

CHEMBIO DIAGNOSTICS, INC.
Form 10-K/A
January 03, 2013

UNITED STATES
Securities and Exchange Commission
Washington, D.C. 20549
FORM 10-K/A

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2011

or
 TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission File No. 0-30379
CHEMBIO DIAGNOSTICS, INC.
(Exact name of registrant as specified in its charter)
Nevada 88-0425691
(State or other jurisdiction of (I.R.S. Employer Identification
incorporation or organization) No.)
3661 Horseblock Road, 11763
Medford, NY
(Address of principal executive (Zip Code)
offices)

Registrant's telephone number, including area code (631) 924-1135

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
None	None

Securities registered pursuant to section 12(g) of the Act:

Common Stock, \$0.01 par value
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ___ No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ___ No X

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 Website, 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 (Do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of the last business day of the Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was \$22,598,000.

As of March 6, 2012, the registrant had 63,668,096 common shares outstanding.

* Without asserting that any of the issuer's directors or executive officers, or the entities that own more than five percent of the outstanding shares of the Registrant's common stock, are affiliates, the shares of which they are beneficial owners have not been included in shares held by non-affiliates solely for this calculation.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this “Amendment”) to the Annual Report on Form 10-K of Chembio Diagnostics, Inc. (the “Company”) for the fiscal year ended December 31, 2011, is being filed to correct a typographical error in the date of the previously filed “Report of Independent Registered Public Accounting Firm” from ParenteBeard LLC for the fiscal year ended December 31, 2010, for which the original copy was dated March 3, 2011, but for which the filed copy was incorrectly dated March 8, 2012.

In addition, pursuant to the rules of the Securities and Exchange Commission (the “SEC”), “Item 8. Financial Statements and Supplementary Data” is being filed in its entirety in this Amendment. The only change from the original filing has been the aforementioned date correction in the Report of Independent Registered Public Accounting Firm from ParenteBeard LLC for the fiscal year ended December 31, 2010.

Consistent with the rules of the SEC, the certifications of the Company’s principal executive officers and principal financial and accounting officer as of the date of this Amendment are attached as exhibits to this Amendment. The only change in these certifications is their date.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and schedules that constitute Item 8 are attached at the end of this Annual Report on Form 10-K. An index to these Financial Statements and schedules is also included on page F-1 of this Annual Report on Form 10-K.

ITEM 15.

Number	Description
3.1	Articles of Incorporation, as amended. (1)
3.2	Amended and Restated Bylaws. (2)
4.1*	Form of Employee Option Agreement. (3)
4.2	1999 Equity Incentive Plan. (4)
4.3	2008 Stock Incentive Plan. (5)
4.4	Rights Agreement, dated March 8, 2010 (6)
4.5	Form of Warrant (to be filed by amendment) [to be revised]
10.1*	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (7)
10.2*	Employment Agreement dated March 5, 2010 with Javan Esfandiari. (8)
10.3	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (9)
10.4	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9)
10.5	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (9)
10.6	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (9)
10.7	Secured Term Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.8	Secured Revolving Demand Note, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.9	Loan and Security Agreement, dated as of June 14, 2010, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (10)
10.10	Revolving Term Note, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
10.11	Loan and Security Agreement, dated as of July 22, 2011, by and among the Registrant, Chembio Diagnostics Systems, Inc. and HSBC Bank, NA (11)
14.1	Ethics Policy (12)
21	List of Subsidiaries (13)
23.1	Consent of BDO USA, LLP, Independent Registered Public Accountants. (13)
23.2	Consent of ParenteBeard LLC, Independent Registered Public Accountants. (13)
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.
101.INS	XBRL Instance Document (13)
101.SCH	XBRL Taxonomy Extension Schema Document (13)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (13)
101.DEF	XBRL Taxonomy Definition Linkbase Document (13)
101.LAB	XBRL Taxonomy Label Linkbase Document (13)
101.PRE	XBRL Taxonomy Presentation Linkbase Document (13)
1	Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.
2	Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.

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

- 4 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
 - 5 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
 - 6 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
 - 7 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
 - 8 Incorporated by reference to the Registrant's registration statement on Form S-1/A filed with the Commission on March 11, 2010.
 - 9 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
 - 10 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.
 - 11 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 3, 2011.
 - 12 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 30, 2006.
 - 13 Incorporated by reference to the Registrant's annual report on Form 10-K filed with the Commission on March 8, 2012.
- (*) An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this registration statement.
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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

Date: January 3, 2013 By /s/ Lawrence A. Siebert
Lawrence A. Siebert
President, Chief Executive Officer and
Chairman of the Board

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors and Stockholders of
Chembio Diagnostics, Inc. and Subsidiary
Medford, New York

We have audited the accompanying consolidated balance sheet of Chembio Diagnostics, Inc. and Subsidiary (the "Company") as of December 31, 2011 and the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiary as of December 31, 2011, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

BDO USA, LLP

/s/ BDO USA, LLP

Melville, New York
March 8, 2012

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors and Stockholders of
Chembio Diagnostics, Inc. and Subsidiary
Medford, New York

We have audited the accompanying consolidated balance sheet of Chembio Diagnostics, Inc. and Subsidiary (the "Company") as of December 31, 2010 and the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chembio Diagnostics, Inc. and Subsidiary as of December 31, 2010, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

PARENTEBEARD LLC

/s/ PARENTEBEARD LLC

New York, New York
March 3, 2011

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

- ASSETS -

	December 31, 2011	December 31, 2010
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,010,954	\$ 2,136,351
Accounts receivable, net of allowance for doubtful accounts of \$30,000 and \$35,000 for 2011 and 2010, respectively	2,998,449	3,946,398
Inventories	2,300,286	1,349,161
Prepaid expenses and other current assets	681,893	204,824
TOTAL CURRENT ASSETS	8,991,582	7,636,734
FIXED ASSETS, net of accumulated depreciation	1,062,276	813,214
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	4,749,622	-
License agreements, net of current portion	500,000	600,000
Deposits on manufacturing equipment	139,790	-
Deposits and other assets	42,474	36,226
TOTAL ASSETS	\$ 15,485,744	\$ 9,086,174

- LIABILITIES AND STOCKHOLDERS' EQUITY -

CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,789,500	\$ 2,055,943
Current portion of loans payable	53,550	55,817
Deferred revenue	-	65,000
License fee payable	-	875,000
Current portion of obligations under capital leases	14,576	24,697
TOTAL CURRENT LIABILITIES	2,857,626	3,076,457
OTHER LIABILITIES:		
Loans payable - net of current portion	133,484	186,197
Obligations under capital leases - net of current portion	-	14,576
TOTAL LIABILITIES	2,991,110	3,277,230

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY:

Preferred stock – 10,000,000 shares authorized, none outstanding

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Common stock - \$.01 par value; 100,000,000 shares authorized, 63,368,096 and 62,238,983 shares issued and outstanding for 2011 and 2010, respectively	633,681	622,390
Additional paid-in capital	40,124,225	39,658,617
Accumulated deficit	(28,263,272)	(34,472,063)
TOTAL STOCKHOLDERS' EQUITY	12,494,634	5,808,944
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 15,485,744	\$ 9,086,174

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF INCOME
FOR THE YEARS ENDED

	December 31, 2011	December 31, 2010
REVENUES:		
Net product sales	\$ 17,422,311	\$ 13,516,359
License and royalty revenue	140,322	432,238
R&D, milestone and grant revenue	1,825,403	2,756,106
TOTAL REVENUES	19,388,036	16,704,703
Cost of product sales	9,997,733	8,604,004
GROSS MARGIN	9,390,303	8,100,699
OPERATING EXPENSES:		
Research and development expenses	4,878,119	2,586,308
Selling, general and administrative expenses	3,424,297	2,940,721
	8,302,416	5,527,029
INCOME FROM OPERATIONS	1,087,887	2,573,670
OTHER INCOME (EXPENSES):		
Other expense	-	(3,923)
Interest income	6,298	4,147
Interest expense	(18,623)	(14,727)
	(12,325)	(14,503)
INCOME BEFORE INCOME TAXES	1,075,562	2,559,167
Income tax (benefit) provision	(5,133,229)	45,823
NET INCOME	\$ 6,208,791	\$ 2,513,344
Basic net income per share	\$ 0.10	\$ 0.04
Diluted net income per share	\$ 0.09	\$ 0.04
Weighted average number of shares outstanding, basic	62,998,402	62,102,861
Weighted average number of shares outstanding, diluted	68,450,220	70,920,915

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2011 AND 2010

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital Amount	Accumulated Deficit Amount	Total Amount
Balance at December 31, 2009	61,979,901	\$ 619,799	\$ 39,453,522	\$ (36,985,407)	\$ 3,087,914
Warrants and options:					
Excercised	259,082	2,591	35,020	-	37,611
Stock option compensation	-	-	170,075	-	170,075
Net income	-	-	-	2,513,344	2,513,344
Balance at December 31, 2010	62,238,983	\$ 622,390	\$ 39,658,617	\$ (34,472,063)	\$ 5,808,944
Warrants and options:					
Excercised	1,129,113	11,291	276,261	-	287,552
Stock option compensation	-	-	189,347	-	189,347
Net income	-	-	-	6,208,791	6,208,791
Balance at December 31, 2011	63,368,096	\$ 633,681	\$ 40,124,225	\$ (28,263,272)	\$ 12,494,634
See accompanying notes to consolidated financial statements					

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED

	December 31, 2011	December 31, 2010
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$ 20,335,985	\$ 14,534,632
Cash paid to suppliers and employees	(18,055,252)	(13,507,202)
Interest received	6,298	4,147
Interest paid	(18,623)	(14,727)
Net cash provided by operating activities	2,268,408	1,016,850
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(726,680)	(182,292)
Net cash used in investing activities	(726,680)	(182,292)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option and warrant exercises	287,552	37,611
Proceeds from loan	-	250,000
Payment of license obligation	(875,000)	-
Payment of loan obligation	(54,980)	(32,517)
Payment of capital lease obligation	(24,697)	(21,536)
Net cash (used in) provided by financing activities	(667,125)	233,558
INCREASE IN CASH AND CASH EQUIVALENTS	874,603	1,068,116
Cash and cash equivalents - beginning of the period	2,136,351	1,068,235
Cash and cash equivalents - end of the period	\$ 3,010,954	\$ 2,136,351
RECONCILIATION OF NET INCOME TO NET CASH PROVIDED BY OPERATING ACTIVITIES:		
Net Income	\$ 6,208,791	\$ 2,513,344
Adjustments:		
Depreciation and amortization	437,828	283,743
Provision for deferred taxes	(5,155,713)	-
Provision for doubtful accounts	(5,000)	15,000
Loss on retirement/sale of fixed asset	-	3,923
Share based compensation	189,347	170,075
Changes in assets and liabilities:		
Accounts receivable	952,949	(2,185,071)
Inventories	(951,125)	206,742
Prepaid expenses and other current assets	(70,978)	61,813
Deposits and other assets	(6,248)	93,334
Accounts payable and accrued liabilities	733,557	149,780

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Deferred research and development revenue	(65,000)	(295,833)
Net cash provided by operating activities	\$ 2,268,408	\$ 1,016,850

Supplemental disclosures for non-cash investing and financing activities:

Deposits on manufacturing equipment transferred to fixed assets	\$ -	\$ 338,375
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See accompanying notes to consolidated financial statements

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the “Company” or “Chembio”) and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company’s main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Lateral Flow Rapid HIV tests represented nearly 74% of the Company’s product revenues in 2011. The Company’s products based on its patented DPP® platform represented approximately 24% of the Company’s product revenues in 2011. The Company also has other rapid tests that together represented approximately 2% of sales in 2011. The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio’s products are sold under the Company’s STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Alere, 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 products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

(a) Principles of Consolidation:

The consolidated financial statements include the accounts of the Company, and its wholly owned subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

(b) Use of Estimates:

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make assumptions and estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods covered thereby. Actual results could differ from these estimates. Judgments and estimates of uncertainties are required in applying the Company’s accounting policies in certain areas. The following are some of the areas requiring significant judgments and estimates: determinations of the useful lives of assets, estimates of allowances for doubtful accounts, inventory reserves and deferred tax assets.

(c) Fair Value of Financial Instruments:

The carrying value for cash and cash equivalents, accounts receivable and accounts payable, approximate fair value because of the immediate or short-term maturity of these financial instruments. The Company’s debt relates to borrowings under its credit facilities and term loan (see Note 7), which approximates fair value due to market interest rates.

(d) Statements of Cash Flows:

For purposes of the statements of cash flows the Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

(e) Concentrations of Credit Risk:

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the FDIC Insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company’s ability to obtain letters of credit from certain foreign customers, and its diverse customer base both in number of customers and geographic locations. We currently do not require collateral for accounts receivable.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2011 AND 2010

(f)Inventories:

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost or market. Cost is determined on the first-in, first-out method.

(g)Fixed Assets:

Fixed assets are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter.

(h)License Agreement:

In February 2008, the Company entered into a sublicense agreement (see Note 6) for which it had initially recorded an asset of \$1,000,000. This asset is being expensed over an estimated economic life of ten years, based on the expected lifespan of our then current HIV products. The current portion of this asset is \$100,000 as of December 31, 2011 and 2010 and is reported in prepaid expenses and other current assets. The long-term portion as of December 31, 2011 and 2010 is \$500,000 and \$600,000, respectively and is reflected in other assets on the consolidated balance sheet.

(i)Impairment of Long-Lived Assets and Intangible Assets

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. We believe that the carrying values of our long-lived tangible and intangible assets were realizable at December 31, 2011 and 2010, respectively.

(j)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. As of December 31, 2011 and 2010, an aggregate of none and \$65,000, respectively of advanced revenues was unearned.

On June 15, 2010, the Company adopted Financial Accounting Standards Board ("FASB") issued authoritative guidance ("guidance") prospectively for the recognition of revenue under the milestone method. The Company applies the milestone method of revenue recognition for certain collaborative research projects defining milestones at the inception of the agreement.

(k)Research and Development:

Research and development (R&D) costs are expensed as incurred. During the fourth quarter of 2010 the Company was awarded \$1,466,875 in Qualified Therapeutic Discovery Project grants ("QTDP") for the years 2010 and 2009 under Section 48D of the Internal Revenue Code, as enacted under the Patient Protection and Affordable Care Act of 2010. This was reflected as a reduction of R&D costs for the year ended December 31, 2010.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2011 AND 2010

(l) Stock-Based Compensation:

Stock-based compensation expense is calculated using the Black-Scholes valuation model based on awards ultimately expected to vest, reduced for forfeitures, and expensed on a straight-line basis over the requisite service period of the grant.

(m) Income Taxes:

The Company accounts for income taxes under the provisions of FASB Guidance. The deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

The Guidance also prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The Guidance also provides guidance related to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to uncertain tax positions will be recorded in tax expense.

(n) Earnings Per Share

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

	For the years ended	
	December 31, 2011	December 31, 2010
Basic	62,998,402	62,102,861
Diluted	68,450,220	70,920,915

Basic earnings per share is computed by dividing net earnings attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings per share for the year ended December 31, 2011 and 2010 reflects the potential dilution from the exercise or conversion of other securities into common stock.

The following securities, presented on a common share equivalent basis, have been used in the diluted per share computations:

	For the years ended	
	December 31, 2011	December 31, 2010
1999 and 2008 Plan Stock Options	5,451,818	5,638,310
Other Stock Options	-	124,625
Warrants	-	3,055,119
	5,451,818	8,818,054

There were 708,631 and none options and warrants outstanding as of December 31, 2011 and 2010, respectively, which were not included in the calculation of diluted income per share for the years ended because their effect would have been anti-dilutive.

(o) 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.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2011 AND 2010

NOTE 3 — INVENTORIES:

Inventories consist of the following at:

	December 31, 2011	December 31, 2010
Raw materials	\$ 1,340,177	\$ 785,693
Work in process	390,162	235,548
Finished goods	569,947	327,920
	\$ 2,300,286	\$ 1,349,161

NOTE 4 — FIXED ASSETS:

Fixed assets consist of the following at December 31:

	December 31, 2011	December 31, 2010
Machinery and equipment	\$ 1,982,926	\$ 1,635,466
Furniture and fixtures	221,299	207,485
Computer and telephone equipment	460,842	348,503
Leasehold improvements	595,492	482,215
Automobiles	29,228	29,228
	3,289,787	2,702,897
Less accumulated depreciation and amortization	(2,227,511)	(1,889,683)
	\$ 1,062,276	\$ 813,214

Included in fixed assets is \$8,000 and \$24,000, net of accumulated depreciation of \$103,000 and \$87,000 of assets held under capital leases as of December 31, 2011 and 2010, respectively. Fixed assets also include \$223,000 in equipment, which has been delivered and set-up but is undergoing validation and as such is currently not being depreciated. Depreciation expense for the 2011 and 2010 years aggregated \$338,000 and \$284,000, respectively.

As of December 31, 2011, the Company had paid deposits on various pieces of equipment aggregating \$139,790 and is reflected in Other Assets on the balance sheet. The Company is further committed to an additional obligation of \$151,910 as various milestones are achieved by the various vendors.

NOTE 5 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at December 31,:

	December 31, 2011	December 31, 2010
Accounts payable – suppliers	\$ 1,258,465	\$ 883,719
Accrued commissions	205,588	114,451
Accrued royalties / license fees	480,297	352,285

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Accrued payroll	174,398	162,740
Accrued vacation	156,884	129,732
Accrued bonuses	284,375	140,325
Accrued income taxes	11,523	-
Accrued expenses – other	217,970	272,691
TOTAL	\$ 2,789,500	\$ 2,055,943

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2011 AND 2010

NOTE 6 — 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 an exclusive license of our DPP® technology for a specific field of use. The license fee become fully earned and non-refundable based upon certain conditions being met in June of 2010. In addition, the Company recognizes income from R&D milestones when those milestones are reached and non-milestone contracts and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of December 31, 2011 and 2010, an aggregate of none and \$65,000 of advanced revenues was unearned.

NOTE 7 — 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 December 31, 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 December 31, 2011.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

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The Company currently maintains its operating, payroll, and primary cash accounts at HSBC. The balance due on the Term Note as of December 31, 2011 was \$182,000 and nothing was drawn down on the Demand or equipment Note as of December 31, 2011.

Future minimum payments under the Term Note, excluding interest, as of December 31, 2011 were as follows:

Periods ending December 31,

2012	\$48,501
2013	51,236
2014	54,126
2015	28,122
	181,985
Less:	
current	
maturities	(48,501)
	\$133,484

In June 2009, the Company purchased a vehicle for use by the CEO and obtained financing in the amount of \$29,000. 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 December 31, 2011 was \$5,000.

Future minimum payments under this obligation, excluding interest as of December 31, 2011 were as follows:

Year ending December 31,

2012	\$5,049
	5,049
Less:	
current	
maturities	(5,049)
	\$-

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. 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 which was paid 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 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.

NOTE 8 — OBLIGATIONS UNDER CAPITAL LEASES:

The Company is obligated under capitalized leases for certain manufacturing and computer equipment.

Future minimum lease payments under these capitalized lease obligations, including interest as of December 31, 2011 were as follows:

Year ending December 31,

2012	\$15,203
	15,203
Less imputed	
interest	(627)
Present value	
of future	
minimum lease	
payments	14,576

Less current maturities	(14,576)
	\$-

These leases have annual interest rates ranging from 13% - 15%.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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NOTE 9 — RELATED PARTIES:

In September 2006, the Company entered into distribution and licensing agreements with Alere, Inc. (“Alere”). As of December 31, 2011, Alere owns 8.48% of the Company. See Note 15 where Alere is listed as customer 1.

During the quarter ended December 31, 2008, Alere notified the Company that they had entered into a contract with Bio-Rad Laboratories, Inc. (“Bio-Rad”) for royalties on Bio-Rad’s patent for the detection of HIV-2 antibodies. The agreement also provided for Alere to pay past royalties. On June 25, 2009, the Company and Alere entered into a letter agreement whereby certain obligations were agreed to be paid from future revenues. The obligations included the Company’s royalties owed under its agreements with Alere on lateral flow licenses. All such royalty obligations were fully paid in 2010.

NOTE 10 — INCOME TAXES:

The provision (benefit) for income taxes for the years ended December 31, 2011 and 2010, is comprised of the following:

	2011	2010
Current		
Federal	\$ 22,082	\$ 45,122
State	402	701
Total current provision	22,484	45,823
Deferred		
Federal	(5,155,713)	-
State	-	-
Total deferred provision	(5,155,713)	-
Total provision	\$ (5,133,229)	\$ 45,823

The Company had an ownership change as described in Internal Revenue Code Sec. 382 during 2004 (“2004 change”). As a result, the Company’s net operating losses prior to the 2004 change of \$5,832,516 are subject to an annual limitation of \$150,608 and for the first five (5) years are entitled to a BIG (Built-In-Gains) of \$488,207 per year. These net operating losses expire in 2018 through 2024.

The Company had a second ownership change during 2006 (“2006 change”). The net operating losses incurred between the 2004 change and the 2006 change of \$8,586,861 are subject to an annual limitation of \$1,111,831 and for the first five (5) years are entitled to a BIG of \$1,756,842 per year. These net operating losses expire in 2018 through 2028.

After applying the above limitations, at December 31, 2011, the Company has post-change net operating loss carry-forwards of approximately \$14,225,901 which expire between 2020 and 2028. In addition the Company has research and development tax credit carryforwards of approximately \$582,000 for the year ended December 31, 2011, which expire between 2025 and 2031.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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Prior to 2011 and through September 30, 2011, the Company had a full valuation allowance recorded against deferred tax assets. In the fourth quarter of 2011, based on our sustained profitable operating performance over the past three years and our positive outlook for taxable income in the future, the Company reevaluated its deferred tax asset. Based upon the guidance under ASC 740 that it was more likely than not that the Company would realize the benefit of such deferred tax assets, the Company reversed \$5,156,000 of the valuation allowance previously recorded against its deferred tax assets. The Company still maintains a full valuation allowance on research and development tax credits. Deferred tax assets consist of at December 31,

	2011		2010	
Current assets				
Inventory reserves	\$	260,665	\$	198,000
Accrued expenses		145,426		-
Less valuation allowance		-		(198,000)
Net current deferred asset	\$	406,091	\$	-
Noncurrent assets				
Net operating loss carry-forwards	\$	4,837,466	\$	6,618,000
Research and development credit		581,576		594,000
Other		132,734		34,000
Gross noncurrent deferred tax assets		5,551,776		7,246,000
Depreciation		(220,578)		-
Noncurrent deferred tax assets		5,331,198		7,246,000
Less valuation allowances		(581,576)		(7,246,000)
Net noncurrent deferred tax assets	\$	4,749,622	\$	-

A reconciliation of the Federal statutory rate to the effective rate applicable to income (loss) before income taxes is as follows:

	Year Ending December 31,			
	2011		2010	
Federal income tax (benefit) at statutory rates	34	%	34	%
State income taxes, net of federal benefit	0	%	0	%
Nondeductible expenses	6.4	%	2	%
Change in valuation allowance	-514.3	%	-34.4	%
Other	-0.7	%	0.2	%
Income tax (benefit)	-474.6	%	1.8	%

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2011, the Company does not have a liability for uncertain tax positions.

The Company files Federal and New York state income tax returns. Tax years for fiscal 2008 through 2010 are open and potentially subject to examination by the federal and New York state taxing authorities.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2011 AND 2010

NOTE 11 — STOCKHOLDERS' EQUITY:

(a) Common Stock

During 2011, options to purchase 615,415 shares of the Company's common stock were exercised at exercise prices ranging from of \$.13 to \$.22.

During 2010, options to purchase 259,082 shares of the Company's common stock were exercised at exercise prices ranging from of \$.13 to \$.22.

(b) Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized and none outstanding. These shares can become issuable upon an approved resolution by the board of directors and the filing of a Certificate of Designation with the state of Nevada.

(c) 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 December 31, 2011, the Company had warrants outstanding to purchase 33,381 shares of common stock at a price of \$.81. On February 5, 2012 these warrants to purchase shares of common stock expired.

In January 2010, certain warrants to purchase an aggregated 4,960,370 shares of common stock expired, at an average exercise price of \$.474. In August 2010, certain warrants to purchase an aggregated 94,650 shares of common stock expired, at an average exercise price of \$.687.

NOTE 12 — 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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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 13 — EMPLOYEE STOCK OPTION PLAN:

The Company has a 1999 Stock Option Plan ("SOP") originally covering 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 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. As of December 31, 2011, there were 1,575,500 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 December 31, 2011, there were 134,997 options exercised, 4,551,568 options outstanding and 1,313,435 options still available to be issued under the SIP.

The Company's results for the years ended December 31, 2011 and 2010 include stock-based compensation expense totaling \$189,000 and \$170,000, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold (\$18,000 and \$20,000, respectively), research and development (\$56,000 and \$86,000, respectively) and selling, general and administrative expenses (\$115,000 and \$64,000, respectively). In accordance with ASC 718 the Company has not recorded a deferred tax asset related to the net operating losses resulting from the exercise of disqualifying stock options in the accompanying financial statements. The cumulative amount of unrecognized tax benefits at December 31, 2011 was immaterial, and if the Company is able to utilize this benefit in the future it would result in a credit to additional paid in capital.

Stock option compensation expense in the years ended December 31, 2011 and 2010 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the

entire award.

The weighted average estimated fair value of stock options granted in the years ended December 31, 2011 and 2010 was \$.29 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 historical volatility of our stock and other contributing factors. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has minimal history of employee exercise of options to date.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
 DECEMBER 31, 2011 AND 2010

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

	For the years ended	
	December 31, 2011	December 31, 2010
Expected term (in years)	3.75	4
Expected volatility	111.45%	116.82%
Expected dividend yield	n/a	n/a
Risk-free interest rate	0.78%	1.43%

The Company granted 500,000 and 781,250 new options during the year ended December 31, 2011 to employees and members of the board of directors, respectively at an average exercise price of \$.54 and \$.35, respectively per share. On May 3, 2011 and effective May 9, 2011 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 500,000 shares of the Company's common stock exercise price for these options was to be equal to the VWAP (Volume Weighted Average Price) market price for the Company's common stock on May 9, 2011. The options become exercisable evenly on the second and third anniversaries of the effective 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 effective date of grant.

The following table provides stock options activity for the years ended December 31, 2011 and 2010:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2010	5,586,900	\$ 0.15	3.59 years	\$ 756,990
Granted	300,000	\$ 0.27		
Exercised	(259,082)	\$ 0.15		\$ 27,900
Forfeited/expired /cancelled	(97,250)	\$ 0.26		
Outstanding at December 31, 2010	5,530,568	\$ 0.16	2.82 years	\$ 1,497,063
Granted	1,281,250	\$ 0.43		
Exercised	(615,416)	\$ 0.13		\$ 192,500
Forfeited/expired/cancelled	(69,334)	\$ 0.36		
Outstanding at December 31, 2011	6,127,068	\$ 0.21	2.61 years	\$ 1,339,693
Exercisable at December 31, 2011	3,580,394	\$ 0.17	2.03 years	\$ 906,157

The following table summarizes information about stock options outstanding at December 31, 2011:

Range of Exercise Prices	Shares	Stock Options Outstanding			Stock Options Exercisable	
		Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Exercise Price	Aggregate Intrinsic Value

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0.13 -								
\$ 0.13	4,020,318	2.15	\$ 0.13	\$ 1,165,892	2,773,644	\$ 0.13	\$ 804,357	
0.14 -								
\$ 0.22	381,500	1.13	0.22	76,300	381,500	0.22	76,300	
0.23 -								
\$ 0.45	1,081,250	4.29	0.33	96,563	281,250	0.33	24,563	
0.46 -								
\$ 0.54	644,000	3.48	0.52	-	144,000	0.48	-	
Total	6,127,068	2.61	\$ 0.21	\$ 1,338,755	3,580,394	\$ 0.17	\$ 905,219	

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

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As of December 31, 2011, there was \$287,000 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 1.17 years. The total fair value of shares vested during the years ended December 31, 2011 and 2010, was \$149,000 and \$124,000, respectively.

NOTE 14 — GEOGRAPHIC INFORMATION:

FASB Guidance 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 product 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 sales by geographic area are as follows:

	For the years ended	
	December 31, 2011	December 31, 2010
Africa	\$ 2,340,635	\$ 6,129,167
Asia	1,784,817	255,212
Europe	57,206	107,060
North America	8,522,878	5,977,108
South America	4,716,775	912,812
	\$ 17,422,311	\$ 13,516,359

Sales to Africa decreased in 2011 primarily due to less sales in Ethiopia of approximately \$3.08 million and Nigeria of approximately \$.64 million. Sales in Asia increased from a new distributor in the Middle East of \$1.70 million. Sales in 2011 and 2010 to North America were primarily from sales in the U.S of approximately \$7.21 million and \$5.28 million, respectively and sales in 2011 and 2010 to South America were primarily from sales in Brazil of approximately \$4.66 million and \$822,000, respectively.

NOTE 15 — COMMITMENTS AND CONTINGENCIES:

Employment Contracts:

The Company has contracts with two key employees. The contracts call for salaries presently aggregating \$510,000 per year. One contract expires in May 2013 and one contract expires in March 2013. The following table is a schedule of future minimum salary commitments:

2012	\$545,000
2013	172,500
	\$717,500

Pension Plan:

The Company has a 401(k) plan established for its employees. Effective January 1, 2011 the Company elected to match 40% of the first 5% (or 2% of salary) that an employee contributes to their 401(k) plan. Expenses related to this matching contribution aggregated \$74,464 and none for the years ended December 31, 2011 and 2010, respectively.

Obligations Under Operating Leases:

The Company leases industrial space used for office, R&D and manufacturing facilities, currently with a monthly rent of \$18,223. The current lease expires on April 30, 2014. We entered into two additional leases in 2011, one effective November 1, 2011 and the second, signed in December, effective January 1, 2012, the principal terms of these leases are the same as the one entered into in 2009 which was as follows: (a) a lease term ending April 30, 2014; (b) an initial rent of \$11,350 per month ; (c) the monthly rent for year two of the lease will increase by the lower of (i) the change in the consumer price index, or (ii) five percent; and (d) the monthly rent for years three through five of the lease will increase each year by the lower of (i) the change in the consumer price index, or (ii) two and one half percent.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

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The following is a schedule of future minimum rental commitments (assuming no increases):

Years ending December 31,

2012	\$217,899
2013	217,899
2014	70,355
	\$506,153

Rent expense was \$177,200 and \$174,200 for the years ended December 31, 2011 and 2010, respectively.

Economic Dependency:

The following table delineates sales the Company had to customers in excess of 10% of total sales for the periods indicated:

	For the years ended		For the years ended		Accounts
	December 31, 2011	% of	December 31, 2010	% of	Receivable
	Sales	Sales	Sales	Sales	As of
					December 31,
					2011
Customer 1	\$ 7,208,712	41	\$ 5,281,111	39	\$ 782,300
Customer 2	4,662,607	27	*	*	685,692
Customer 3	1,713,390	10	-	-	450,000
Customer 4	*	*	3,689,865	27	-

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

The Company had no vendor in excess of 10% of total purchases for the period ended December 31, 2011.

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 would affect operating results adversely.

NOTE 16 — COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS:

In 2011 and 2010, the Company earned \$1.8 million and \$2.8 million, respectively from research revenues and milestones. The Company is now involved in additional feasibility and development contracts related to its DPP® technology. The total expended on R&D in 2011 and 2010, not including regulatory and QTDP, was approximately \$3.1 million and \$2.9 million, respectively. During the fourth quarter of 2010 the Company was awarded \$1.47 million from the Qualified Therapeutic Discovery Project grant, which reduced 2010 R&D expenses to \$1.4 million.

a. Oswaldo Cruz Foundation/Fiocruz:

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

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2011 AND 2010

In 2011, FIOCRUZ informed the Company that ANVISA (the Brazilian regulatory agency) had approved the DPP® Leishmaniasis, Syphilis Screen and Leptospirosis assays for use in Brazil. This approval triggered milestone events of \$305,000, \$100,000 and \$100,000, respectively. In accordance with guidance, management has concluded the FIOCRUZ events recorded in 2011 met the definition of milestone events. The Company earned an aggregate of \$505,000 and \$625,000 in milestone revenues from FIOCRUZ for the year ended December 31, 2011 and 2010, respectively.

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

c. Infectious Disease Research Institute (IDRI) Agreement:

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

As of December 31, 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 year and will be recognized when the milestone is met.

d. National Institutes of Health (NIH) Grant:

In June 2009, the Company received a \$3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. The Company earned, for the years ended December 31, 2011 and 2010, \$690,000 and \$656,000, respectively from this grant. The Company has earned an aggregate of \$2,389,000 from this grant from inception through December 31, 2011, of which \$800,000 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 year ended December 31, 2011, \$350,000, from this grant. The Company has earned \$429,000 from this grant from inception through December 31, 2011, of which \$79,000 was paid to sub-contractors.

Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration (FDA), United States Department of Agriculture, certain 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.

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