

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

November 12, 2008

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

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FORM 10 - Q

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

For the quarterly period ended September 30, 2008

000-30379

(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada  
(State or other  
jurisdiction of  
incorporation)

88-0425691  
(IRS Employer  
Identification  
Number)

3661 Horseblock Road  
Medford, New York 11763

(Address of principal executive offices including zip code)

(631) 924-1135

(Registrant's telephone number, including area code)

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

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

Yes  No

Indicate by check mark whether the registrant 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 November 10, 2008, the Registrant had 61,944,901 shares outstanding of its \$.01 par value common stock.

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Quarterly Report on FORM 10-Q For The Period Ended

September 30, 2008

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## PART I

## Item 1. FINANCIAL STATEMENTS

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

- ASSETS -	September 30, 2008 (UNAUDITED)	December 31, 2007
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 999,429	\$ 2,827,369
Accounts receivable, net of allowance for doubtful accounts of \$10,301 and \$10,045 for 2008 and 2007, respectively	2,021,169	946,340
Inventories	1,192,127	1,453,850
Prepaid expenses and other current assets	256,000	243,748
<b>TOTAL CURRENT ASSETS</b>	<b>4,468,725</b>	<b>5,471,307</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>953,762</b>	<b>829,332</b>
<b>OTHER ASSETS:</b>		
License agreements, net of current portion	1,035,366	255,948
Deposits and other assets	27,820	28,410
	<b>\$ 6,485,673</b>	<b>\$ 6,584,997</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,319,117	\$ 2,175,791
Deferred research and development revenue	100,000	43,334
Current portion of license fee payable	375,000	-
Current portion of obligations under capital leases	18,148	23,458
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,812,265</b>	<b>2,242,583</b>
<b>OTHER LIABILITIES:</b>		
Obligations under capital leases - net of current portion	65,747	79,588
License fee payable - net of current portion	500,000	-
<b>TOTAL LIABILITIES</b>	<b>3,378,012</b>	<b>2,322,171</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
	619,449	605,375

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Common stock - \$.01 par value;  
 100,000,000 shares authorized 61,944,901  
 and 60,537,534 shares issued and  
 outstanding as of 2008 and 2007,  
 respectively

Additional paid-in capital	39,232,274	39,003,148
Accumulated deficit	(36,744,062)	(35,345,697)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>3,107,661</b>	<b>4,262,826</b>
	\$ 6,485,673	\$ 6,584,997

See accompanying notes

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

	Three months ended		Nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
<b>REVENUES:</b>				
Net sales	\$ 3,406,803	\$ 2,158,438	\$ 8,111,015	\$ 6,603,976
Research grant income	109,361	155,099	487,661	250,655
<b>TOTAL REVENUES</b>	<b>3,516,164</b>	<b>2,313,537</b>	<b>8,598,676</b>	<b>6,854,631</b>
Cost of sales	1,859,554	1,328,528	4,583,335	4,217,903
<b>GROSS PROFIT</b>	<b>1,656,610</b>	<b>985,009</b>	<b>4,015,341</b>	<b>2,636,728</b>
<b>OPERATING EXPENSES:</b>				
Research and development expenses	758,851	483,188	1,952,436	1,385,073
Selling, general and administrative expenses	1,133,288	1,174,530	3,475,262	3,490,099
	1,892,139	1,657,718	5,427,698	4,875,172
<b>LOSS FROM OPERATIONS</b>	<b>(235,529)</b>	<b>(672,709)</b>	<b>(1,412,357)</b>	<b>(2,238,444)</b>
<b>OTHER INCOME (EXPENSES):</b>				
Other income (expense)	-	-	-	120,862
Interest income	3,587	30,603	29,958	125,513
Interest expense	(5,112)	(6,408)	(15,966)	(11,107)
	(1,525)	24,195	13,992	235,268
<b>LOSS BEFORE INCOME TAXES</b>	<b>(237,054)</b>	<b>(648,514)</b>	<b>(1,398,365)</b>	<b>(2,003,176)</b>
Provision for income taxes	-	-	-	-
<b>NET LOSS</b>	<b>(237,054)</b>	<b>(648,514)</b>	<b>(1,398,365)</b>	<b>(2,003,176)</b>
Dividends payable in stock to preferred stockholders	-	362,959	-	1,073,837
<b>NET LOSS ATTRIBUTABLE TO</b>	<b>\$ (237,054)</b>	<b>\$ (1,011,473)</b>	<b>\$ (1,398,365)</b>	<b>\$ (3,077,013)</b>

COMMON  
STOCKHOLDERS

Basic and diluted loss per share	\$	(0.00)	\$	(0.07)	\$	(0.02)	\$	(0.24)
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Weighted average number of shares outstanding, basic and diluted	61,944,901	14,043,208	61,036,181	12,701,494
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See accompanying notes

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

	September 30, 2008	September 30, 2007
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers	\$ 7,523,847	\$ 6,935,884
Cash paid to suppliers and employees	(8,982,976)	(8,760,425)
Interest received	29,958	125,513
Interest paid	(15,966)	(11,107)
Net cash used in operating activities	(1,445,137)	(1,710,135)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(363,652)	(171,501)
Net cash used in investing activities	(363,652)	(171,501)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of warrants	-	31,000
Payment of accrued interest	-	(90,000)
Payment of dividends	-	(60,000)
Payment of capital lease obligation	(19,151)	(34,443)
Net cash used in financing activities	(19,151)	(153,443)
<b>NET (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		
	(1,827,940)	(2,035,079)
Cash and cash equivalents - beginning of the period	2,827,369	4,290,386
Cash and cash equivalents - end of the period	\$ 999,429	\$ 2,255,307
<b>RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:</b>		
Net Loss	\$ (1,398,365)	\$ (2,003,176)
<b>Adjustments:</b>		
Depreciation and amortization	239,222	213,158
Loss on retirement of fixed assets	-	12,146
Provision for doubtful accounts	256	(11,210)
Common stock, options and warrants issued as compensation	268,159	275,360



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Changes in assets and liabilities:

Accounts receivable	(1,075,085)	(75,037)
Inventories	261,723	(60,786)
Prepaid expenses and other assets	(816,039)	(24,912)
Other assets and deposits	-	(8,056)
Deferred revenue	56,666	-
Accounts payable and accrued expenses	143,326	(27,622)
Licenses fee payable	875,000	-
Net cash used in operating activities	\$ (1,445,137)	\$ (1,710,135)

Supplemental disclosures for non-cash investing and financing activities:

Value of common stock issued upon cashless warrant exercise	\$ 14,074	\$ -
Value of warrants/options/stock issued allocated to additional paid-in capital	-	61,181
Accreted dividend to preferred stock	-	1,073,837
Value of Common stock issued as payment of dividend	-	1,072,157
Value of Preferred stock converted to common stock	-	178,733
Assets acquired under capital leases	-	102,860

See accompanying notes

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

NOTE 1—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 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. Two of the veterinary tests are 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, for example the Clearview® label owned by Inverness Medical Innovations, Inc., 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 future 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. The Company has recently completed its first two products that employ the DPP® and has a number of additional products under development that employ the DPP®.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although revenues and gross margins increased in the nine months ended September 30, 2008 as compared to the same period in 2007, the Company continues to generate significant operating losses through September 30, 2008. At September 30, 2008, the Company had a positive stockholders’ equity of \$3,108,000 and working capital of \$1,656,000. The Company estimates that its resources are sufficient to fund its needs through the end of 2008 and it is considering alternatives to provide for its capital requirements for 2009 and beyond in order to continue as a going concern. The Company’s liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) the Company’s investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make; and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will be successful in raising sufficient capital.

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The consolidated interim financial information as of September 30, 2008 and for the nine-month periods ended September 30, 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 September 30, 2008, and consolidated results of operations, and cash flows for the nine month periods ended September 30, 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.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

## (b) Inventories:

Inventory consists of the following at:

	September 30, 2008	December 31, 2007
Raw Materials	\$ 645,364	\$ 705,873
Work in Process	415,586	234,077
Finished Goods	131,177	513,900
	\$ 1,192,127	\$ 1,453,850

## (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		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Basic	61,944,901	14,043,208	61,036,181	12,701,494
Diluted	61,944,901	14,043,208	61,036,181	12,701,494

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 and nine month periods ended September 30, 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 diluted per share computations:

	For the three months ended		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
1999 & 2008 Plan Stock Options	2,797,482	2,396,136	2,565,655	1,929,471
Other Stock Options	124,625	124,625	124,625	124,625
Warrants	10,163,244	26,196,085	16,183,547	26,191,683
Convertible Preferred Stock	-	26,553,340	-	26,811,978

## (d) Employee Stock Option Plan:

The Company's Stock Option Plans (the "Plans") are 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 September 30, 2008 and 2007 include share-based compensation expense totaling \$24,000 and \$70,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development (\$14,000 and \$29,000, respectively) and selling, general and administrative expenses (\$10,000 and \$41,000, respectively). The nine-month periods ended September 30, 2008 and 2007 include share-based compensation expense totaling \$268,000 and \$275,000, 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 (\$75,000 and \$161,000, respectively) and selling, general and administrative expenses (\$175,000 and \$114,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

Stock option compensation expense in the three- and nine-month periods ended September 30, 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 nine-month periods ended September 30, 2008 and 2007 was \$.13 and \$.44 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.

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

	For the three months ended		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Expected term (in years)	n/a	5	1 to 4	5
Expected volatility	n/a	106.31%	109.33-112.33%	102.84-104.80%
Expected dividend yield	n/a	n/a	n/a	n/a
Risk-free interest rate	n/a	4.60%	1.91 to 2.98%	4.50-5.06%

The Company granted 967,650 options under the Plans during the nine-months ended September 30, 2008 at exercise prices ranging from \$.13 to \$.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 for which the exercise price was greater than \$.48 per share (an aggregate of 1,846,500 options). The expense related to this modification was \$18,000 and was expensed in the first quarter of 2008.

The following table provides stock option activity for the nine months ended September 30, 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	967,650	\$ 0.18		
Exercised	-	-		
Forfeited/expired	(450,500)	\$ 0.58		

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Outstanding at September 30, 2008	2,718,650	\$	0.38	3.42 years	\$	9,558
Exercisable at September 30, 2008	2,150,650	\$	0.39	3.28 years	\$	6,390

As of September 30, 2008, there was \$94,000 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 1.52 years. The total fair value of stock options vested during the nine-month periods ended September 30, 2008 and 2007 was approximately \$273,000 and \$267,000, respectively.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

## (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.

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		For the nine months ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Africa	\$ 1,397,297	\$ 1,308,180	\$ 3,698,178	\$ 2,722,434
Asia	80,300	15,850	211,040	115,544
Europe	49,215	45,834	130,935	90,239
Middle East	122,190	-	277,340	174,218
North America	645,124	750,333	1,688,874	3,313,415
South America	1,112,677	38,241	2,104,648	188,126
	\$ 3,406,803	\$ 2,158,438	\$ 8,111,015	\$ 6,603,976

## (f) Accounts payable and accrued liabilities

Accounts payable and accrued liabilities consist of:

	September 30, 2008	December 31, 2007
Accounts payable – suppliers	\$ 689,384	\$ 726,174
Accrued commissions	135,884	14,251
Accrued royalties / licenses	1,104,618	852,119
Accrued payroll	187,334	279,598
Accrued vacation	134,957	155,480
Accrued legal and accounting	25,000	10,000
Accrued expenses – other	41,940	138,169
TOTAL	\$ 2,319,117	\$ 2,175,791

## (g) Recent Accounting Pronouncements affecting the Company

In September 2006, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“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 nonfinancial assets and liabilities which is expected to be determined by the first quarter of fiscal 2009.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

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.

In December 2007, the FASB issued 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 FASB issued SFAS 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.

In May 2008, the FASB issued SFAS No. 162, “The Hierarchy of Generally Accepted Accounting Principles”. The new standard is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. generally accepted accounting principles (GAAP) for nongovernmental entities. Prior to the issuance of SFAS 162, GAAP hierarchy was defined in the American Institute of Certified Public Accountants (AICPA) Statement on Auditing Standards (SAS) No. 69, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board Auditing amendments to AU Section 411, The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles.



CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

(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 expensed over an estimated economic life of ten years. The current portion of this asset is \$100,000 and is reported in prepaid expenses and other current assets. The long-term portion as of September 30, 2008 is \$825,000 and is reflected in other assets along with other unexpensed long-term license fees of \$210,000.

(i) Deferred Revenue

The Company recognizes income from research projects and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of September 30, 2008, \$100,000 of advanced revenues was unearned.

NOTE 3—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 \$375,000 is payable by December 31, 2008, with the additional \$500,000 being payable by December 31, 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 has begun manufacturing products under the sublicense agreement, 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 (see Note 2(h)).

NOTE 4—STOCKHOLDERS’ EQUITY:

Common Stock and Warrants:

During the June 30, 2008 quarter, warrants to purchase 9,323,854 shares of the Company’s common stock were exercised on a cashless basis, resulting in the issuance of 1,407,367 shares of common stock. These warrants were exercised on a cashless basis in connection with the Company’s preferred stock and warrant amendments that were completed on December 19, 2007, and the Company received no cash consideration for these issuances of common stock.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
(UNAUDITED)

## NOTE 5—COMMITMENTS AND CONTINGENCIES:

## (a) Economic Dependency:

The following table delineates sales the Company had to customer(s) in excess of 10% of total sales for the periods indicated:

	For the three months ended				For the nine months ended				Accounts Receivable	
	Sept. 30, 2008		Sept. 30, 2007		Sept. 30, 2008		Sept. 30, 2007		As of	
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sept. 30, 2008	Sept. 30, 2007
Customer 1	\$1,077,000	32%	n/a	n/a	\$2,060,000	25%	n/a	n/a	\$ 865,000	n/a
Customer 2	\$1,139,000	33%	\$723,000	34%	\$2,638,000	33%	\$1,933,000	29%	\$ 606,000	\$ 411,000
Customer 3	\$ 605,000	18%	\$628,000	29%	\$1,570,000	19%	\$1,581,000	24%	\$ 59,000	\$ 425,000
Customer 4	n/a	n/a	n/a	n/a	n/a	n/a	\$1,398,000	21%	n/a	\$ -

The following table delineates purchases the Company made from vendor(s) in excess of 10% of total purchases for the periods indicated:

	For the three months ended				For the nine months ended				Accounts Payable	
	Sept. 30, 2008		Sept. 30, 2007		Sept. 30, 2008		Sept. 30, 2007		As of	
	Purchases	% of Purch.	Purchases	% of Purch.	Purchases	% of Purch.	Purchases	% of Purch.	Sept. 30, 2008	Sept. 30, 2007
Vendor 1	\$ 149,000	20%	\$143,000	27%	\$ 367,000	18%	\$ 251,000	14%	\$ 49,000	\$ 4,000
Vendor 2	\$ 49,000	7%	\$ 57,000	11%	\$ 190,000	10%	\$ 130,500	7%	\$ 27,000	\$ 18,000

## (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:

During the first quarter of 2008, we were informed that our designation in Nigeria as one of the screening tests will be changed to that of a confirmatory test, in the first quarter of 2009. Consequently we expect our sales to Nigeria to decrease in 2009 as compared to 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 this new specification, packaged HIV Rapid Test Control Packs containing the new HIV Controls have been in distribution since May 2008. The FDA has classified this voluntary recall as a Class II recall, "a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences are remote". Approximately \$22,000 in costs has been incurred through September 30, 2008. We have completed all of our recall activity, including monitoring and final product disposition.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 2008  
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(e) DPP® Agreements:

a. Brazil:

On January 29, 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 using 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, 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. 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 Bio-Manguinhos for one of our rapid HIV tests.

On October 2, 2008 the Company announced a new technology transfer supply and license agreement for its DPP® HIV 1/2 rapid test (for use with oral fluid or whole blood samples) with the Oswaldo Cruz Foundation of Brazil ("FIOCRUZ"). FIOCRUZ, which is affiliated with the Brazilian Ministry of Health, is a supplier for therapeutics, vaccines and diagnostic tests for the Brazilian Ministry of Health. Under the terms of the agreement with FIOCRUZ, a minimum of 2.5 million of these tests will be purchased for a period of time, followed by an additional period during which components for tests will be purchased, followed by royalties for a period of five years. The total purchases by FIOCRUZ from Chembio will ultimately be determined by the demand for the product by the national program, the pace of the technology transfer, and FIOCRUZ's manufacturing capacity. Sales are anticipated to begin during 2009 once the products are approved for sale in Brazil, at which time a technology transfer fee will be payable to Chembio.

b. Bio-Rad:

On April 16, 2008 we announced a new development agreement with Bio-Rad Laboratories, Inc. 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. Our agreement with Bio-Rad contemplates that we will enter into a license agreement no later than December 2008 subject to the satisfaction of certain development and other conditions.

## 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 ongoing basis we review our estimates and assumptions. Our estimates were based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly from December 31, 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, our ability to obtain necessary regulatory approvals for our products, and 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. The Company also supplies certain test components pursuant to technology transfer agreements that it has with the Oswaldo Cruz Foundation of Brazil. All of the Company’s other 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 completed development of two products that employ DPP® and has a number of products under development that employ the DPP®.

The Company has several Research & Development and Regulatory projects underway. Some highlights of these projects are set forth below.

#### Research & Development - Dual Path Platform (DPP®)

We achieved solid progress in our research and development activities during the third quarter with our Dual Path Platform (DPP®) technology. DPP® is our patented point of care diagnostic (“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.

Our initial DPP® antibody detection products for HIV 1-2 (for use with oral fluid or blood samples) and for canine leishmaniasis have been validated, and production lots have been completed for shipment during the fourth quarter of 2008 for regulatory approval in Brazil in accordance with our agreements signed in January and September 2008. We are now moving toward validation of our DPP® HIV-1 POC confirmatory test and our Leptospirosis rapid POC test that we are developing pursuant to our January 2008 agreement with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation, which is affiliated with the Brazilian Ministry of Health.

The contracts we have signed with the Oswaldo Cruz Foundation, which involve technology transfer fees, as well as product sales and royalties, not only enable us to recover our research and development expenditures for these initial DPP® products, they also help to fund our manufacturing scale-up that will be applicable to many more DPP® products. The know-how that we have developed in connection with the development of these new products for this customer may also be applicable to other products that we may develop in the future for other customers or under our own brand.

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. We believe that this collaboration will enable us to capitalize on some of the unique capabilities of DPP®. Our agreement with Bio-Rad contemplates that we will enter into a license agreement no later than December 2008 subject to the satisfaction of certain developments and other conditions. We believe there is a substantial likelihood that these conditions will be satisfied.

We have continued to pursue OEM opportunities for the development of POC products based on DPP®, including but not limited to bacterial infections, veterinary applications, and sexually transmitted diseases. We are doing feasibility studies for companies representing these fields as a first step toward establishing longer term collaborations for new products that we would develop for these potential partners. 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. 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.

Progress on DPP® HIV Oral Fluid Test – We continue to believe that there is an unmet need for an oral fluid HIV test that can address market needs more efficiently than currently available products. We believe that our whole blood tests, even with our outstanding marketing partner and our small sample volume required for their use still may not be sufficient in order for us to access large segments of the public health market that have developed a preference for less invasive tests that can be performed with oral fluid samples. During the 2008 third quarter, we transferred this product into our manufacturing operation, and we are now preparing the product dossier for its inclusion in global programs and for commencement of clinical trials in support of a PMA application that we intend to submit to the FDA during 2009. Also during the third quarter we completed an agreement with the Oswaldo Cruz Foundation of Brazil related to 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 –

Our most recent data indicates 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. We anticipate that during the fourth quarter of 2008 development of the DPP® Syphilis Combo test will be completed and this product will be validated.

Regulatory

During the three month period ended September 30, 2008, the FDA approved our supplemental PMA application. This approval permits us to extend the age range of individuals that can be tested with our two FDA-approved rapid HIV tests from 18 years old and above to 13 years old and above. Lowering the testing age range from 18 to 13 years is consistent with the latest United States Centers for Disease Control (“CDC”) recommendations that routine screening for HIV be performed on all patients between the ages of 13 to 64. Of the more than one million adults and adolescents estimated to be living with HIV infection in the United States, approximately 232,700 or 21%, are unaware of their infection. According to CDC reports, in 2006, 56,500 or 5%, of the people living with HIV were between the ages of 13 and 24. These individuals cannot receive appropriate treatment for their HIV disease and may unknowingly continue to transmit the virus to others. In September 2006, the CDC changed its recommendations to suggest that all people in the United States between the ages of 13 and 64 years be routinely tested for HIV in healthcare settings. This testing can be performed in primary care facilities, emergency rooms, and clinics for substance abuse and pregnant women. Several states have now begun to implement these recommendations. Embracing these recommendations, California recently enacted a law that will require (as of January 1, 2009) private health insurance companies in the state to cover the cost of HIV testing regardless of whether the testing is related to a primary diagnosis.

From a public health perspective, the shift in the CDC recommendations from risk-based to routine "opt-out" testing is anticipated to lower the rate of new HIV infections. For individuals, early testing is essential to provide earlier access to care with a greatly improved prognosis. The objectives of the recommendations are many and include increasing HIV screening of patients, fostering earlier detection of infection, identifying and counseling persons with HIV infection and connecting them to clinical and prevention services, and further reducing transmission of HIV in the United States.

We continue to make progress on obtaining a Community European (CE) marking for our products to indicate conformity with European Union health, safety and environmental requirements. In August 2007 we received certification under ISO (International Organization for Standardization) 13.485: 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 our two rapid HIV tests that are already FDA approved as was as our rapid test for Chagas. In October we received a CE marking for our Chagas product enabling us to market this test into several countries not previously available.. Materials required for the HIV CE marking study were shipped in June 2008 to the regulatory agency in Europe and evaluations of both products were completed in August 2008. We intend to submit the Technical File to our European Notified Body during the fourth quarter of 2008, and the technical file review is anticipated to be completed by the end of the fourth quarter. We anticipate receiving a CE marking no later than the first quarter of 2009.

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 this new specification, packaged HIV Rapid Test Control Packs containing the new HIV Controls have been in distribution since May 2008. The FDA has classified this voluntary recall as a Class II recall, "a situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences are remote". We have completed all of our recall activity, including monitoring and final product disposition.

#### 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 "Amendments") were approved by the Company and the requisite percentages of the holders of the Preferred Stock and of the Non-Employee Warrants. Subsequent to approval of 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 Amendments 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.

During the June 30, 2008 quarter, warrants to purchase 9,323,854 shares of the Company's common stock were exercised on a cashless basis, resulting in the issuance of 1,407,367 shares of common stock. These warrants were exercised on a cashless basis in connection with the Company's preferred stock and warrant amendments that were completed on December 19, 2007, and the Company received no cash consideration for these issuances of common stock.

## RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2008 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2007

The Company is selecting certain line items to provide further details of its results of operations. Items selected are determined by management to be significant for the current period reported and may be different from prior periods. In addition, some reclassifications may have been made to prior periods to conform to the current period's presentation.

## Revenues:

Selected Product  
Categories:

	For the three months ended			
	September 30, 2008	September 30, 2007	\$ Change	% Change
HIV	\$ 3,097,898	\$ 1,975,120	\$ 1,122,778	56.85%
TB	112,672	10,910	101,762	932.74%
Other	196,233	172,408	23,825	13.82%
Net Product Sales	3,406,803	2,158,438	1,248,365	57.84%
Research grant income	109,361	155,099	(45,738)	-29.49%
Total Revenues	\$ 3,516,164	\$ 2,313,537	\$ 1,202,627	51.98%

Revenues for our HIV tests and related products during the three months ended September 30, 2008 increased by approximately \$1,123,000 over the same period in 2007. This was primarily attributable to increased sales in Brazil, due to increased testing in that region. The increase in TB sales of \$102,000 for the three months ended 2008 over 2007 was due to an increase in the number of customers for our veterinary TB products and promotional offers made during the quarter. The decrease in grant and development income was due to revenue generated from fees, 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 \$753,000. During the first quarter of 2008, we were informed that our designation in Nigeria as one of the screening tests will be changed to that of a confirmatory test beginning in the first quarter of 2009 when Nigeria 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 performed. Consequently, we expect our sales to Nigeria to decrease in 2009. Sales of HIV products to Inverness, which has exclusive marketing rights for the Company's two rapid HIV test products approved in the U.S., were approximately \$605,000 for the three months ended September 30, 2008.

## Gross Margin:

Gross Margin related to	For the three months ended			
Net Product Sales:	September 30, 2008	September 30, 2007	\$ Change	% Change
Gross Margin per Statement of Operations	\$ 1,656,610	\$ 985,009	\$ 671,601	68.18%

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Less: Research grant income	109,361	155,099	(45,738)	-29.49%
Gross Margin from Net Product Sales	\$ 1,547,249	\$ 829,910	\$ 717,339	86.44%
Gross Margin %	45.42%	38.45%		

The increase in our gross margin resulted primarily from increased average unit selling prices on product sold in Brazil and to Inverness, net of an expense for product returns, to accommodate a customer, of approximately \$50,000.

## 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
	September 30, 2008	September 30, 2007		
<b>Clinical &amp; Regulatory Affairs:</b>				
Wages and related costs	\$ 61,438	\$ 45,713	\$ 15,725	34.40%
Consulting	17,267	22,000	(4,733)	-21.51%
Clinical Trials	41,305	21,415	19,890	92.88%
Other	8,532	1,785	6,747	377.98%
<b>Total Regulatory</b>	<b>\$ 128,542</b>	<b>\$ 90,913</b>	<b>\$ 37,629</b>	<b>41.39%</b>
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	\$ 411,958	\$ 243,418	168,540	69.24%
Consulting	64,981	41,120	23,861	58.03%
Share-based compensation	9,738	28,669	(18,931)	-66.03%
Materials and supplies	74,232	54,466	19,766	36.29%
Other	69,400	24,602	44,798	182.09%
<b>Total other than Regulatory</b>	<b>\$ 630,309</b>	<b>\$ 392,275</b>	<b>\$ 238,034</b>	<b>60.68%</b>
<b>Total Research and Development</b>	<b>\$ 758,851</b>	<b>\$ 483,188</b>	<b>\$ 275,663</b>	<b>57.05%</b>

Expenses for Clinical & Regulatory Affairs for the three months ended September 30, 2008 increased by \$37,600 as compared to the same period in 2007. This was primarily due to costs associated with untrained user studies we initiated in order to develop user instructions for our DPP® oral fluid HIV test, partially offset by a reduction in the use of outside consultants.

Expenses other than Clinical & Regulatory Affairs increased by approximately \$238,000 for the three months ended September 30, 2008 as compared with the same period in 2007. These increases were primarily related to an increase in wages and related costs of \$168,000 which includes approximately \$60,000 in recruiting and moving expenses. In addition, consulting expenses increased by \$24,000 primarily due to subcontractor payments related to grant work along with an increase of \$20,000 in the use of materials related to our work on the DPP® feasibility studies, which was partially offset by a decrease of \$19,000 in the cost of share-based compensation related to the value of common stock and employee stock options issued to employees.

Subject to funding 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.





## Selling, General and Administrative Expense:

Selected expense lines:	For the three months ended		\$ Change	% Change
	September 30, 2008	September 30, 2007		
Wages and related costs	\$ 319,499	\$ 365,938	\$ (46,439)	-12.69%
Consulting	44,973	54,397	(9,424)	-17.32%
Commissions, License and Royalties	438,630	249,152	189,478	76.05%
Share-based compensation	14,082	40,755	(26,673)	-65.45%
Marketing Materials	6,047	15,698	(9,651)	-61.48%
Investor Relations	42,046	66,297	(24,251)	-36.58%
Legal, Accounting and Sox 404 compliance	123,612	237,907	(114,295)	-48.04%
Travel, Entertainment and Trade Shows	29,628	50,547	(20,919)	-41.39%
Other	114,771	93,839	20,932	22.31%
<b>Total S, G &amp;A</b>	<b>\$ 1,133,288</b>	<b>\$ 1,174,530</b>	<b>\$ (41,242)</b>	<b>-3.51%</b>

Selling, general and administrative expense for the three months ended September 30, 2008 remained fairly level as compared with the same period in 2007. Increases in commission, license and royalty expenses were partially offset by reductions in wages and related expenses, consulting, marketing materials, investor relations, legal and accounting, travel and entertainment costs.

## Other Income and Expense:

Other Income and Expense	For the three months ended		\$ Change	% Change
	September 30, 2008	September 30, 2007		
Interest income	\$ 3,587	\$ 30,603	\$ (27,016)	-88.28%
Interest expense	(5,112)	(6,408)	1,296	-20.22%
<b>Total Other Income and Expense</b>	<b>\$ (1,525)</b>	<b>\$ 24,195</b>	<b>\$ (25,720)</b>	<b>-106.30%</b>

Interest income for the three months ended September 30, 2008 decreased due to a decrease in funds available to invest.

## RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2007

The Company is selecting certain line items to provide further details of its results of operations. Items selected are determined by management to be significant for the current period reported and may be different from prior periods. In addition, some reclassifications may have been made to prior periods to conform to the current period's presentation.

## Revenues:

Selected Product Categories:	For the nine months ended		\$ Change	% Change
	September 30, 2008	September 30, 2007		
HIV	\$ 7,228,915	\$ 5,935,013	\$ 1,293,902	21.80%
TB	254,604	94,053	160,551	170.70%
Other	627,496	574,910	52,586	9.15%
Net Product Sales	8,111,015	6,603,976	1,507,039	22.82%
Research grant income	487,661	250,655	237,006	94.55%
Total Revenues	\$ 8,598,676	\$ 6,854,631	\$ 1,744,045	25.44%

Revenues for our HIV tests and related products during the nine months ended September 30, 2008 increased by approximately \$1,294,000 over the same period in 2007. This was primarily attributable to increased sales in Africa and Brazil, due to increased testing in those regions, and sales to our distributor in the United States, partially offset by no sales to Mexico in 2008. Sales to Mexico in the first nine months of 2007 were approximately \$1,398,000. Sales of our Tuberculosis products increased by \$161,000 in the nine month period ended September 30, 2008 over the same period in 2007. The increase in grant and development income was due primarily 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 \$2,337,000. During the first quarter of 2008 we were informed that our designation in Nigeria as one of the screening tests will be changed to that of a confirmatory test beginning in the first quarter of 2009 when Nigeria 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 performed. Consequently, we expect our sales to Nigeria to decrease in 2009. Sales to Inverness of our HIV products were approximately \$1,570,000.

## Gross Margin:

Gross Margin related to	For the nine months ended		\$ Change	% Change
	September 30, 2008	September 30, 2007		
Net Product Sales:	\$ 4,015,341	\$ 2,636,728	\$ 1,378,613	52.28%

Gross Margin per  
Statement of  
Operations

Less: Research grant income	487,661	250,655	237,006	94.55%
Gross Margin from Net Product Sales	\$ 3,527,680	\$ 2,386,073	\$ 1,141,607	47.84%
Gross Margin %	43.49%	36.13%		

The increase in our gross margin resulted primarily from increased average unit selling prices on product sold in Brazil and to Inverness, our U.S. distributor, net of an increase in the inventory reserve of approximately \$150,000, or 3%, of net sales, for potential unsold expiring products and an expense of \$50,000 for product return, to accommodate a customer.

## Research and Development:

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

Selected expense lines:	For the nine months ended			
	September 30, 2008	September 30, 2007	\$ Change	% Change
<b>Clinical &amp; Regulatory Affairs:</b>				
Wages and related costs	\$ 194,897	\$ 135,972	\$ 58,925	43.34%
Consulting	24,683	79,732	(55,049)	-69.04%
Clinical Trials	138,792	33,355	105,437	316.11%
Other	53,096	6,485	46,611	718.75%
<b>Total Regulatory</b>	<b>\$ 411,468</b>	<b>\$ 255,544</b>	<b>\$ 155,924</b>	<b>61.02%</b>
<b>R&amp;D Other than Regulatory:</b>				
Wages and related costs	\$ 992,927	\$ 652,993	339,934	52.06%
Consulting	104,981	69,142	35,839	51.83%
Share-based compensation	75,197	161,174	(85,977)	-53.34%
Materials and supplies	190,746	164,135	26,611	16.21%
Other	177,117	82,085	95,032	115.77%
<b>Total other than Regulatory</b>	<b>\$ 1,540,968</b>	<b>\$ 1,129,529</b>	<b>\$ 411,439</b>	<b>36.43%</b>
<b>Total Research and Development</b>	<b>\$ 1,952,436</b>	<b>\$ 1,385,073</b>	<b>\$ 567,363</b>	<b>40.96%</b>

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2008 increased by \$156,000 as compared to the same period in 2007. This increase was primarily due to the hiring of an additional member in the Clinical and Regulatory Affairs department, clinical trial expenses related to an amendment of our PMA claims to include the 13-17 year-old age group, and oral fluid studies performed with our FDA-approved (for blood matrices) HIV 1/2 STAT-PAK® and our prototype DPP® HIV product, which was partially offset by a reduction in the use of outside consultants.

Expenses other than Clinical & Regulatory Affairs increased by approximately \$411,000 for the nine months ended September 30, 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. The increases were partially offset by the \$86,000 reduction in the cost of share-based compensation related to the value of common stock and employee stock options issued to employees.

## Selling, General and Administrative Expense:

Selected expense lines:	For the nine months ended			
	September 30, 2008	September 30, 2007	\$ Change	% Change

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Wages and related costs	\$ 1,003,733	\$ 1,148,426	\$ (144,693)	-12.60%
Consulting	141,582	165,042	(23,460)	-14.21%
Commissions, License and Royalties	1,093,791	622,425	471,366	75.73%
Share-based compensation	173,825	114,184	59,641	52.23%
Marketing Materials	22,548	57,906	(35,358)	-61.06%
Investor Relations	111,747	161,524	(49,777)	-30.82%
Legal, Accounting and Sox 404 compliance	474,555	630,416	(155,861)	-24.72%
Travel, Entertainment and Trade Shows	71,847	120,838	(48,991)	-40.54%
Bad Debt Allowance	6,062	(11,210)	17,272	-154.08%
Other	375,572	480,548	(104,976)	-21.85%
Total S, G &A	\$ 3,475,262	\$ 3,490,099	\$ (14,837)	-0.43%

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Selling, general and administrative expense for the nine months ended September 30, 2008 remained relatively level as compared with the same period in 2007. Increases in commission, license and royalty expenses, and expenses related to the issuance of options to employees were partially offset by reductions in wages and related expenses, consulting, marketing materials, investor relations, legal and accounting, travel and entertainment, and other costs.

#### Other Income and Expense:

Other Income and Expense	For the nine months ended		\$ Change	% Change
	September 30, 2008	September 30, 2007		
Other income	\$ -	\$ 120,862	\$ (120,862)	-100.00%
Interest income	29,958	125,513	(95,555)	-76.13%
Interest expense	(15,966)	(11,107)	(4,859)	43.75%
Total Other Income and Expense	\$ 13,992	\$ 235,268	\$ (221,276)	-94.05%

Other income for the first nine months of 2007 consisted of \$133,000, net of expenses, from New York State related to a program for qualified emerging technology companies, which was partially offset by a retirement of fixed assets. The Company had no Other income in the first nine months of 2008. Interest income for the nine months ended September 30, 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

	For the nine months ended		\$ Change	% Change
	September 30, 2008	September 30, 2007		
Net cash used in operating activities	\$ (1,445,137)	\$ (1,710,135)	\$ 264,998	-15.50%
Net cash used in investing activities	(363,652)	(171,501)	(192,151)	112.04%
Net cash utilized by financing activities	(19,151)	(153,443)	134,292	-87.52%
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	\$ (1,827,940)	\$ (2,035,079)	\$ 207,139	-10.18%

The Company's decrease in cash and cash equivalents for the nine months ended September 30, 2008 was less than the decrease in cash for the same period in 2007. The reduction in this decrease during the 2008 period is primarily attributable to less cash used in operations, partially offset by the purchase of fixed assets.

The Company had a working capital surplus of approximately \$1,656,000 at September 30, 2008 and a working capital surplus of approximately \$3,229,000 at December 31, 2007. The Company estimates that its resources are sufficient to fund its needs through the end of 2008 and it is considering alternatives to provide for its capital requirements for 2009 and beyond in order to continue as a going concern. 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.

We believe that we can achieve profitable operating results based upon a sales level of approximately \$4-\$5 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 objective is to realize development income and license income or to endeavor to secure non-dilutive funding sources to the extent needed. There is no assurance that we will be able to accomplish this. Notwithstanding some of the risks and uncertainties mentioned above we anticipate a strong fourth quarter based upon our current product order backlog and the progress we are making on opportunities related to our DPP® technology. We have continued to manage our expenses and cash flow and have made moving product from R&D into production a priority, and we are seeing the success of that effort as we release our initial DPP® products into the market during the fourth quarter of 2008.



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

Chembio's business is currently focused on two major product lines: The first major product line is our base business of rapid tests based upon lateral flow technologies comprised primarily 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 revenues and therefore our growth have come from our 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 the manufacturer of two of the four FDA PMA approved tests, to participate in this growth. Although market conditions for rapid HIV tests being used in developing countries with high rates of HIV prevalence have become increasingly competitive, we have been able to grow our revenues in those regions where our test has been selected in the testing protocol. However, 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 and standards for 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. Nevertheless, PEPFAR is very likely to be a significant part of our revenue base for some time to come as it has been reauthorized for 2008-2013 for nearly \$50 billion, up from \$15 billion during its initial five years. We are therefore clearly looking at ways to increase our participation in PEPFAR and other donor funded programs if we can do so profitably. Additional markets for our HIV tests will become available as we receive our CE mark, and this also may help to mitigate this risk. We also believe that new HIV tests for which we have now completed development on our DPP® platform and which can use oral fluid samples will enable us to expand the available market for our tests. 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.

Our second major product line 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.

During the third quarter we signed an additional agreement with the Oswaldo Cruz Foundation of Brazil, (FIOCRUZ), the fourth such agreement we signed with this organization this year and the fifth overall. Under the terms of the new agreement with FIOCRUZ, a minimum of 2.5 million of the HIV 1-2 rapid tests for use with oral fluid or whole blood samples will be purchased for a period of time, followed by an additional period during which components for tests will be purchased, followed by royalties for a period of five years. The total purchases by FIOCRUZ from Chembio will ultimately be determined by the demand for the product by the national program, the pace of the technology transfer, and FIOCRUZ's manufacturing capacity. Sales are anticipated to begin during 2009 once the products are approved for sale in Brazil, at which time a technology transfer fee will be payable to Chembio. Chembio's 2004 agreement with FIOCRUZ for Chembio's lateral flow rapid HIV test for use with whole blood samples, HIV 1/2 STAT PAK®, has been very successful, thus providing the parties with a mutually strong preexisting relationship for this latest agreement and the agreements entered in January.

Based upon a number of factors, we believe that our operating results can show continued improvement in the fourth quarter of 2008 as compared with the third quarter of 2008. Included in the current order backlog are confirmed purchase orders in excess of \$500,000 for our first commercial DPP® product. This product is for Canine Leishmaniasis, the product that we have now completed development of in connection with one of the three agreements we signed with FIOCRUZ in January of this year. During the first and second quarters of 2009, we anticipate receiving technology transfer payments from FIOCRUZ in excess of \$500,000 as the products under these

agreements are approved for sale in Brazil. We also believe that we will receive strong demand for this and the other products under these agreements during 2009, providing a significant increment of sales over our base of lateral flow products which we also believe will grow.

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. We believe that this collaboration will enable us to capitalize on some of the unique capabilities of DPP®. Our agreement with Bio-Rad contemplates that we will enter into a license agreement no later than December 2008 subject to the satisfaction of certain development and other conditions. We believe there is a substantial likelihood that these conditions will be satisfied.

We are also in discussions with a select group of leading companies and other organizations to develop OEM products for these companies based on the use of DPP® in their core marketing areas, including but not limited to bacterial infections, veterinary applications, and sexually transmitted diseases. In some cases we are doing feasibility studies for these companies as a first step toward concluding agreements for new products that we would exclusively license develop and manufacture for them using our patented technology and manufacturing expertise. There cannot be any assurance that any of these discussions will result in definitive license, development or manufacturing agreements, nor can there be any assurance that such products, if they are successfully completed, will be successfully commercialized.

We are also developing DPP® products under Chembio brands that would address significant global market opportunities in POC testing that we have identified. 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. During the third quarter we completed initial validation of our DPP® oral fluid and blood HIV test enabling us to move forward on full validation, clinical studies and other activities in support of an FDA Pre-Marketing Approval application and to determine the best means of bringing this product to the US and global markets. 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.

#### ITEM 4T. CONTROLS AND PROCEDURES

##### Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2008 (the end of the period covered by this report). Based on this evaluation, our principal executive officer and principal financial officer concluded that our current disclosure controls and procedures (as defined in Rules 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934) are effective.

##### Changes in Internal Control over Financial Reporting

Our management evaluated our internal control over financial reporting and there have been no changes during the fiscal quarter ended September 30, 2008 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	Registration Rights Agreement, dated as of May 5, 2004, by and among the Registrant and the Purchasers listed therein. (2)
4.2	Lock-Up Agreement, dated as of May 5, 2004, by and among the Registrant and the shareholders of the Registrant listed therein. (2)
4.3	Amended Form of Common Stock Warrant issued pursuant to the May 4, 2004 Stock and Warrant Purchase Agreement. (11)
4.4	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)
4.5	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)
4.6	Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (9)
4.7	Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (11)
4.8	Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (9)
4.9	Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (4)
4.10	Registration Rights Agreement, dated June 29, 2006. (4)
4.11	Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
4.12	Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (6).
4.13	Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (11)
4.14	Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (11)
4.15	Form of Employee Option Agreement. (11)
4.16	Amended Form of Warrant used for Consultant Services, and in connection with the Company's 2004 merger. (11)
4.17	1999 Equity Incentive Plan (13)
4.18	2008 Stock Incentive Plan (14)
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)
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)

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- 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.

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

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: November 12, 2008 By: /s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 12, 2008 By: /s/ Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)