CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
November 03, 2011

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

FORM 10 - Q

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

For the quarterly period ended September 30, 2011

OR

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

For the transition period from: ______ to ________

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

Nevada	88-0425691
(State or other 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)
___N/A___
(Former Name or Former Address, if Changed Since Last Report)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ] (Do not check if a smaller reporting company)	Smaller reporting company [X]

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 1, 2011, the Registrant had 63,315,096 shares outstanding of its $.01 par value common stock.

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

September 30, 2011

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Chembio Diagnostics, Inc.

PART I
Item 1. FINANCIAL STATEMENTS

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

	- ASSETS -			
	September 30, 2011		December 31, 2010	
	(UNAUDITED)			
CURRENT ASSETS:				
Cash and cash equivalents	$	3,045,348	$	2,136,351
Accounts receivable, net of allowance for doubtful accounts of $20,000 and $35,000 for 2011 and 2010, respectively		2,657,781		3,946,398
Inventories		2,588,225		1,349,161
Prepaid expenses and other current assets		188,841		204,824
TOTAL CURRENT ASSETS		8,480,195		7,636,734
FIXED ASSETS, net of accumulated depreciation		848,799		813,214
OTHER ASSETS:				
License agreements, net of current portion		525,000		600,000
Deposits on manufacturing equipment		208,460		-
Deposits and other assets		36,226		36,226
TOTAL ASSETS	$	10,098,680	$	9,086,174
- LIABILITIES AND STOCKHOLDERS' EQUITY -				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$	2,346,410	$	2,055,943
Current portion of loans payable		341,013		55,817
Deferred revenue		490,522		65,000
License fee payable		-		875,000
Current portion of obligations under capital leases		21,071		24,697
TOTAL CURRENT LIABILITIES		3,199,016		3,076,457
OTHER LIABILITIES:				
Loans payable - net of current portion		145,859		186,197
Obligations under capital leases - net of current portion		-		14,576
TOTAL LIABILITIES		3,344,875		3,277,230
COMMITMENTS AND CONTINGENCIES				

STOCKHOLDERS' EQUITY:				
Preferred stock – 10,000,000 shares authorized, none outstanding		-		-
Common stock - $.01 par value; 100,000,000 shares authorized, 63,315,096 and 62,238,983 shares issued and outstanding for 2011 and 2010, respectively		633,151		622,390
Additional paid-in capital		40,064,570		39,658,617
Accumulated deficit		(33,943,916)		(34,472,063)
TOTAL STOCKHOLDERS' EQUITY		6,753,805		5,808,944
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$	10,098,680	$	9,086,174

See accompanying notes to condensed consolidated financial statements

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

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
REVENUES:				
Net product sales	$ 5,526,883	$ 3,786,572	$ 11,516,325	$ 8,337,133
License and royalty revenue	25,000	61,789	125,322	400,758
R&D, milestone and grant revenue	369,904	656,642	1,529,972	2,299,970
TOTAL REVENUES	5,921,787	4,505,003	13,171,619	11,037,861
Cost of product sales	3,251,054	2,296,502	6,524,266	5,428,020
GROSS MARGIN	2,670,733	2,208,501	6,647,353	5,609,841
OPERATING EXPENSES:				
Research and development expenses	1,242,295	1,230,100	3,697,309	2,822,455
Selling, general and administrative expenses	949,237	801,854	2,412,867	2,143,715
	2,191,532	2,031,954	6,110,176	4,966,170
NET INCOME FROM OPERATIONS	479,201	176,547	537,177	643,671
OTHER INCOME (EXPENSES):				
Other expense	-	(3,923)	-	(3,923)
Interest income	1,278	1,018	4,315	2,747
Interest expense	(4,874)	(5,666)	(13,345)	(9,927)
	(3,596)	(8,571)	(9,030)	(11,103)
NET INCOME BEFORE INCOME TAXES	475,605	167,976	528,147	632,568
Provision for income taxes	-	-	-	-
NET INCOME	$ 475,605	$ 167,976	$ 528,147	$ 632,568
Basic net income per share	$ 0.01	$ 0.00	$ 0.01	$ 0.01

Diluted net income per share	$ 0.01	$ 0.00	$ 0.01	$ 0.01
Weighted average number of shares outstanding, basic	63,304,584	62,146,847	62,887,212	62,068,204
Weighted average number of shares outstanding, diluted	68,137,033	67,264,551	67,645,878	67,226,283

See accompanying notes to condensed consolidated financial statements

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

	September 30, 2011	September 30, 2010
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	$ 14,460,236	$ 10,179,232
Cash paid to suppliers and employees	(12,897,517)	(9,964,407)
Interest received	1,278	1,110
Interest paid	(4,874)	(2,204)
Net cash provided by operating activities	1,559,123	213,731
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(282,175)	(188,193)
Net cash used in investing activities	(282,175)	(188,193)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	280,393	27,073
Payment of license obligation	(875,000)	-
(Payment of) and proceeds from loan obligation, net	244,858	231,010
Payment of capital lease obligation	(18,202)	(15,873)
Net cash (used in) provided by financing activities	(367,951)	242,210
INCREASE IN CASH AND CASH EQUIVALENTS	908,997	267,748
Cash and cash equivalents - beginning of the period	2,136,351	1,068,235
Cash and cash equivalents - end of the period	$ 3,045,348	$ 1,335,983
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net Income	$ 528,147	$ 632,568
Adjustments:		

Depreciation and amortization		321,590		212,838
Provision for doubtful accounts		(15,000)		-
Loss on retirement/sale of fixed asset		-		3,923
Share based compensation		136,321		141,864
Changes in assets and liabilities:				
Accounts receivable		1,303,617		(858,629)
Inventories		(1,239,064)		(327,538)
Prepaid expenses and other current assets		15,983		76,122
Deposits and other assets		(208,460)		101,234
Accounts payable and accrued liabilities		290,467		510,509
Deferred research and development revenue		425,522		(279,160)
Net cash provided by operating activities	$	1,559,123	$	213,731
Supplemental disclosures for non-cash investing and financing activities:				
Deposits on manufacturing equipment transferred to fixed assets	$	-	$	300,000

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2011
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's primary products include three rapid tests employing lateral flow technology 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. More recently the Company has begun commercializing products using the Company's patented Dual Path Platform technology (DPP®), which included products that detect other infectious diseases as well as HIV. Lateral flow rapid HIV tests represented approximately 76% of the Company's net product sales in the nine months ended September 30, 2011 compared with nearly 93% for the nine months ended September 30, 2010. DPP® rapid tests represented approximately 23% of the Company's net product sales in the nine months ended September 30, 2011 compared with less than 1% for the nine months ended September 30, 2010. The Company also has other rapid tests that together represented approximately 1% and 7% of net product sales in the first nine months of 2011 and 2010, respectively. The Company's products are sold, directly and through distributors, to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, and medical professionals both domestically and internationally. Chembio's products are sold under the Company's STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Alere North America, Inc. ("Alere"), which is the Company's exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company's new products and all of those that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2009, 2010 and 2011 to date, the Company has completed development of its first five products that employ the DPP®, and the Company has additional products under development that employ the DPP®.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation:

The following (a) condensed balance sheet as of December 31, 2010, which has been derived from audited financial statements, and (b) the unaudited interim condensed financial statements as of September 30, 2011 and for the three- and nine-month periods ended September 30, 2011 and 2010 have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures, which are normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations, although we believe that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the Financial Statements and the notes thereto, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of the Company's condensed consolidated financial position as of September 30, 2011, its condensed consolidated results of operations for the three- and nine-month periods ended September 30, 2011 and 2010 and its cash flows for the nine-month periods ended September 30, 2011 and 2010, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

(b) Revenue Recognition

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

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

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

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2011
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(c) Inventories:

Inventories consist of the following at:

	September 30, 2011	December 31, 2010
Raw materials	$ 1,358,241	$ 785,693
Work in process	595,421	235,548
Finished goods	634,563	327,920
	$ 2,588,225	$ 1,349,161

(d) Earnings Per Share:

Basic earnings per share is computed by dividing net income or loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted income or (loss) per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. The following securities, presented on a common share equivalent basis for the three- and nine-month periods ended September 30, 2011 and 2010, have been included in the diluted per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Basic	63,304,584	62,146,847	62,887,212	62,068,204
Diluted	68,137,033	67,264,551	67,645,878	67,226,283

The following securities, presented on a common share equivalent basis for the three- and nine-month periods ended September 30, 2011 and 2010, have been included in the diluted per share computations as these securities exercise prices were less than the stock price as of September 30, 2011 and 2010, respectively:

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
1999 and 2008 Plan Stock Options	4,832,449	5,117,704	4,758,666	5,158,079
Other Stock Options	-	-	-	-
Warrants	-	-	-	-
	4,832,449	5,117,704	4,758,666	5,158,079

There were 1,946,937 and 3,373,354 options and warrants outstanding as September 30, 2011 and 2010, respectively, that were not included in the calculation of diluted income per share for the nine months ended because their effect would have been anti-dilutive. There were 1,902,981 and 3,373,354 options and warrants outstanding as of September 30, 2011 and 2010, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended September 30, 2011 and 2010, respectively, because the effect would have been anti-dilutive as of September 30, 2011 and 2010, respectively.

(e) Employee Stock Option Plan:

The Company had a 1999 Stock Option Plan (“SOP”). The number of options available under the SOP was 3,000,000 shares of Common Stock. As of September 30, 2011, there were 1,588,500 outstanding options under this SOP. No additional options may be issued under the SOP more than 10 years after its adoption.

Effective June 3, 2008, the Company’s stockholders voted to approve the 2008 Stock Incentive Plan (“SIP”), with 5,000,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011 the Company’s stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 1,000,000 to 6,000,000. Under the terms of the SIP, the Compensation Committee of the Company’s Board has the discretion to select the persons to whom awards are to be granted. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of September 30, 2011, there were 84,995 options exercised, 4,601,568 options outstanding and 1,313,437 options still available to be issued under the SIP.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month periods ended September 30, 2011 and 2010 was $.26 and none per share, respectively and for the nine-month periods ended September 30, 2011 and 2010 was $.20 and $.22 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon the historical volatility of our stock. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has limited history of employee exercise of options to date.

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

	For the three months ended			For the nine months ended			
	September 30, 2011		September 30, 2010	September 30, 2011		September 30, 2010	
Expected term (in years)	3.75		n/a	3.75		5	
Expected volatility	92.11-117.9	%	n/a	97.11-117.9	%	116.82	%
Expected dividend yield	n/a		n/a	n/a		n/a	
Risk-free interest rate	.57-1.39	%	n/a	.57-1.24	%	1.43	%

The Company's results for the three-month periods ended September 30, 2011 and 2010 include share-based compensation expense totaling $80,000 and $28,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold ($6,000 and $4,000, respectively), research and development ($14,000 and $13,000, respectively) and selling, general and administrative expenses ($60,000 and $11,000, respectively). The results for the nine-month periods ended September 30, 2011 and 2010 include share-based compensation expense totaling $136,000 and $142,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold ($12,000 and $17,000, respectively), research and development ($40,000 and $72,000, respectively) and selling, general and administrative expenses ($84,000 and $53,000, respectively). No income tax benefit has been recognized in the statement of operations for share-based compensation arrangements due to the history of pre-2009 operating losses.

Stock option compensation expense for the three- and nine-month periods ended September 30, 2011 and 2010 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite service period for each vesting portion of the award, except for those that vested immediately whereby the estimated fair value was expensed immediately.

The following table provides stock option activity for the nine months ended September 30, 2011:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2010	5,530,568	$ 0.16	2.82 years	$ 1,497,063
Granted	1,281,250	$ 0.43		
Exercised	(562,416)	$ 0.13		
Forfeited/expired/cancelled	(59,334)	$ 0.34		
Outstanding at September 30, 2011	6,190,068	$ 0.21	2.85 years	$ 1,134,600
Exercisable at September 30, 2011	3,643,394	$ 0.13	2.30 years	$ 782,931

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As of September 30, 2011, there was $338,000 of net unrecognized compensation cost related to stock options that have not vested, which is expected to be recognized over a weighted average period of approximately 1.4 years. The total fair value of stock options vested during the three-month periods ended September 30, 2011 and 2010, was approximately $49,000 and none, respectively. The total fair value of stock options vested during the nine-month periods ended September 30, 2011 and 2010, was approximately $149,000 and $125,000, respectively.

(f) Geographic Information:

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

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

	For the three months ended		For the nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Africa	$ 456,303	$ 2,273,872	$ 1,549,274	$ 3,591,743
Asia	221,261	28,312	314,884	215,958
Europe	7,286	23,804	49,605	84,436
North America	2,820,017	1,326,186	6,628,629	4,193,957
South America	2,022,016	134,398	2,973,933	251,039
	$ 5,526,883	$ 3,786,572	$ 11,516,325	$ 8,337,133

(g) Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consist of:

	September 30, 2011	December 31, 2010
Accounts payable – suppliers	$ 1,309,507	$ 883,719
Accrued commissions	201,965	114,451
Accrued royalties / license fees	339,437	352,285
Accrued payroll	134,704	162,740
Accrued vacation	162,833	129,732
Accrued bonuses	100,000	140,325
Accrued expenses – other	97,964	272,691
TOTAL	$ 2,346,410	$ 2,055,943

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
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(h) Recent Accounting Pronouncements Affecting the Company

Revenue Arrangements with Multiple Deliverables

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

NOTE 3 — COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS:

(a) Oswaldo Cruz Foundation/Fiocruz:

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

In July 2011, FIOCRUZ informed the Company that ANVISA (the Brazilian regulatory agency) had approved the DPP® Leptospirosis assay for use in Brazil. This approval triggered a milestone event of $100,000. In accordance with guidance, management has concluded the FIOCRUZ event recorded in the third quarter for Leptospirosis met the definition of milestone events. The Company earned $100,000 for the three months ended September 30, 2011.

Under the Leptospirosis contract, there are additional royalties and purchase commitments due to the Company over the remaining life of the Agreement.

During the three months ended September 30, 2011 and 2010 the Company recognized $100,000 and $400,000, respectively in milestone revenues from FIOCRUZ.

During the nine months ended September 30, 2011 and 2010 the Company recognized $505,000 and $625,000, respectively in milestone revenues from FIOCRUZ.

(b) Infectious Disease Research Institute (IDRI) Agreement:

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

As of September 30, 2011, the Company received an aggregate of $390,000 in research and development payments from this agreement. Future milestone payments of $10,000 are expected over the next quarter and will be recognized when the milestones are met.

(c) National Institutes of Health (NIH) Grant:

In June 2009, the Company received a $3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. The Company earned, for the three- and nine-month periods ended September 30, 2011, $159,000 and $519,000, respectively from this grant. The Company earned an aggregate of $2,207,000 from this grant from inception through September 30, 2011, of which $757,000 was paid to sub-contractors.

In March 2011, the Company received a $2.4 million, three-year grant from the United States National Institutes of Health to complete development of a test for Tuberculosis. Grants are invoiced after expenses are incurred. The Company earned, for the three- and nine-month periods ended September 30, 2011, $97,000 and $252,000, respectively, from this grant. The Company earned $280,000 from this grant from inception through September 30, 2011 of which $27,000 was paid to sub-contractors.

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

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

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

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

The Security Agreement contains covenants that place restrictions on the Company's operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, restrictions on fundamental changes. The Security Agreement also requires that the Company maintain a minimum tangible net worth at all times of greater than $3,000,000 and EBITDA to CMLTD plus interest cannot be less than 1.25 to 1.00 for any fiscal year. (EBITDA is earnings before interest, taxes, depreciation and amortization; CMLTD is defined as, for any one-year period, the current scheduled principal payments required to be paid for the applicable period.). The Company was in compliance with all required financial covenants at September 30, 2011.

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

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

The Security Agreement contains covenants that place restrictions on the Company's operations, including covenants relating to mergers, debt restrictions, capital expenditures, tangible net worth, net profit, leverage, fixed charge coverage, employee loan restrictions, distribution restrictions (common stock and preferred stock), dividend restrictions, restrictions on lease payments to affiliates, restrictions on changes in business, asset sale restrictions, restrictions on acquisitions and intercompany transactions, restrictions on fundamental changes. The Company was in compliance with all required financial covenants at September 30, 2011.

The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of September 30, 2011 was $194,000 and as of September 30, 2011 nothing was drawn down on the

Demand Note, while $285,626 was drawn down on the Equipment Note.

Future minimum payments under the Term Note, excluding interest, as of September 30, 2011 were as follows:

Periods ending September 30,

2012	$47,840
2013	50,538
2014	53,389
2015	42,009
	193,699
Less: current maturities	(47,840)
	$145,859

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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, 2011 was $7,547 and is reflected with the Term Note above on the balance sheet as current portion of loans payable.

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

NOTE 5 — RIGHTS AGREEMENT:

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

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

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

NOTE 6 — WARRANTS

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

As of September 30, 2011, the Company had warrants outstanding to purchase 1,218,915 shares of common stock at prices ranging from $.40 to $1.00, with a weighted average of $.468. On October 5, 2011 warrants to purchase 1,144,117 shares of common stock expired.

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NOTE 7 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

(a) Economic Dependency:

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

	For the three months ended				For the nine months ended				Accounts Receivable
	September 30, 2011		September 30, 2010		September 30, 2011		September 30, 2010		As of
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	September 30, 2011
Customer 1	$ 1,912,199	35	$ 1,090,599	29	$ 5,386,670	47	$ 3,540,525	42	$ 714,974
Customer 2	2,012,425	36	*	*	2,936,270	25	*	*	762,121
Customer 3	573,957	10	*	*	*	*	1,763,895	21	468,165
Customer 4	*	*	1,289,184	34	*	*	*	*	91,814
Customer 5	*	*	735,750	19	*	*	*	*	80,196

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

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

	For the three months ended				For the nine months ended		Accounts Payable
	September 30, 2011		September 30, 2010		September 30, 2011	September 30, 2010	As of
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases		