

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

May 12, 2008

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

FORM 10 - Q

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

For the quarterly period ended March 31, 2008

000-30379
(Commission File Number)

Chembio Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

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

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

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

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

Yes No

Indicate by check mark whether the registrant 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 May 12, 2008, the Registrant had 60,537,534 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-Q For The Period Ended

March 31, 2008

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PART I

Item 1. FINANCIAL STATEMENTS

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

- ASSETS -

	March 31, 2008 (UNAUDITED)	December 31, 2007
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,764,735	\$ 2,827,369
Accounts receivable, net of allowance for doubtful accounts of \$26,052 and \$10,045 for 2008 and 2007, respectively	952,894	946,340
Inventories	1,505,451	1,453,850
Prepaid expenses and other current assets	315,325	243,748
TOTAL CURRENT ASSETS	4,538,405	5,471,307
FIXED ASSETS, net of accumulated depreciation	932,750	829,332
OTHER ASSETS:		
License agreements, net of current portion	1,115,754	255,948
Deposits and other assets	28,410	28,410
	\$ 6,615,319	\$ 6,584,997

**- LIABILITIES AND
 STOCKHOLDERS' EQUITY -**

CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 1,991,946	\$ 2,175,791
Deferred research and development revenue	30,833	43,334
Current portion of license fee payable	375,000	-
Current portion of obligations under capital leases	18,650	23,458
TOTAL CURRENT LIABILITIES	2,416,429	2,242,583
OTHER LIABILITIES:		
Obligations under capital leases - net of current portion	75,131	79,588
License fee payable - net of current portion	500,000	-

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TOTAL LIABILITIES	2,991,560	2,322,171
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Common stock - \$.01 par value; 100,000,000 shares authorized 60,537,534 shares issued and outstanding as of 2008 and 2007	605,375	605,375
Additional paid-in capital	39,162,263	39,003,148
Accumulated deficit	(36,143,879)	(35,345,697)
TOTAL STOCKHOLDERS' EQUITY	3,623,759	4,262,826
	\$ 6,615,319	\$ 6,584,997

See accompanying notes

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

	March 31, 2008	March 31, 2007
REVENUES:		
Net sales	\$ 2,237,971	\$ 2,025,322
Research grant income	126,757	12,998
TOTAL REVENUES	2,364,728	2,038,320
Cost of sales	1,302,806	1,378,501
GROSS PROFIT	1,061,922	659,819
OPERATING EXPENSES:		
Research and development expenses	626,336	318,730
Selling, general and administrative expenses	1,247,154	1,252,226
	1,873,490	1,570,956
LOSS FROM OPERATIONS	(811,568)	(911,137)
OTHER INCOME (EXPENSES):		
Other income	-	133,008
Interest income	18,979	52,321
Interest expense	(5,593)	(2,997)
	13,386	182,332
LOSS BEFORE INCOME TAXES	(798,182)	(728,805)
Provision for income taxes	-	-
NET LOSS	(798,182)	(728,805)
Dividends payable in stock to preferred stockholders	-	353,979
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (798,182)	\$ (1,082,784)
Basic and diluted loss per share	\$ (0.01)	\$ (0.09)
Weighted average number of shares outstanding, basic and diluted	60,537,534	11,717,079
See accompanying notes		

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

	March 31, 2008	March 31, 2007
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers	\$ 2,358,174	\$ 2,336,931
Cash paid to suppliers and employees	(3,245,657)	(2,796,292)
Interest received	18,979	52,321
Interest paid	(5,593)	(2,997)
Net cash used in operating activities	(874,097)	(410,037)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of fixed assets	(179,272)	(22,415)
Net cash used in investing activities	(179,272)	(22,415)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	-	31,000
Payment of accrued interest	-	(30,000)
Payment of capital lease obligation	(9,265)	(10,269)
Net cash utilized by financing activities	(9,265)	(9,269)
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,062,634)	(441,721)
Cash and cash equivalents - beginning of the period	2,827,369	4,290,386
Cash and cash equivalents - end of the period	\$ 1,764,735	\$ 3,848,665
RECONCILIATION OF NET INCOME TO NET CASH FROM OPERATING ACTIVITIES:		

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Net loss	\$	(798,182)	\$	(728,805)
Adjustments:				
Depreciation and amortization		75,854		67,503
Provision for doubtful accounts		16,000		10,987
Common stock, options and warrants issued as compensation		174,090		16,408
Changes in operating assets and liabilities:				
Accounts receivable		(22,554)		287,624
Inventories		(51,601)		(192,191)
Prepaid expenses and other current assets		(86,552)		9,510
Other assets and deposits		(859,806)		11,896
License fee payable		875,000		-
Deferred revenue		(12,501)		-
Accounts payable and accrued expenses		(183,845)		107,031
Net cash used in operating activities	\$	(874,097)	\$	(410,037)
Supplemental disclosures for non-cash investing and financing activities:				
Value of warrants issued allocated to additional paid-in capital		-		20,000
Accreted dividend to preferred stock		-		353,979
Value of Common stock issued as payment of dividend		-		262,053
Value of Preferred stock converted to common stock		-		20,925
See accompanying notes				

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
 MARCH 31, 2008
 (UNAUDITED)

NOTE1—DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the “Company” or “Chembio”) and its subsidiaries develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company’s main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. The Company also has a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for veterinary tuberculosis, the first one of which is USDA approved. The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio’s products are sold under the Company’s STAT PAK® or SURE CHECK ® registered trademarks or under the private labels of its marketing partners, such as is the case with the Clearview® label owned by Inverness Medical Innovations, Inc., which is the Company’s exclusive marketing partner for its rapid HIV test products in the United States. The preceding products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company’s future products are based on its patented Dual Path Platform (DPP™), which is a unique point of care platform that has certain advantages over lateral flow technology. The Company has a number of products under development that employ the DPP™.

NOTE2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The consolidated interim financial information as of March 31, 2008 and for the three month periods ended March 31, 2008 and 2007 have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles 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-KSB for the fiscal year ended December 31, 2007, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of consolidated financial position as of March 31, 2008, and consolidated results of operations, and cash flows for the three month periods ended March 31, 2008 and 2007, 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) Inventories:

Inventory consists of the following at:

	March 31, 2008	December 31, 2007
Raw Materials	\$ 612,498	\$ 705,873
Work in Process	390,935	234,077
Finished Goods	502,018	513,900

\$ 1,505,451 \$ 1,453,850
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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2008
(UNAUDITED)

(c) Earnings Per Share

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

	For the three months ended	
	March 31, 2008	March 31, 2007
Basic	60,537,534	11,717,079
Diluted	60,537,534	11,717,079

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of other securities into Common Stock, but only if dilutive. Diluted loss per share for the three month periods ended March 31, 2008 and 2007 is the same as basic loss per share, since the effects of the calculation were anti-dilutive due to the fact that the Company incurred losses for all periods presented. The following securities, presented on a common share equivalent basis, have been excluded from the per share computations:

	For the three months ended	
	March 31, 2008	March 31, 2007
1999 Plan Stock Options	2,291,269	1,621,750
Other Stock Options	124,625	124,625
Warrants	19,487,099	23,114,990
Convertible Preferred Stock	-	17,574,184

(d) Employee Stock Option Plan:

Effective January 1, 2006, the Company's Plan is accounted for in accordance with the recognition and measurement provisions of Statement of Financial Accounting Standards Share-Based Payment ("FAS 123(R)"), which replaces FAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion ("APB") No. 25, Accounting for Stock Issued to Employees, and related interpretations. FAS 123(R) requires compensation costs related to share-based payment transactions, including employee stock options, to be recognized in the financial statements. In addition, the Company adheres to the guidance set forth within SEC Staff Accounting Bulletin No. 107 ("SAB 107"), which provides the Staff's views regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides interpretations with respect to the valuation of share-based payments for public companies.

As a result of the adoption of FAS 123(R), the Company's results for the three-month periods ended March 31, 2008 and 2007 include share-based compensation expense totaling \$159,000 and \$16,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$19,000 and none, respectively), research and development (\$59,000 and \$1,000, respectively) and selling, general and administrative expenses (\$81,000 and \$15,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

Stock option compensation expense in the three-month periods ended March 31, 2008 and 2007 represent the estimated fair value of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value of stock options granted in the three month periods ended March 31, 2008 and 2007 was \$.42 and \$.52 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 no history of employee exercise of options to-date.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
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MARCH 31, 2008
(UNAUDITED)

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

	For the three months ended	
	March 31, 2008	March 31, 2007
Expected term (in years)	1 to 4	5
Expected volatility	109.33%	104.80%
Expected dividend yield	n/a	n/a
Risk-free interest rate	1.91 to 2.46%	4.50%

The Company granted 534,000 options under the Plan during the three months ended March 31, 2008 at exercise prices ranging from \$.15 to \$0.22 per share. On February 15, 2008 the Compensation Committee of the Company's Board of Directors approved the reduction of the exercise price to \$.48 of all employee options where the exercise price was greater than \$.48 per share (an aggregate of 1,846,500 options). The expense related to this modification in the first quarter of 2008 was \$18,000.

The following table provides stock option activity for the three months ended March 31, 2008:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2007	2,201,500	\$ 0.64	3.52 years	\$ -
Impact of re-price (for accounting purposes treated as a cancellation and re-issue):				
effect as if cancelled	(1,846,500)	\$ 0.64		
effect as if re-issued	1,846,500	\$ 0.48		
Granted	534,000	\$ 0.22		
Exercised	-	-		
Forfeited/expired	(255,000)	\$ 0.73		
Outstanding at March 31, 2008	2,480,500	\$ 0.54	3.71 years	\$ -
Exercisable at March 31, 2008	1,836,500	\$ 0.42	3.55 years	\$ -

As of March 31, 2008, there was \$150,000 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted average period of approximately 1.33 years. The total fair value of stock options vested during the three-month periods ended March 31, 2008 and 2007, was approximately \$139,000 and \$186,000, respectively.

(e) Geographic Information:

SFAS No. 131, “Disclosures about Segments of an Enterprise and Related Information” 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.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2008
(UNAUDITED)

The Company produces only one group of similar products known collectively as “rapid medical tests”. As per the provisions of SFAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	For the three months ended	
	March 31, 2008	March 31, 2007
Africa (excluding Nigeria)	\$ 437,060	\$ 166,124
Nigeria	849,702	202,500
Asia	101,009	41,213
Europe	43,940	27,011
Middle East	100,841	118,959
North America	635,765	1,460,925
South America	69,654	8,590
	\$ 2,237,971	\$ 2,025,322

(f) Accounts payable and accrued liabilities

Accounts payable and accrued liabilities consist of:

	March 31, 2008	December 31, 2007
Accounts payable – suppliers	\$ 670,552	\$ 726,174
Accrued commissions	34,857	14,251
Accrued royalties / licenses	752,421	852,119
Accrued payroll	146,568	279,598
Accrued vacation	133,250	155,480
Accrued legal and accounting	135,865	10,000
Accrued expenses – other	118,433	138,169
TOTAL	\$ 1,991,946	\$ 2,175,791

(g) Recent Accounting Pronouncements affecting the Company

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This statement does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, and all interim periods within those fiscal years. In February 2008, the FASB released FASB Staff Position (FSP FAS 157-2 – Effective Date of FASB Statement No. 157) which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years beginning after November 15, 2008 and interim periods within those fiscal years. The implementation of

SFAS No. 157 for financial assets and liabilities, effective January 1, 2008, did not have an impact on the Company's financial position and results of operations. The Company is currently evaluating the impact of adoption of this statement on its non-financial assets and liabilities in which is expected to be determined by the first quarter of fiscal 2009.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS No. 159"). SFAS No. 159 permits entities to choose to measure, on an item-by-item basis, specified financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are required to be reported in earnings at each reporting date. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, the provisions of which are required to be applied prospectively. The Company adopted this Statement as of January 1, 2008 and has elected not to apply the fair value option to any of its financial instruments.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2008
(UNAUDITED)

In December 2007, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 141 (revised 2007), Business Combinations, which replaces SFAS No 141. The statement retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. SFAS No. 141R is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008.

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements – an Amendment of ARB No. 51.” SFAS 160 establishes accounting and reporting standards pertaining to ownership interests in subsidiaries held by parties other than the parent, the amount of net income attributable to the parent and to the noncontrolling interest, changes in a parent’s ownership interest, and the valuation of any retained noncontrolling equity investment when a subsidiary is deconsolidated. This statement also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. The adoption of SFAS 160 is not currently expected to have a material effect on the Company’s consolidated financial position, results of operations, or cash flows.

In March 2008, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 161, “Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement No. 133.” The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity’s financial position, financial performance, and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The company is currently evaluating the impact of adopting SFAS. No. 161 on its financial statements.

(h) License Agreement

During the quarter ended March 31, 2008, the Company entered into a sublicense agreement (see Note 3) for which it has recorded an asset of \$1,000,000. This asset is being amortized over an estimated beneficial life of ten years. The current portion of this amortization is \$100,000 and is reflected in current assets. The unamortized balance as of March 31, 2008 is \$875,000 and is reflected in other assets along with other unamortized long-term license fees of \$240,754.

NOTE3—LICENSE FEE 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 Institute Pasteur of Paris, France, for HIV-2 patents. Pursuant to the terms of the Agreement, Bio-Rad sublicensed to the Company patents related to the use of HIV-2. In exchange for the use of the patents, the Agreement provides that the Company will pay Bio-Rad a \$1,000,000 sublicense fee, \$500,000 payable during 2008, of which \$125,000 has been paid and \$500,000 payable in 2009. The Company will also pay Bio-Rad a royalty on net sales in the United States and Canada of rapid test immunoassay tests sold under the Company’s name (a) for simultaneously detecting “HIV type 1 + HIV type 2” antibodies and/or antigens; (b) being operated with the Company’s Point of Care Rapid Test Platform; and (c) allowing

visual and automated signal reading and interpretation through a single test unit format. The Company will be manufacturing products under the sublicense agreement immediately, but it does not currently have any sales that are subject to the royalty. 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, and is being amortized over 10 years.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2008
(UNAUDITED)

NOTE4—COMMITMENTS AND CONTINGENCIES:

(a) Economic Dependency:

The Company had sales to three customers in excess of 10% of total sales in the three months ended March 31, 2008. Sales to these customers approximated \$782,000, \$541,000 and \$272,000, respectively. This represents approximately 71% of net sales. Accounts receivable as of March 31, 2008 from these customers approximated \$258,000, \$317,000 and none, respectively.

The Company had sales to three customers in excess of 10% of total sales in the three months ended March 31, 2007. Sales to these customers approximated \$1,004,000, \$345,000 and \$286,000, respectively. This represents approximately 81% of net sales. Accounts receivable as of March 31, 2007 from these customers approximated \$432,000, \$278,000 and \$286,000, respectively.

The Company had purchases from one vendor in excess of 10% of total purchases for the three months ended March 31, 2008. Purchases from this vendor approximated \$118,000. Accounts payable as of March 31, 2008 to this vendor approximated \$10,000.

The Company had purchases from one vendor in excess of 10% of total purchases for the three months ended March 31, 2007. Purchases from this vendor approximated \$147,000. Accounts payable as of March 31, 2007 to this vendor approximated \$51,000.

(b) Governmental Regulation:

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

(c) Nigeria Algorithm:

During the first quarter we were informed that our designation in Nigeria as one of the screening tests has changed to that of the confirmatory test as this country moves from a parallel to a serial testing algorithm (a testing algorithm is a protocol defining how selected tests are used. In a parallel algorithm two tests are used simultaneously, while in a serial algorithm a screen test is performed first and if positive a second confirmatory test is run) by the end of 2008. Consequently, after shipment of outstanding orders, we expect our sales to Nigeria to decrease in the balance of 2008.

(d) Voluntary Component Recall

In April 2008, we initiated a voluntary recall of two lots of Control kits used with our HIV 1-2 Stat Pak® Assay distributed by Inverness under its Clearview® brand. Control kits are to be used in order to verify the operator's ability to properly perform the test and to interpret the results. These kits are supplied directly to Inverness by our vendor in accordance with our specifications and instructions. In the case of these two lots of Control kits, although they met

our specifications, they were at the lower limit of such specifications, and this produced some issues with the interpretation of the control kit results by certain customers. Chembio has provided the kit supplier with a more clearly defined specification and has reviewed copies of revised manufacturing and testing procedures to ensure implementation of the new specification. Based upon these new specifications, packaged HIV Rapid Test Control Packs containing the new HIV Controls were ready for customer distribution. We have classified this recall as Class III recall “a situation in which there is little chance that using or being exposed to the device will cause health problems”. We have taken a reserve for potential costs related to this recall of \$40,000.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2008
(UNAUDITED)

(e) DPP™ Agreements:

a. Bio-Manguinhos:

On January 29th 2008 we signed three new technology transfer, supply and license agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil for products we are completing development of on DPP™. Two products being developed will be used in screening programs funded by Brazil's Ministry of Health for the control and eradication of Leishmaniasis and Leptospirosis, respectively, which are both blood-borne infectious diseases that are endemic to Brazil. A third test being developed is for the confirmation of HIV-1 in patients who have tested positive with a screening test. Under these agreements once the three products are approved for sale in Brazil, which we anticipated to be well before year end 2008, Chembio will receive approximately \$500,000 in royalty payments, and will also begin to receive purchase orders during the succeeding 12 month period of at least approximately \$2 million based upon the aggregate minimum purchase amounts under these agreements. We expect these initial DPP™ product revenues to occur this year. Thereafter, following this 12 month period the agreement allows for production of the products to be transferred to Brazil, subject to certain royalty payments. These agreements are similar to Chembio's 2004 agreement with this Bio-Manguinhos for one of our rapid HIV tests.

b. Bio-Rad:

On April 16, 2008 we announced a new development agreement with Bio-Rad Laboratories, Inc., one of the world's leading in vitro diagnostic and life science companies. The agreement with Bio-Rad is for the development of a new multiplex product that would be developed on DPP™ and which would be marketed exclusively by Bio-Rad under a limited DPP™ license from Chembio.

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

Overview

This discussion and analysis should be read in conjunction with the accompanying Consolidated Financial Statements and related notes. Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an on-going basis we review our estimates and assumptions. Our estimates were based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly from December 31, 2007.

In addition, certain statements made in this report may constitute "forward-looking statements". These forward-looking statements involve known or unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Specifically, 1) our ability to obtain necessary regulatory approvals for our products; and 2) our ability to increase revenues and operating income, is dependent upon our ability to develop and sell our products, general economic conditions, and other factors. You can identify forward-looking statements by terminology such as "may," "could", "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continues" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

The following management discussion and analysis relates to the business of the Company and its subsidiaries, which develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main products presently commercially available are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. The Company also has a rapid test for Chagas disease (a parasitic disease endemic in Latin America) as well as a line of rapid tests for tuberculosis, including tests for tuberculosis in animals which is USDA approved. The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. Chembio's products are sold either under the Company's STAT-PAK® or SURE CHECK® registered trademarks or under the private labels of its marketing partners, such as is the case with the Clearview® label owned by Inverness Medical Innovations, Inc., ("Inverness") which is the Company's exclusive

marketing partner for its rapid HIV test products in the United States. The preceding products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company's future products are based on its patented Dual Path Platform (DPP™), which is a unique point of care platform that has certain advantages over lateral flow technology. The Company has a number of products under development that employ the DPP™.

Critical Accounting Policies and Estimates

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets, accounting for complex financial instruments and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2007, see our annual report on Form 10-KSB for the period ended December 31, 2007, which was filed with the SEC on March 12, 2008.

Recent Events

On December 19, 2007 (the “Closing Date”) amendments to the governing documents for the Company’s Series A, Series B and Series C Convertible Preferred Stock (collectively, the “Preferred Stock”) and for certain warrants and options (collectively, the “Non-Employee Warrants”) not including options or warrants issued to employees or directors in their capacity as such (these actions collectively, the “Plan”) were approved by the Company and the requisite percentages of the holders of the Preferred Stock and of the Non-Employee Warrants. Subsequent to these amendments, among other matters, all the Preferred Stock and certain of the Non-Employee Warrants were converted to shares of the Company’s common stock. A description of the terms of the Plan is included in Note 1 of our annual report on Form 10-KSB for the period ended December 31, 2007 which was filed with the SEC on March 12, 2008.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2008 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2007

Revenues:

Selected Product Categories:	For the three months ended		\$ Change	% Change
	March 31, 2008	March 31, 2007		
HIV	\$ 1,920,986	\$ 1,811,365	\$ 109,621	6.05%
TB	95,155	27,300	67,855	248.55%
Other	221,830	186,657	35,173	18.84%
Net Sales	2,237,971	2,025,322	212,649	10.50%
Research grant income	126,757	12,998	113,759	875.20%
Total Revenues	\$ 2,364,728	\$ 2,038,320	\$ 326,408	16.01%

Revenues for our HIV tests during the three months ended March 31, 2008 increased by approximately \$110,000 over the same period in 2007. This was primarily attributable to increased sales in Africa, due to increased testing in this region, and sales to our distributor in the United States, partially offset by no sales to Mexico in 2008. Sales to Mexico in the first quarter of 2007 were approximately \$1,090,000. Sales of our Tuberculosis products increased by \$68,000 in the three month period ended March 31, 2008 over the same period in 2007. The increase in grant and development income was due to revenue generated from grant and feasibility studies for our patented DPP™ technology. Sales to Africa (see Note 2(e) of the financial statements) were primarily from Nigeria of approximately \$850,000. During the first quarter we were informed that our designation in Nigeria as one of the screening tests has changed to that of the confirmatory test as this country moves from a parallel to a serial testing algorithm (a testing algorithm is a protocol defining how selected tests are used. In a parallel algorithm two tests are used simultaneously, while in a serial algorithm a screen test is performed first and if positive a second confirmatory test is run) by the end of 2008. Consequently, after shipment of outstanding orders, we expect our sales to Nigeria to decrease in 2008. Sales to Inverness of our HIV products were approximately \$541,000.

Gross Margin:

Gross Margin related to	For the three months ended		\$ Change	% Change
	March 31, 2008	March 31, 2007		
Net Product Sales:	\$ 1,061,922	\$ 659,819	\$ 402,103	60.94%

Gross Margin per				
Statement of Operations				
Less: Research grant				
income	126,757	12,998	113,759	875.20%
Gross Margin from Net				
Product Sales	\$ 935,165	\$ 646,821	\$ 288,344	44.58%
Gross Margin %	41.79%	31.94%		

The increase in our gross margin resulted primarily from increased average unit selling prices on product sold to Inverness, our U.S. distributor. In addition a reserve for potential costs related to a voluntary recall of a component lowered the gross margin in the 2008 period by approximately \$40,000 or 1.7% of net sales.

Research and Development:

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

Selected expense lines:	For the three months ended		\$ Change	% Change
	March 31, 2008	March 31, 2007		
Clinical & Regulatory Affairs:				
Wages and related costs	\$ 66,836	\$ 46,922	\$ 19,914	42.44%
Consulting	6,435	11,273	(4,838)	-42.92%
Clinical Trials	74,180	1,500	72,680	4845.33%
Other	21,241	1,397	19,844	1420.47%
Total Regulatory	\$ 168,692	\$ 61,092	\$ 107,600	176.13%
R&D Other than Regulatory:				
Wages and related costs	\$ 276,180	\$ 194,966	81,214	41.66%
Consulting	5,000	10,084	(5,084)	-50.42%
Share-based compensation	53,224	708	52,516	7417.51%
Materials and supplies	90,644	24,767	65,877	265.99%
Other	32,596	27,113	5,483	20.22%
Total other than Regulatory	\$ 457,644	\$ 257,638	\$ 200,006	77.63%
Total Research and Development	\$ 626,336	\$ 318,730	\$ 307,606	96.51%

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2008 increased by \$107,600 as compared to the same period in 2007. This was primarily due to consulting and clinical trial expenses related to an amendment of our PMA claims to include the 12 -17 year old age group as well as oral fluid studies performed with our FDA-approved (for blood matrices) HIV 1/2 STAT-PAK™ and our prototype DPP™ HIV product.

Expenses other than Clinical & Regulatory Affairs increased by approximately \$200,000 in the three months ended March 31, 2008 as compared with the same period in 2007. These increases were primarily related to an increase in the work related to feasibility studies for our DPP™ platform and to work related to grant income received, both resulting in an increase in our personnel and material costs. In addition the \$52,500 cost of share-based compensation related to the value of common stock and employee stock options issued to employees also contributed to the increase.

Subject to cash availability, the Company currently plans to continue to increase its spending on research and development in 2008 because it believes such spending will result in the deployment of new and innovative products that are based on the newly patented DPP™ technology.

The Company has several Research & Development and Regulatory projects underway. Some highlights include:

Research & Development - Dual Path Platform (DPP™)

During the year to date we have made significant progress in implementing our strategy for the deployment of our Dual Path Platform (DPP™) technology. DPP™ is our patented point of care (“POC”) platform which, when combined with our experience in product development and manufacturing, is creating multiple long term revenue opportunities across many potential POC testing applications.

On January 29th 2008 we signed three new technology transfer, supply and license agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil for products we are completing development of on DPP™. Our DPP™ test platform was selected because of the high sensitivity and specificity of prototypes evaluated by Bio-Manguinhos and because of the unique multiplexing capabilities of DPP™. Two of the products being developed will be used in screening programs funded by Brazil’s Ministry of Health for the control and eradication of Leishmaniasis and Leptospirosis, respectively, which are both blood-borne infectious diseases that are endemic to Brazil. A third test being developed is for the confirmation of HIV-1 in patients who have tested positive with a screening test. Bio-Manguinhos, also known as the Immunobiological Technology Institute, is the largest producer of vaccines and kits for diagnosis of infectious and parasitic diseases in Latin America. Bio-Manguinhos is affiliated with the Brazilian Ministry of Health. The DPP™ POC screening tests will complement the current Bio-Manguinhos national program, which currently only uses laboratory-based technologies. The HIV-1 confirmatory test will allow for the simultaneous binding and uniform delivery of samples to multiple HIV-1 antigens printed in the detection zone, providing results equivalent to Western blot in a simple POC format that provides results within 20 minutes rather than hours. We expect that commercial sales will begin during the second half of 2008 upon completing development of each of the tests and regulatory approval in Brazil.

On April 16 we announced a new development agreement with Bio-Rad Laboratories, Inc., one of the world's leading in vitro diagnostic and life science companies. The agreement with Bio-Rad is for the development of a new multiplex product that would be developed on DPP™ and which would be marketed exclusively by Bio-Rad under a limited DPP™ license from Chembio. We believe that this collaboration will enable us to capitalize on some of the unique capabilities of DPP.

Our collaboration with Pall Corporation, initially reported during 2007, is proceeding well. In December we announced the completion of the feasibility studies that had been funded by Pall Corporation in connection with an OEM multiplex product opportunity. During the first quarter the parties agreed that Chembio would perform additional studies that were funded by Pall and which we completed satisfactorily in April. We are currently discussing additional studies that will be necessary to determine product configuration and design. Thereupon we would finalize a product development, license and manufacturing agreement with Pall.

We have also made substantial progress in incorporating other technologies into our DPP™ products such as fluorescence and reader technologies. These technologies, which are patented or patent-pending, will provide performance features that we believe will enhance our future product offerings to our customers. We believe that POC testing will increasingly incorporate reader and information technologies that can cost-effectively improve the reproducibility of results, remove subjectivity from the interpretation of results, allow for the documentation and dissemination of results without additional steps being required by the clinician, and enable improved levels of detection. Our recent studies have shown that DPP™ is particularly useful in the deployment of these technologies. Specifically, we have seen that the improved membrane clearance that results from the independent application of the sample to the test zone on our DPP™ provides markedly reduced background and improved clearance, which essentially means that readers can more effectively detect and quantify results. This was most recently evident in our ongoing HIV studies (see below) where we compared our prototype DPP™ HIV rapid test with certain FDA PMA approved products.

We have several other collaborations that we are pursuing for additional OEM products with which our select customers desire to capitalize on market opportunities they have identified. Our OEM customers have specialized knowledge and marketing expertise in their selected markets. There can be no assurance that any of these projects, including those with Bio-Manguinhos, Pall and Bio-Rad, will result in completed products or that such products, if successfully completed, will be successfully commercialized. Nevertheless, the depth and breadth of new product opportunities that we have with DPP are the most the Company has ever had.

We are also developing DPP™ products under Chembio brands that would address significant global market opportunities in POC testing that we have identified. These products include but are not limited to our oral fluid HIV test and our combination screen and confirm POC syphilis test being developed pursuant to a Cooperative Research & Development Agreement in collaboration with the United States Centers for Disease Control. During the first quarter we conducted studies with prototypes of each of these products that produced very encouraging results, as discussed below.

Progress on DPP™ HIV Oral Fluid Test – We believe that there is an unmet need for an oral fluid HIV test that can better address market requirements than currently available products. This test should be capable of testing on all blood matrices as well (finger stick whole blood, venous whole blood, serum and plasma). We have developed a prototype of such a test using our DPP™ technology together with other proprietary materials and components. During this past quarter we made progress in finalizing the design features for this product. We are completing a pre-clinical study on known HIV positive patients that we believe will allow us to initiate clinical trials in support of a FDA PMA approval. We think that this product, if successfully commercialized, will help to ensure our long term position in the global rapid HIV test market. During the second quarter we plan to finalize the design of this product (See RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS).

Progress on DPP™ Syphilis Screen and Confirm Multiplex Test –

Background: According to recent data presented at the March 2008 National STD Prevention Conference, the preliminary 2007 syphilis data from CDC show that the national rate of primary and secondary syphilis (the most infectious stages of the disease), increased 12% between 2006 and 2007. According to the 2005 Market Monitor Report, approximately 32 million syphilis tests were performed in the U.S., approximately 40% of which are done in public health and other non-hospital clinical settings. Globally, there are about 12 million new Syphilis cases each year as estimated by the World Health Organization. Current POC rapid screening tests, none of which are marketed in the U.S., are unable to distinguish between current and past infection. The only confirmatory tests used in the United States, such as RPR and VDRL, cannot use whole blood, thereby limiting their ability to be used in a POC setting where the use of a finger stick blood would be more appropriate.

Opportunity: Chembio has completed development of a prototype of a new syphilis test that would permit separate detection of both treponemal and non-treponemal antibodies within the same POC device, that would use a single whole blood sample, and that would provide results in a hand-held reader within 20 minutes, thereby providing the clinician with definitive disease state information at the POC. The immediacy of the confirmed test result while the patient is still at the location would mean the patient could be provided treatment at the POC, greatly reducing the number of patients not being treated because they don't return for their test results. Patent-pending materials provided by CDC, combined with Chembio's patented DPP technology and other proprietary technologies, are being used to develop this screen and confirm product.

Recent Results: Our most recent data show that the DPP Syphilis Combo test can achieve a high level of performance (sensitivity and specificity) compared to the reference tests. Additional work is required to optimize the performance of the DPP test. Chembio believes that development will be completed and the product validated within six months.

Regulatory

We are conducting a study that when completed will provide us with the data set required for submission to the FDA in order to amend the age range that can be tested with our two FDA-approved rapid HIV tests from 18 years old and above to 13 years old and above. This will enhance the marketability of these products in the United States at least. This study and associated submission will be a supplement to our Pre-Marketing Approval (PMA), which we plan to submit as soon as practical. Although we anticipate we will receive approval of this PMA amendment this year, there is no assurance that the FDA will approve these additional claims based upon our submission.

We continue to make progress on getting our products CE marked. Last August we received certification under ISO (International Organization for Standardization) 13485: 2003, the quality system that is most recognized throughout the European Community for medical device products seeking a CE marking. We then engaged a European Notified Body in connection with our plans to obtain a CE marking for these products. Materials required for the study were shipped to the regulatory agency in Europe last month and evaluations of both products are supposed to be completed during the second quarter. Based upon this timetable we will submit the Technical File to our Notified Body late 2Q08 – early 3Q08. The technical file review is anticipated to be completed well before the end of the third quarter. We would therefore anticipate receiving CE marking during the fourth quarter.

In April 2008, we initiated a voluntary recall of two lots of Control kits used with our HIV 1-2 Stat Pak® Assay distributed by Inverness under its Clearview® brand. Control kits are to be used in order to verify the operator's ability to properly perform the test and to interpret the results. These kits are supplied directly to Inverness by our vendor in accordance with our specifications and instructions. In the case of these two lots of Control kits, although they met our specifications, they were at the lower limit of such specifications, and this produced some issues with the interpretation of the control kit results by certain customers. Chembio has provided the kit supplier with a more clearly defined specification and has reviewed copies of revised manufacturing and testing procedures to ensure implementation of the new specification. Based upon these new specifications, packaged HIV Rapid Test Control

Packs containing the new HIV Controls were ready for customer distribution. We have classified this recall as Class III recall “a situation in which there is little chance that using or being exposed to the device will cause health problems”.

Selling, General and Administrative Expense:

Selected expense lines:	For the three months ended		\$ Change	% Change
	March 31, 2008	March 31, 2007		
Wages and related costs	\$ 345,785	\$ 382,177	\$ (36,392)	-9.52%
Consulting	44,316	34,199	10,117	29.58%
Commissions, License and Royalties	256,204	207,009	49,195	23.76%
Share-based compensation	72,151	456	71,695	15722.59%
Marketing Materials	8,902	17,510	(8,608)	-49.16%
Investor Relations	59,080	47,827	11,253	23.53%
Legal, Accounting and Sox 404 compliance	259,424	248,140	11,284	4.55%
Travel, Entertainment and shows	20,367	37,329	(16,962)	-45.44%
Bad Debt Allowance	6,062	10,725	(4,663)	-43.48%
Other	174,863	266,854	(91,991)	-34.47%
Total S, G &A	\$ 1,247,154	\$ 1,252,226	\$ (5,072)	-0.41%

Selling, general and administrative expense for the three months ended March 31, 2008 remained level as compared with the same period in 2007. Increases in commission, license and royalty expenses as well as expenses related to the issuance of options to employees contributed to this increase. These increases were offset by reductions in wages and related expenses, travel and entertainment costs as well as other expenses. Our periodic review of our allowance for doubtful accounts resulted in an increase of the allowance in the three months ended March 31, 2008.

Other Income and Expense:

Other Income and Expense	For the three months ended		\$ Change	% Change
	March 31, 2008	March 31, 2007		
Other income (expense)	\$ -	\$ 133,008	\$ (133,008)	-100.00%
Interest income	18,979	52,321	(33,342)	-63.73%
Interest expense	(5,593)	(2,997)	(2,596)	86.62%
Total Other Income and Expense	\$ 13,386	\$ 182,332	\$ (168,946)	-92.66%

The Company received \$133,000 in 2007, net of expenses, from New York State related to a program for qualified emerging technology companies, resulting in the decrease in other income. Interest income for the three months ended March 31, 2008 decreased due to a decrease in funds available to invest. The addition of capital leases at the end of 2007 resulted in the increase in interest expense in 2008 over 2007.

LIQUIDITY AND CAPITAL RESOURCES

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	For the three months ended			
	March 31, 2008	March 31, 2007	\$ Change	% Change
Net cash used in operating activities	\$ (874,097)	\$ (410,037)	\$ (464,060)	113.18%
Net cash used in investing activities	(179,272)	(22,415)	(156,857)	699.79%
Net cash utilized by financing activities	(9,265)	(9,269)	4	-0.04%
NET (DECREASE) IN CASH	\$ (1,062,634)	\$ (441,721)	\$ (620,913)	140.57%

The Company had a decrease in cash for the three months ended March 31, 2008 that exceeded the amount of the decrease in cash for the same period in 2007. The excess of the decrease during the 2008 period is primarily attributable to greater amounts of cash used in operations and for the purchase of fixed assets.

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The Company had a working capital surplus of approximately \$2,122,000 at March 31, 2008 and a working capital surplus of approximately \$3,229,000 at December 31, 2007. The Company believes its resources are sufficient to fund its needs through the end of 2008 and into early 2009, although its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent, if any, to which that revenue growth improves operating cash flows; (3) the Company's expenditures for research and development, facilities, marketing, regulatory approvals, and other expenditures it may determine to make; (4) the Company's investment in capital equipment and the extent to which this investment improves cash flow through operating efficiencies and (5) the Company's ability to obtain development and license fees from OEM partners.

The following table lists the future payments required on the Company's debt and certain other contractual obligations as of March 31, 2008:

OBLIGATIONS	Total	Less than 1 Year	1-3 Years	4-5 Years	Greater than 5 Years
Capital Leases (1)	\$ 124,093	\$ 30,316	\$ 85,716	\$ 8,061	\$ -
Operating Leases	138,840	128,160	10,680	-	-
Other Long Term Obligations(2)	1,533,333	732,500	740,833	30,000	30,000
Total Obligations	\$ 1,796,266	\$ 890,976	\$ 837,229	\$ 38,061	\$ 30,000

(1) This represents capital leases used to purchase capital equipment. (Obligations inclusive of interest).

(2) This represents contractual obligations for fixed cost licenses and employment contracts.

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

Chembio's business is now divided into two distinct business components: The first component is our base of growing revenues derived from the rapid tests that we developed using lateral flow technologies; this primarily consists of our rapid HIV tests, but also includes our currently marketed rapid tests for veterinary and human tuberculosis, and for Chagas Disease. Almost all of our product revenue growth has been from our rapid HIV tests, although in the first quarter we also had revenue growth from our niche line of veterinary tuberculosis tests. Our improving gross margins are primarily attributable to the incremental sales resulting from the introduction one year ago in the United States market of our FDA-approved rapid HIV tests. We believe that the demand for rapid HIV tests will increase in the United States as well as globally, and we believe we are well positioned as one of the only FDA PMA approved US-based manufacturers of tests, to participate in this growth. Market conditions for rapid HIV tests being used in developing countries with high rates of HIV prevalence, have become increasingly competitive. Programs such as the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund vest decisions for product selection with the host governments, and this often results in selections of products that are produced under different standards and/or that have different costs of manufacturing, regulatory compliance, and/or intellectual property. A significant portion of our sales since 2005 have come from these programs which is a risk we are endeavoring to mitigate through our other business development activities. Additional markets for our HIV tests will become available as we receive our CE mark, and this also may help to mitigate this risk. In any case we are pursuing strategies to outsource at least some of our manufacturing in order to more effectively participate in these markets. If we can continue to grow our revenues, we should also continue to realize economies of scale in our current facility as we did in 2007 and the year to date, thereby further improving our gross margins. We continue implementing a series of process and efficiency projects that have also improved margins.

The second business component now is our DPP™ business, a business which we established last year after we received our patent covering this technology. Within this second component we have an OEM business strategy and an emerging Chembio branded product line that is being developed. We have made significant progress in implementing our strategy for the deployment of our Dual Path Platform technology, both OEM and branded, and we believe this business will drive long term growth at Chembio.

Under the new agreements we signed with Bio-Manguinhos (see Research & Development), once the three products under these agreements are approved for sale in Brazil, which we anticipate well before year end 2008, Chembio will receive approximately \$500,000 in royalty payments, and will also begin to receive purchase orders during the succeeding 12-month period of at least approximately \$2 million based upon the aggregate minimum purchase amounts under these agreements. We expect these initial DPP™ product revenues to occur this year. Thereafter, following this 12 month period the agreement allows for production of the products to be transferred to Brazil, subject to certain royalty payments. These agreements are similar to Chembio's 2004 agreement with the same entity (Bio-Manguinhos) for one of our rapid HIV tests.

On April 16, 2008 we announced a new funded development agreement with Bio-Rad Laboratories, Inc., one of the world's leading in-vitro diagnostic and life science companies. The agreement with Bio-Rad is for the development of a new multiplex product that would be developed at Chembio on DPP and which would be marketed exclusively by Bio-Rad. Once we reach certain milestones under this agreement, we anticipate being able to provide additional information concerning this collaboration with Bio-Rad. We are currently discussing with Pall Corporation additional studies that are necessary to determine product configuration and design. Upon successful completion of those studies, we would finalize a product development, license and manufacturing agreement with Pall. We have several other OEM product opportunities under discussion. There can be no assurance that any of these projects will result in completed products or that such products, if successfully completed, will be successfully commercialized.

As discussed above (see Research & Development) we have made significant progress in the development of two Chembio branded products (DPP HIV Oral Fluid and DPP Syphilis Screen & Confirm), and we have identified other products for which we believe there is a significant market opportunity and unmet need. We anticipate that the pre-clinical studies for our DPP™ HIV test will be completed shortly and that we will be able to move forward on clinical studies in support of an FDA Pre-Marketing Approval application during the balance of the year, and to determine the best means of bringing this product to the US and global market. We believe that there are several attractive alternatives available. We also believe there will be significant interest for the marketing of our combination Syphilis Screen and Confirm test. We are focused on commercializing this product and identifying potential marketing strategies for it, both in the US and globally. We believe that both of these products may be able to contribute meaningful revenues to Chembio in 2009. Sales of our USDA approved products for veterinary tuberculosis have grown and if this growth continues it will provide a source of meaningful cash flow.

We believe that we can achieve profitable operating results based upon a sales level of approximately \$3-\$4 million per quarter, depending on product mix, efficiencies and other factors, including the extent to which we invest in product development. Until we are able to consistently attain such level of sales and profitability, our strategy is to realize development income and license income in connection with our DPP business strategy in order to fund operating losses. Notwithstanding some of the risks and uncertainties mentioned above our current order backlog is at a record level and the depth and breadth of opportunities we have as a result of our DPP™ technology has never been greater. At the end of the first quarter we took certain steps to lower certain overhead costs, which together with our product development efforts, we anticipate will improve cash flow, subject to and partially offset by the anticipated increased research and development expenditures, in part to support funded development contracts, but also in order to maximize our ability to complete products and conclude more agreements related to our DPP™ technology, such as our agreements with Bio Rad, Bio-Manguinhos, Pall Corporation and our syphilis and HIV DPP™ product. If necessary, with these future revenue opportunities in place, we believe our ability to raise additional capital from strategic or other investors, if necessary, will be improved. There can be no assurance of our attaining such sales levels, profitability, development and license income, or capital, or of completing such products or agreements.

ITEM 4T. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

(a) Management's Quarterly Report on Internal Control Over Financial Reporting. The Company's management is responsible for establishing and maintaining an adequate system of internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)). Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures are effective such that the information relating to us required to be disclosed in our Securities and Exchange Commission ("SEC") reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the United States. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. This quarterly report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this quarterly report.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during the last fiscal quarter of the period covered by this report that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 6. EXHIBITS.

Number	Description
3.1	Articles of Incorporation, as amended. (3)
3.2	Amended and Restated Bylaws. (1)
4.1	Second Amended and Restated Certificate of Designation of the Relative Rights and Preferences of the Series A Convertible Preferred Stock of the Registrant. (11)
4.2	Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein. (2)
4.3	Lock-Up Agreement, dated as of May 5, 2004, by and among the Registrant and the shareholders of the Registrant listed therein. (2)
4.4	Amended Form of Common Stock Warrant issued pursuant to the May 4, 2004 Stock and Warrant Purchase Agreement. (11)
4.5	Form of \$0.90 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum. (2)
4.6	Form of \$0.60 Warrant issued to Mark L. Baum pursuant to the Consulting Agreement dated as of May 5, 2004 between the Registrant and Mark L. Baum. (2)
4.7	Second Amended and Restated Certificate of Designation of Preferences, Rights, and Limitations of Series B 9% Convertible Preferred Stock of the Registrant. (11)
4.8	Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (9)
4.9	Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (11)
4.10	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)
4.11	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (4)
4.12	Registration Rights Agreement, dated June 29, 2006. (4)
4.13	Second Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series C 7% Convertible Preferred Stock of the Registrant. (11)
4.14	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
4.15	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (6).
4.16	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (11)
4.17	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (11)
4.18	Form of Employee Option Agreement. (11)
4.19	Amended Form of Warrant used for Consultant Services, and in connection with the Company's 2004 merger. (11)
4.20	1999 Equity Incentive Plan (13)
10.1	Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (5)
10.2	Employment Agreement dated April 23, 2007 with Javan Esfandiari. (12)
10.3	Series A Convertible Preferred Stock and Warrant Purchase Agreement (the "Stock and Warrant Purchase Agreement"), dated as of May 5, 2004, by and among the Registrant and the purchasers listed therein. (2)
10.4	Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)

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- 10.5 Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (10)
- 10.6 Equity Exchange Agreement, dated as of January 28, 2005, by and between the Registrant and Kurzman Partners, LP. (10)
- 10.7 Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
- 10.8 Form of Secured Debenture, dated June 29, 2006. (4)
- 10.9 Security Agreement, dated June 29, 2006, among the Company, Chembio Diagnostic Systems, Inc., and purchasers of the Company's Secured Debentures. (4)
- 10.10 Subsidiary Guarantee, dated June 29, 2006, made by Chembio Diagnostic Systems, Inc., in favor of Purchasers of the Company's Secured Debentures. (4)
- 10.11 Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 10.12 Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (6)
- 10.13 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (6)
- 10.14 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.15 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (6)
- 10.16 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (6)
- 10.17 Settlement Agreement, dated September 29, 2006, between the Registrant and StatSure. (6)
- 10.18 Contract for Transfer of Technology and Materials with Bio-Manguinhos. (7)
- 10.19 License and Supply Agreement dated as of August 30, 2002 by and between Chembio Diagnostic Systems Inc. and Adaltis Inc. (8)
- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
- (2) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on May 14, 2004.
- (3) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.
- (4) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.
- (5) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
- (6) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
- (7) Incorporated by reference to the Registrant's registration statement on Form SB-2/A filed with the Commission on August 4, 2004.
- (8) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on June 7, 2004.
- (9) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 31, 2005.
- (10) Incorporated by reference to the Registrant's registration statement on Form SB-2 filed with the Commission on March 28, 2005.
- (11) Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
- (12) Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed with the Commission on May 3, 2007.
- (13) Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: M a y 1 2 , B y : / s / L a w r e n c e A .
2008 Siebert
Lawrence A. Siebert
Chief Executive Officer
(Principal Executive
Officer)

Date: M a y 1 2 , B y : / s / R i c h a r d J . L a r k i n
2008
Richard J. Larkin
Chief Financial Officer
(Principal Financial and
Accounting Officer)