplementing these studies with studies that are ongoing in Africa, one of which we expect to be completed during the fourth quarter, as well as with our clinical studies in the US as they are completed. During the third quarter, and continuing during the fourth quarter, we have made significant progress toward commencing the regulatory approval process for this product in the United States. We have identified and have completed one agreement with a clinical testing site, and we are working on other agreements which are pending. We anticipate completing a portion of the clinical trials in support of a Pre-Marketing Approval (PMA) application for this product during the fourth quarter of fiscal 2009. We also anticipate the remainder of the testing to be completed during the first half of 2010, and a PMA approval during early 2011. This product will enable Chembio to participate in the oral fluid testing market segments in the United States and globally, where we believe there is a significant opportunity not available to blood tests. In addition, upon satisfactory completion of the PMA, we would consider moving forward for over-the-counter approval of this product.

- DPP® Syphilis Screen & Confirm - The first phase of a multi-center evaluation sponsored by the World Health Organization commenced during the third quarter and we expect to have the first phase results before the end of the fourth quarter. During the third quarter, we submitted a proposed clinical plan to the FDA (Pre-IDE "Investigational Device Exemption") and we are currently reviewing the FDA response. We have also begun to identify clinical testing sites, have performed additional validation, interfering substance, and cross-reactivity studies on the product at Chembio and at external laboratories. There is no point-of-care test for syphilis cleared for marketing in the United States, and we believe that our product, with its multiplexed capacity to identify both treponemal and non-treponemal markers, provides a reliable indication of an active, untreated case of syphilis at the point of care.

The table below provides a preliminary summary timetable for the regulatory approval and commercialization of the DPP® HIV Screening Assay and the DPP® Syphilis Screen & Confirm Assay in major markets.

Market	DPP® HIV 1/2 Screening Assay	DPP® Syphilis Screen & Confirm
Developing World	2009-2010	2009-2010
CE Mark	1st Half 2011	1st Half 2010
US FDA	1st Half 2011	1st Half 2011

We are also pursuing additional registrations with the USDA to expand the claims and thus the available market for our veterinary tuberculosis products, and to eventually move these products, currently on a lateral flow platform, to our DPP® platform.

Critical Accounting Policies and Estimates

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets, accounting for complex financial instruments and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2008, see our annual report on Form 10-K for the period ended December 31, 2008, which was filed with the SEC on March 18, 2009.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2009 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2008

Revenues:

Selected Product Categories:	For the three months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
HIV	$ 3,432,837	$ 3,097,898	$ 334,939	10.81 %
DPP	203,695	-	203,695	n/a
Other	287,705	308,905	(21,200)	-6.86 %
Net Product Sales	3,924,237	3,406,803	517,434	15.19 %
License and royalty income	31,388	-	31,388	-
Research grant income	408,060	109,361	298,699	273.13 %
Total Revenues	$ 4,363,685	$ 3,516,164	$ 847,521	24.10 %

Revenues for our HIV tests during the three months ended September 30, 2009 increased by approximately $335,000 over the same period in 2008. This was primarily attributable to increased sales in North America, primarily from sales to Inverness of our HIV products which increased by $798,000 to $1,403,000 as well as sales to Mexico of $407,000 and Ethiopia of $173,000, and partially offset by a decrease in sales to Brazil of $393,000 and Nigeria of $708,000. During the third quarter of 2009, we also had sales of $204,000 based on our DPP® technology, which consisted of product components being used for regulatory approvals in Brazil. The increase in research grant income was due to revenue generated from grant and feasibility studies that are related to potential new products utilizing our patented DPP® technology. In addition, research grant income includes some funds from our recent NIH grant for Leptospirosis, which was effective as of June 1, 2009. License and royalty income represents our 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, 2009	September 30, 2008	$ Change	% Change
Gross Margin per Statement of Operations	$ 1,868,966	$ 1,391,442	$ 477,524	34.32 %

Less: Research grant, license and royalty income		439,448			109,361			330,087	301.83 %
Gross Margin from Net Product Sales	$	1,429,518		$	1,282,081		$	147,437	11.50 %
Gross Margin %		36.43	%		37.63	%			

For the year ended December 31, 2008, the Company reclassified its royalty and license expenses to cost of sales. For all periods prior to December 31, 2008, these expenses were previously reflected in S,G&A expenses. Included in our royalty expense for the three-month period ended September 30, 2009 is approximately $200,000 for our share of the royalties paid by Inverness to Bio-Rad Laboratories, Inc. pursuant to Inverness' 2008 HIV-2 sublicense agreement with Bio-Rad, which agreement was first recognized in our 2008 year-end statement for all prior periods, including the third quarter of 2008. In addition, during the third quarter of 2009, the Company accrued for bonus compensation in Cost of Goods Sold of $58,700, which is subject to the attainment of operating objectives that management deems is likely to occur. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Research and Development:

This category includes costs incurred for regulatory approvals, product evaluations and registrations.

Selected expense lines:	For the three months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
Clinical & Regulatory Affairs:				
Wages and related costs	$ 94,517	$ 61,438	$ 33,079	53.84 %
Consulting	14,769	17,267	(2,498)	-14.47 %
Share-based compensation	4,667	-	4,667	-
Clinical trials	29,271	41,305	(12,034)	-29.13 %
Other	14,750	8,532	6,218	72.88 %
Total Regulatory	$ 157,974	$ 128,542	$ 29,432	22.90 %
R&D Other than Regulatory:				
Wages and related costs	$ 422,486	$ 411,958	$ 10,528	2.56 %
Consulting	13,577	64,981	(51,404)	-79.11 %
Share-based compensation	14,722	9,738	4,984	51.18 %
Materials and supplies	105,824	74,232	31,592	42.56 %
Other	62,919	69,400	(6,481)	-9.34 %
Total other than Regulatory	$ 619,528	$ 630,309	$ (10,781)	-1.71 %
Total Research and Development	$ 777,502	$ 758,851	$ 18,651	2.46 %

Total expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2009 increased by approximately $29,000 as compared to the same period in 2008. The Company accrued for bonus compensation in Clinical and Regulatory Affairs of $24,000, which is subject to the attainment of operating objectives that management deems is likely to occur and this was the primary reason for the increase in wages and related costs. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Total expenses for R&D Other than Clinical & Regulatory Affairs decreased by approximately $11,000 in the three months ended September 30, 2009 as compared with the same period in 2008. These decreases were primarily related to a reduction in the use of consultants partially offset by an increase in materials and supplies related to feasibility studies for our DPP® platform and by increasing work related to grant income received. Wages and related costs increased modestly, however the 2008 number includes almost $48,000 in recruiting and related expenses that were not incurred in the current period. In addition, the Company accrued for bonuses in the third quarter of 2009 for R&D Other than Regulatory of $49,600, which is subject to the attainment of operating objectives that management deems is likely to occur. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Selling, General and Administrative Expenses:

Selected expense lines:	For the three months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
Wages and related costs	$ 314,148	$ 319,499	$ (5,351)	-1.67 %
Consulting	35,250	44,973	(9,723)	-21.62 %
Commissons	120,268	173,462	(53,194)	-30.67 %
Share-based compensation	21,378	14,082	7,296	51.81 %
Marketing materials	7,423	6,047	1,376	22.76 %
Investor relations	29,735	42,046	(12,311)	-29.28 %
Legal, accounting and Sox 404 compliance	125,325	123,612	1,713	1.39 %
Travel, entertainment and trade shows	22,712	29,628	(6,916)	-23.34 %
Other	107,571	114,771	(7,200)	-6.27 %
Total S, G &A	$ 783,810	$ 868,120	$ (84,310)	-9.71 %

Selling, general and administrative expenses (S,G&A) for the three months ended September 30, 2009 decreased by 9.7% as compared with the same period in 2008. During the second half of 2008 and continuing in 2009 the Company implemented a series of cost reductions that have resulted in lower S,G&A expenses in almost every category in 2009 year to date, except the decreased sales commissions which resulted from a decrease in commissionable sales (and not from the Company's cost reductions) as compared with the 2008 period. The Company accrued for bonuses in the third quarter of 2009 for S,G&A Expenses of $94,000, which is subject to the attainment of operating objectives that management deems is likely to occur. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Other Income and (Expense):

Other Income and (Expense)	For the three months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
Interest income	$ 2,168	$ 3,587	$ (1,419)	-39.56 %
Interest expense	(2,682)	(5,112)	2,430	-47.54 %
Total Other Income and (Expense)	$ (514)	$ (1,525)	$ 1,011	-66.30 %

Other income and (expenses) for the three months ended September 30, 2009 increased approximately $1,000 as compared with the same period in 2008, primarily as a result of a reduction in interest expense net of 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, 2009 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2008

Revenues:

Selected Product Categories:	For the nine months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
HIV	$ 7,829,276	$ 7,228,915	$ 600,361	8.30 %
DPP	619,530	-	619,530	n/a
Other	796,233	882,100	(85,867)	-9.73 %
Net Product Sales	9,245,039	8,111,015	1,134,024	13.98 %
License and royalty income	83,710	-	83,710	-
Research grant income	954,058	487,661	466,397	95.64 %
Total Revenues	$ 10,282,807	$ 8,598,676	$ 1,684,131	19.59 %

Revenues for our HIV tests during the nine months ended September 30, 2009 increased by approximately $600,000 over the same period in 2008. This was primarily attributable to increased sales to Inverness of our HIV products, which increased by $1,880,000 to $3,450,000, and by sales to Brazil of $162,000, which were partially offset by decreased sales in Africa, primarily Nigeria, which decreased in the first nine months of 2009 by approximately $2,291,000 compared to the first nine months of 2008 and sales to Uganda which decreased $429,000, which were partially offset by increased sales to Ethiopia of approximately $1,319,000. During the first quarter of 2009, we had our first significant sales of product based on our DPP® technology and additional sales in the third quarter of 2009. The increase in grant and development income was due to revenue generated from grant and feasibility studies that are related to potential new products utilizing our patented DPP® technology. In addition, grant and development revenue includes some funds from our recent NIH grant for Leptospirosis which grant was effective as of June 1, 2009. License and royalty income represents royalties from Brazil under our 2004 technology transfer agreement.

Gross Margin:

Gross Margin related to Net Product Sales:	For the nine months ended September 30, 2009	September 30, 2008	$ Change	% Change
Gross Margin per Statement of Operations	$ 4,229,600	$ 3,236,430	$ 993,170	30.69 %
Less: Research grant, license and royalty income	1,037,768	487,661	550,107	112.81 %
Gross Margin from Net Product Sales	$ 3,191,832	$ 2,748,769	$ 443,063	16.12 %
Gross Margin %	34.52 %	33.89 %		

For the year ended December 31, 2008, the Company reclassified its royalty and license expenses to cost of goods sold. For all periods prior to December 31, 2008 these expenses were previously reflected in S,G&A expenses. Included in our royalty expense for the nine-month period ended September 30, 2009 is our share of the royalties paid by Inverness to Bio-Rad Laboratories, Inc. with respect to an HIV-2 sublicense agreement. Because we were not informed of such agreement including amounts due for the past royalties, until the fourth quarter of 2008, the quarterly reports for the first three quarters of 2008 do not reflect this expense. If this expense had been reflected in the nine-month period ended September 30, 2008, it would have increased royalty expense for that period by approximately $182,000 or 2.20%. This would have increased the dollar change in Gross Margin over the nine-month period ended September 30, 2008 from approximately $443,000 to $625,000 and changed the Gross Margin for the 2008 period to 31.69%. In addition, during the third quarter of 2009, the Company accrued for bonus compensation in Cost of Goods Sold of $58,700, which is subject to the attainment of operating objectives that management deems is likely to occur. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Research and Development:

This category includes costs incurred for regulatory approvals, product evaluations and registrations.

Selected expense lines:	For the nine months ended September 30, 2009	September 30, 2008	$ Change	% Change
Clinical & Regulatory Affairs:				
Wages and related costs	$ 225,546	$ 194,897	$ 30,649	15.73 %
Consulting	29,950	24,683	5,267	21.34 %
Share-based compensation	8,249	-	8,249	-
Clinical trials	46,051	138,792	(92,741)	-66.82 %
Other	24,204	53,096	(28,892)	-54.41 %
Total Regulatory	$ 334,000	$ 411,468	$ (77,468)	-18.83 %
R&D Other than Regulatory:				

Wages and related costs	$	1,121,206	$	992,927	$	128,279		12.92	%
Consulting		63,548		104,981		(41,433	)	-39.47	%
Share-based compensation		52,458		75,197		(22,739	)	-30.24	%
Materials and supplies		360,316		190,746		169,570		88.90	%
Other		196,331		177,117		19,214		10.85	%
Total other than Regulatory	$	1,793,859	$	1,540,968	$	252,891		16.41	%
Total Research and Development	$	2,127,859	$	1,952,436	$	175,423		8.98	%

Total expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2009 decreased by approximately $77,000 as compared to the same period in 2008. This was primarily due to clinical trial expenses in the 2008 period related to an amendment of our PMA(Pre-Marketing Approval) age claims to include the 12 -17 year old age group. In addition, during the third quarter of 2009, the Company accrued for bonus compensation in Clinical and Regulatory Affairs of $24,000, which is subject to the attainment of operating objectives that management deems is likely to occur. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Total expenses Other than Clinical & Regulatory Affairs increased by approximately $253,000 in the nine months ended September 30, 2009 as compared with the same period in 2008. These increases were primarily related to an increase in the work related to feasibility studies for our DPP® platform and to work related to grant income received, both resulting in an increase in our personnel and material costs, partially offset by a reduction in the use of consultants and the reduced cost (as compared with the 2008 period) of equity-based compensation related to the value of common stock and employee stock options issued to employees. In addition, during the third quarter of 2009, the Company accrued for bonus compensation in R&D Other than Regulatory of $49,600, which is subject to the attainment of operating objectives that management deems is likely to occur. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Selling, General and Administrative Expenses:

Selected expense lines:	For the nine months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
Wages and related costs	$ 751,401	$ 1,003,733	$ (252,332)	-25.14 %
Consulting	143,121	141,582	1,539	1.09 %
Commissons	286,564	314,880	(28,316)	-8.99 %
Share-based compensation	67,942	173,825	(105,883)	-60.91 %
Marketing materials	17,360	22,548	(5,188)	-23.01 %
Investor relations	37,049	111,747	(74,698)	-66.85 %
Legal, accounting and Sox 404 compliance	347,343	474,555	(127,212)	-26.81 %
Travel, entertainment and trade shows	47,467	71,847	(24,380)	-33.93 %
Other	303,826	381,634	(77,808)	-20.39 %
Total S, G &A	$ 2,002,073	$ 2,696,351	$ (694,278)	-25.75 %

S,G&A expenses for the nine months ended September 30, 2009 decreased by 25.7% as compared with the same period in 2008. During the second half of 2008 and continuing in 2009, the Company implemented a series of cost reductions that have resulted in lower S,G&A expenses in almost every category in 2009 year to date, except for reductions in sales commissions that resulted from decreased commissionable sales as compared with the 2008 period. Our periodic review of our allowance for doubtful accounts resulted in a $10,000 increase to the allowance in the nine months ended September 30, 2009. In addition, during the third quarter of 2009, the Company accrued for bonus compensation in S,G&A Expenses of $94,000, which is subject to the attainment of operating objectives that management deems is likely to occur. The Company anticipates accruing for a similar amount in the fourth quarter of 2009.

Other Income and (Expense):

Other Income and (Expense)	For the nine months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
Other (expense)	$ (6,696)	$ -	$ (6,696)	-
Interest income	7,083	29,958	(22,875)	-76.36 %
Interest expense	(8,210)	(15,966)	7,756	-48.58 %
Total Other Income and (Expense)	$ (7,823)	$ 13,992	$ (21,815)	-155.91 %

Other income and (expense) for the nine months ended September 30, 2009 decreased approximately $22,000 as compared with the same period in 2008 primarily as a result of a decrease in interest income due to a decrease in available funds to invest in interest-bearing accounts as well as a reduction in interest rates, combined with a loss on the sale of a fixed asset.

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LIQUIDITY AND CAPITAL RESOURCES

	For the nine months ended			
	September 30, 2009	September 30, 2008	$ Change	% Change
Net cash provided by (used in) operating activities	$947,825	$(1,445,137)	$2,392,962	-165.59 %
Net cash used in investing activities	(296,285)	(363,652)	67,367	-18.53 %
Net cash provided by (used) in financing activities	13,047	(19,151)	32,198	-168.13 %
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$664,857	$(1,827,940)	$2,492,527	-136.36 %

The Company had an increase in cash for the nine months ended September 30, 2009 as compared to a decrease in cash for the same period in 2008. The increase during the 2009 and the decrease during the 2008 period is primarily attributable to the cash provided or used in operations.

The Company had working capital of approximately $2,098,000 at September 30, 2009 and working capital of $1,664,000 at December 31, 2008. The Company estimates that its resources are sufficient to fund its needs through the next twelve months or that, in the alternative; it could raise additional capital, although the terms under which that capital could be raised would likely be very dilutive to current shareholders. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) the Company's investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment (including production equipment of $323,500 which the Company paid $250,000 as of September 30, 2009) and the extent to which the Company improves cash flow through operating efficiencies. There are no assurances that the Company will remain profitable or generate positive cash flow by the end of 2009 or, in the alternative, be successful in raising sufficient capital to fund its needs through September 30, 2010.

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

Chembio's profit for the third quarter increased significantly over that of the second quarter, which was our first ever profitable quarter. The increased profits in the third quarter over the profits reported in the second quarter were largely based on the growth in our US rapid HIV test sales, complemented by strong international sales of our rapid HIV tests (even though international sales were down somewhat from their record level in the third quarter of 2008), a record amount of contract research and development income, and some DPP® product sales in connection with regulatory submissions by our customer in Brazil. The combined consecutive quarterly profits in the second and third quarters of 2009 more than offset the loss reported for the first quarter of 2009, resulting in a profit for the full nine-month period for the first time in the Company's history.

During the first nine months of 2009, net sales of our FDA-approved rapid HIV tests, exclusively marketed in the United States by Inverness Medical, have increased by $1.89 million, or 120%, to $3.45 million, as compared to $1.57 million in the first nine months of 2008. This increase includes an increase in the three-month period ended September 30, 2009 of $.80 million or 133%, to $1.40 million from $.60 million in the comparable period in 2008.

We are very pleased with the growth we are experiencing this year in the U.S. market and we believe it can and will continue at least through the rest of 2009. We believe this growth is due both to an expansion of the HIV testing market share available to point-of-care tests, as CDC recommendations for routine testing for HIV are increasingly adopted at the point of care, and also due to our products gaining market share. The 139% increase during the third

quarter of 2009 in HIV tests sales to our U.S. marketing partner more than offset a 19% decrease in HIV test sales to international customers during the third quarter of 2009, as compared to the same period in 2008, which happened to be a record quarter for our international HIV test sales. The decrease in international HIV test sales in the third quarter of 2009 as well as in the year to date has primarily been a result of a change in testing protocols used in Nigeria, as we anticipated. In addition, our average selling prices in the U.S. result in a much higher profit margin for an equivalent dollar value of sales. We believe that there are still opportunities to increase our international HIV test sales, including in Nigeria, as well as other markets in Africa, South America, Europe and Asia. During 2009, and particularly in the third quarter we have experienced a strong increase in research and development income, which income has nearly doubled in the year-to-date period to $.95 million, a record amount. This income includes a milestone-based development contract for a DPP®-based multiplex test with Bio Rad Laboratories, Inc., a three-year, $3 million Phase II SBIRR NIH grant we announced in June for Leptospirosis, as well as other feasibility and development agreements with commercial, governmental and non-governmental organizations. We believe that we will soon complete the product development phase in our agreement with Bio Rad. These funded development programs all help to underwrite our long-term commitment to our patented Dual Path Platform point-of-care diagnostics platform.

As our sales mix increasingly includes products being sold in the U.S. market, as has been the case in 2009, we expect our gross profit percentage to further increase. This expectation is the case despite the slight gross margin decrease (calculated on Net Product Sales) in the third quarter of 2009 versus that in 2008. Such decrease is attributable to, among other reasons: a) the third quarter of 2008 did not reflect our share of the HIV-2 royalty agreement between Bio-Rad and Inverness, which we were not able to recognize for all prior periods until we completed our full-year 2008 statement; and b) our recent settlement with Adaltis, described as a subsequent event in the notes to our financial statements, which will eliminate certain royalty expenses related to the peptides used in our HIV tests, which expense averaged approximately $275,000 (at lower than currently anticipated sales levels) during 2006-2008, and which settlement also will lower our cost of the peptides themselves. Although we had a slight decrease in our research & development expense other than regulatory during the third quarter, in the third quarter we began to expend more on items related to clinical and regulatory evaluations, and we expect this to continue, as we progress toward commercializing our initial DPP® products for entry into the US and other markets. Our S,G&A expenses are substantially below year ago levels based on reductions we began implementing during the third quarter of 2008 and which continued through the second quarter of 2009. Based on the improved results we have restored the pay reductions our employees absorbed during the first half of this year. We plan to further recognize outstanding performance with bonuses if the recent trends continue.

Based on our year-to-date product sales in the HIV U.S. market of $3.45 million, and our current backlog, we anticipate that for the full 2009 year we will reach at least $5 million of sales of our rapid HIV tests being sold in the U.S. market, which would be substantially more than a 100% increase from $2.1 million in 2008. We also anticipate that we will be profitable for the fourth quarter of 2009, and therefore for the full year. Our profitability will be reduced to the extent of expenditures, related to clinical evaluations we are commencing for our anticipated 2010 submission of a Pre-Marketing Approval application to the FDA for our DPP® HIV 1/2 Screening Assay for use with oral fluid or blood samples.

As we complete 2009 and begin 2010, we believe that the products for which we are waiting for regulatory approval in Brazil will provide the Company with an important new stream of revenues, and important cash flow from technology transfer fees that will help to underwrite our clinical testing. These and other milestones that we expect to achieve, such as our completion of the product development phase for the multiplex product for Bio-Rad laboratories, Inc., will provide us with further validation of our DPP® technology. During these next twelve months, our efforts will be focused on the launch of our initial DPP® products in Brazil, and on commercializing our DPP® HIV 1/2 screening test for use with oral fluids and our DPP® Syphilis Screen and Confirm test. We also anticipate that we will make progress in our development of tests for Hepatitis C and Influenza, also on our DPP®. We also have certain opportunities for our lateral flow HIV tests in new markets which, if realized, will complement our base business of lateral flow HIV test sales.

Equipment Purchase Commitment:

In January 2009, the Company entered into an agreement with an equipment manufacturer to design and build equipment that will be used to automate the assembling of our tests and lower our production costs. The estimated cost of $323,500 is being paid in installments. As of September 30, 2009, $250,000 has been paid and is reflected in deposits and other assets.

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

PART II. OTHER INFORMATION

(See Next Page)

ITEM 6. EXHIBITS.

Number	Description
3.1	Articles of Incorporation, as amended. (2)
3.2	Amended and Restated Bylaws. (1)
4.1	Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (7)
4.2	Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (9)
4.3	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (7)
4.4	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (3)
4.5	Registration Rights Agreement, dated June 29, 2006. (3)
4.6	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
4.7	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (5).
4.8	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (9)
4.0	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (9)
4.10*	Form of Employee Option Agreement. (9)
4.11	1999 Equity Incentive Plan (11)
4.12	2008 Stock Incentive Plan. (12)
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (4)
10.2*	Employment Agreement dated April 23, 2007 with Javan Esfandiari. (10)
10.3	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (7)
10.4	Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (8)
10.5	Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (3)
10.6	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5)
10.7	Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (5)
10.8	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (5)
10.9	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5)
10.10	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5)
10.11	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (5)
10.12	License and Supply Agreement dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc. (6)
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	

	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the Registrant's registration statement on Form SB-2 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.

(2) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.

(4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.

(5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.

(6) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on June 7, 2004.

(7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 31, 2005.

(8) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on March 28, 2005.

(9) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.

(10) Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed with the Commission on May 3, 2007.

(11) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.

(12) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.

(*) An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.

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, 2009

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

Date: November 4, 2009

By: /s / Richard J. Larkin
Richard J. Larkin
Chief Financial Officer
(Principal Financial and Accounting Officer)