

CHEMBIO DIAGNOSTICS, INC.  
Form 10QSB  
November 01, 2007

---

---

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

---

**FORM 10 - QSB**

---

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

**For the quarterly period ended September 30, 2007**

**000-30379**

*(Commission File Number)*

**Chembio Diagnostics, Inc.**

*(Exact name of registrant as specified in its charter)*

**Nevada            88-0425691**

*(State or other            (IRS*  
*jurisdiction of            Employer*  
*incorporation)        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 Exchange Act 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 shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Transitional Small Business Disclosure Format (check one): Yes \_\_\_\_ No X

As of November 1, 2007, the Registrant had 14,080,155 shares outstanding of its \$.01 par value common stock.

---

---

**Quarterly Report on FORM 10-QSB For The Period Ended**

**September 30, 2007**

**Table of Contents**

**Chembio Diagnostics, Inc.**

	<b>Page</b>
<b>Part I. FINANCIAL INFORMATION:</b>	
Item 1. Financial Statements: Condensed Consolidated Balance Sheets as of September 30, 2007 (unaudited) and December 31, 2006.	F-2
Condensed Consolidated Statements of Operations (unaudited) for the Three and Nine Months ended September 30, 2007 and 2006.	F-3
Condensed Consolidated Statements of Cash Flows (unaudited) for the Nine Months ended September 30, 2007 and 2006.	F-4 to F-5
Notes to Condensed Consolidated Financial Statements (unaudited)	F-6 to F-14
Item 2. Management's Discussion and Analysis and Plan of Operation	1
Item 3. Controls and Procedures	12
<b>Part II. OTHER INFORMATION:</b>	
Item 6. Exhibits	13
<b>SIGNATURES</b>	14

EXHIBITS

F - 1

---

**PART I****Item 1. FINANCIAL STATEMENTS**

**CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

- ASSETS -		
	September 30, 2007 (Unaudited)	December 31, 2006
<b>CURRENT ASSETS:</b>		
Cash	\$ 2,255,307	\$ 4,290,386
Accounts receivable, net of allowance for doubtful accounts of \$10,045 and \$42,967 for 2007 and 2006, respectively	1,436,487	1,350,240
Inventories	1,169,736	1,108,950
Prepaid expenses and other current assets	270,185	204,092
<b>TOTAL CURRENT ASSETS</b>	<b>5,131,715</b>	<b>6,953,668</b>
<b>FIXED ASSETS</b> , net of accumulated depreciation	<b>652,658</b>	<b>603,603</b>
<b>OTHER ASSETS:</b>		
Deposits and other assets	357,362	349,306
	<b>\$ 6,141,735</b>	<b>\$ 7,906,577</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)-</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 1,662,317	\$ 1,709,939
Accrued interest payable	3,159	93,160
Current portion of obligations under capital leases	28,940	37,336
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,694,416</b>	<b>1,840,435</b>
<b>OTHER LIABILITIES:</b>		
Obligations under capital leases - net of current portion	83,894	7,081
Series C preferred stock redemption put	161,390	449,677
<b>TOTAL LIABILITIES</b>	<b>1,939,700</b>	<b>2,297,193</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>PREFERRED STOCK - Series C 7%</b>		
Redeemable Convertible - \$.01 par value: 165 shares issued and outstanding as of 2007 and 2006. Liquidation preference of \$8,397,583	<b>6,837,479</b>	<b>6,549,191</b>

**STOCKHOLDERS' EQUITY****(DEFICIENCY):**

Preferred Stock – 10,000,000 shares  
authorized:

Series A 8% Convertible - \$.01 par  
value: 141.59027 and 149.92119 shares  
issued and outstanding as of 2007 and  
2006, respectively. Liquidation  
preference of \$4,387,605

**2,468,286** 2,504,313

Series B 9% Convertible - \$.01 par  
value: 111.68591 and 113.93591 shares  
issued and outstanding as of 2007 and  
2006, respectively. Liquidation  
preference of \$5,712,830

**3,354,760** 3,555,786

Common stock - \$.01 par value;  
100,000,000 shares authorized  
14,080,155 and 11,296,961 shares  
issued and outstanding as of 2007 and  
2006, respectively

**140,802** 112,970

Additional paid-in capital

**21,551,216** 19,960,618

Accumulated deficit

**(30,150,508)** (27,073,494)

**TOTAL STOCKHOLDERS' EQUITY****(DEFICIENCY)**

**(2,635,444)** (939,807)

**\$ 6,141,735** \$ 7,906,577

*See notes accompanying the condensed consolidated financial statements.*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**

	<b><u>Three months ended</u></b>		<b><u>Nine months ended</u></b>	
	<b>September 30, 2007</b>	September 30, 2006	<b>September 30, 2007</b>	September 30, 2006
<b>REVENUES:</b>				
Net sales	\$ 2,158,438	\$ 942,088	\$ 6,603,976	\$ 3,683,599
Research grant income	155,099	76,102	250,655	209,494
<b>TOTAL REVENUES</b>	<b>2,313,537</b>	1,018,190	<b>6,854,631</b>	3,893,093
Cost of sales	1,328,528	830,819	4,217,903	2,705,749
<b>GROSS PROFIT</b>	<b>985,009</b>	187,371	<b>2,636,728</b>	1,187,344
<b>OVERHEAD COSTS:</b>				
Research and development expenses	483,188	318,048	1,385,073	1,062,319
Selling, general and administrative expenses	1,174,530	1,109,797	3,490,099	3,740,765
	<b>1,657,718</b>	1,427,845	<b>4,875,172</b>	4,803,084
<b>LOSS FROM OPERATIONS</b>	<b>(672,709)</b>	(1,240,474)	<b>(2,238,444)</b>	(3,615,740)
<b>OTHER INCOME (EXPENSES):</b>				
Other income (expense)	-	25,000	120,862	30,000
Interest income	30,603	2,094	125,513	2,980
Interest expense	(6,408)	(360,606)	(11,107)	(382,316)
	<b>24,195</b>	(333,512)	<b>235,268</b>	(349,336)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(648,514)</b>	(1,573,986)	<b>(2,003,176)</b>	(3,965,076)
Income taxes	-	-	-	-
<b>NET LOSS</b>	<b>(648,514)</b>	(1,573,986)	<b>(2,003,176)</b>	(3,965,076)
Dividends payable in stock to preferred stockholders	362,959	220,909	1,073,837	641,769
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	-	538,560	-	1,001,994
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (1,011,473)</b>	\$ (2,333,455)	<b>\$ (3,077,013)</b>	\$ (5,608,839)
<b>Basic and diluted loss per share</b>	<b>\$ (0.07)</b>	\$ (0.21)	<b>\$ (0.24)</b>	\$ (0.56)
	<b>14,043,208</b>	10,961,662	<b>12,701,494</b>	10,014,207

**Weighted average number of  
shares outstanding, basic and  
diluted**

*See notes accompanying the condensed consolidated financial statements.*



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

	Nine months ended	
	September 30, 2007	September 30, 2006
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers	\$ 6,935,884	\$ 4,277,732
Cash paid to suppliers and employees	(8,760,425)	(6,263,092)
Interest received	125,513	2,980
Interest paid	(11,107)	(22,302)
<b>Net cash used in operating activities</b>	<b>(1,710,135)</b>	<b>(2,004,682)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(171,501)	(320,750)
<b>Net cash used in investing activities</b>	<b>(171,501)</b>	<b>(320,750)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Sale of Series C Preferred Stock and associated warrants, net of cash cost of financing of \$50,000	-	3,950,000
Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing of \$2,750	-	997,250
Proceeds from bridge loan	-	1,300,000
Payment on bridge loan	-	(500,000)
Payment of accrued interest	(90,000)	(97,652)
Proceeds from exercise of options	31,000	86,321
Payment of capital lease obligation	(34,443)	(28,379)
Payment of dividends	(60,000)	(140,226)
<b>Net cash (used in) provided by financing activities</b>	<b>(153,443)</b>	<b>5,567,314</b>
<b>NET (DECREASE) INCREASE IN CASH</b>	<b>(2,035,079)</b>	<b>3,241,882</b>
Cash - beginning of the period	4,290,386	232,148
<b>Cash - end of the period</b>	<b>\$ 2,255,307</b>	<b>\$ 3,474,030</b>

*Continues on next page*

*See notes accompanying the condensed consolidated financial statements.*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(CONTINUED)**  
**(UNAUDITED)**

	Nine months ended	
	September 30, 2007	September 30, 2006
<b>RECONCILIATION OF NET LOSS TO NET CASH FROM OPERATING ACTIVITIES:</b>		
<b>Net Loss</b>	<b>\$ (2,003,176)</b>	<b>\$ (3,965,076)</b>
Adjustments:		
Depreciation and amortization	213,158	146,346
Non-cash interest expense	-	331,114
Loss on retirement of fixed assests	12,146	-
Provision for doubtful accounts	(11,210)	7,945
Common stock, options and warrants issued as compensation	275,360	458,412
Changes in current assets and liabilities:		
Accounts receivable	(75,037)	376,693
Inventories	(60,786)	(403,041)
Prepaid expenses and other current assets	(24,912)	115,538
Other assets and deposits	(8,056)	(251,544)
Accounts payable and accrued expenses	(27,622)	1,178,931
<b>Net cash used in operating activities</b>	<b>\$ (1,710,135)</b>	<b>\$ (2,004,682)</b>
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Preferred B issued as payment for financing fees	\$ -	\$ 100,000
Warrants issued with bridge loan	-	-
Value of warrants issued allocated to additional paid-in capital	20,000	1,120,030
Value of common stock and stock options issued	41,181	-
Cost of royalty rate reduction in other assets	-	200,000
Accreted beneficial conversion to preferred stock	-	1,001,994
Accreted dividend to preferred stock	1,073,837	641,769
	<b>1,072,157</b>	<b>522,794</b>

Value of Common stock issued as payment of dividend		
Value of Preferred B issued as payment of dividend	-	89,899
Value of Preferred A converted to common stock	<b>115,957</b>	122,006
Value of Preferred B converted to common stock	<b>62,776</b>	360,651
Assets acquired under capital leases	<b>102,860</b>	-

*See notes accompanying the condensed consolidated financial statements.*

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(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 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. These products all employ single path lateral flow technology. 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.

**NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:***(a) Basis of Presentation:*

The consolidated interim financial information as of September 30, 2007 and for the three- and nine-month periods ended September 30, 2007 and 2006 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 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, 2006, 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, 2007, and consolidated results of operations for the three- and nine-month periods ended September 30, 2007 and 2006 and cash flows for the nine-month periods ended September 30, 2007 and 2006, 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:

	<b>September 30, 2007</b>	December 31, 2006
<b>Raw Materials</b>	<b>\$ 696,086</b>	\$ 629,967
<b>Work in Process</b>	<b>215,565</b>	257,208
<b>Finished Goods</b>	<b>258,085</b>	221,775
	<b>\$ 1,169,736</b>	\$ 1,108,950



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

*(c) Earnings Per Share*

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

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>September 30, 2007</b>	September 30, 2006	<b>September 30, 2007</b>	September 30, 2006
<b>Basic</b>	<b>14,043,208</b>	10,961,662	<b>12,701,494</b>	10,014,207
<b>Diluted</b>	<b>14,043,208</b>	10,961,662	<b>12,701,494</b>	10,014,207

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, 2007 and 2006 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:

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>September 30, 2007</b>	September 30, 2006	<b>September 30, 2007</b>	September 30, 2006
<b>1999 Plan</b>				
<b>Stock Options</b>	<b>2,396,136</b>	1,629,750	<b>1,929,471</b>	1,629,750
<b>Other Stock</b>				
<b>Options</b>	<b>124,625</b>	144,625	<b>124,625</b>	144,625
<b>Warrants</b>	<b>26,196,085</b>	24,713,994	<b>26,191,683</b>	24,713,994
<b>Convertible</b>				
<b>Preferred</b>				
<b>Stock</b>	<b>26,553,340</b>	16,835,036	<b>26,811,978</b>	16,835,036

*(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 September 30, 2007 and 2006 include share-based compensation expense totaling \$71,000 and \$33,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (none and \$3,000, respectively), research and development (\$29,000 and \$6,000, respectively) and selling, general and administrative expenses (\$42,000 and \$24,000, respectively). The nine-month periods ended September 30, 2007 and 2006 include share-based compensation expense totaling \$275,000 and \$247,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (none and \$25,000, respectively), research and development (\$161,000 and \$62,000, respectively) and selling, general and administrative expenses (\$114,000 and \$160,000, 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- and nine-month periods ended September 30, 2007 and 2006 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.

F - 7

---



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

The weighted average estimated fair value of stock options granted in the nine month periods ended September 30, 2007 and 2006 was \$.45 and \$.53 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:

	<u>For the three months ended</u>		<u>For the nine months ended</u>	
	<u>September 30, 2007</u>	<u>September 30, 2006</u>	<u>September 30, 2007</u>	<u>September 30, 2006</u>
<b>Expected term (in years)</b>	<b>5</b>	n/a	<b>5</b>	4 to 5
<b>Expected volatility</b>	<b>106.31%</b>	n/a	<b>102.84% - 106.31%</b>	116.20% - 118.03%
<b>Expected dividend yield</b>	<b>0%</b>	n/a	<b>0%</b>	0%
<b>Risk-free interest rate</b>	<b>4.60%</b>	n/a	<b>4.50% - 5.06%</b>	4.66% - 4.92%

The Company granted 960,000 new options under the Plan during the nine months ended September 30, 2007 at an average exercise price of \$0.57 per share. Options to purchase 128,250 shares of common stock were forfeited during the nine months ended September 30, 2007.

The following table provides stock options activity for the nine months ended September 30, 2007:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2007	1,529,750	\$ 0.70		
Granted	960,000	\$ 0.57		
Exercised	(50,000)	\$ 0.62		
Forfeited/expired	(128,250)	\$ 0.65		
Outstanding at September 30, 2007	2,311,500	\$ 0.65	3.85 years	\$ 7,200
Exercisable at September 30, 2007	1,450,500	\$ 0.51	3.23 years	\$ 7,200

As of September 30, 2007, there was \$243,000 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 1.6 years. The total fair value of stock options vested during the nine month periods ended September 30, 2007 and 2006, was \$267,000 and \$401,000, 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.

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:

F - 8

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

	For the three months ended		For the nine months ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
<b>Africa</b>	\$ 1,308,180	\$ 493,922	\$ 2,722,434	\$ 1,229,083
<b>Asia</b>	15,850	55,125	115,544	206,414
<b>Europe</b>	45,834	16,313	90,239	62,642
<b>Middle East</b>	-	5,505	174,218	13,245
<b>North America</b>	750,333	130,349	3,313,415	279,620
<b>South America</b>	38,241	240,874	188,126	1,892,595
	\$ 2,158,438	\$ 942,088	\$ 6,603,976	\$ 3,683,599

*(f) Accounts payable and accrued liabilities*

Accounts payable and accrued liabilities consist of:

	September 30, 2007	December 31, 2006
<b>Accounts payable – suppliers</b>	\$ 479,272	\$ 679,990
<b>Accrued commissions</b>	12,745	91,920
<b>Accrued royalties / licenses</b>	417,843	461,048
<b>Accrued payroll</b>	128,536	87,637
<b>Accrued vacation</b>	154,588	214,858
<b>Deferred R&amp;D revenue</b>	167,500	-
<b>Accrued legal and accounting</b>	105,000	7,000
<b>Accrued expenses – other</b>	196,833	167,486
<b>TOTAL</b>	\$ 1,662,317	\$ 1,709,939

*(g) Recent Accounting Pronouncements affecting the Company*

Financial Accounting Standards Board (FASB) No. 48, Accounting for Uncertainty in Income Taxes (“FIN 48”)

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109 (FIN 48), which provides clarification related to the process associated with accounting for uncertain tax positions recognized in consolidated financial statements. FIN 48 prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. FIN 48 also provides guidance related to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. We have adopted FIN 48 effective January 1, 2007 and there is no impact of adopting FIN 48 on our consolidated financial statements to date.

Statement of Financial Accounting Standard 159, Fair Value Option for Financial Assets and Financial Liabilities (“FAS 159”)

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 expects to adopt SFAS No. 159 in the first quarter of Fiscal 2008 and is still evaluating the effect, if any, on its financial position or results of operations.

F - 9

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

**NOTE 3 - ACCRUED INTEREST PAYABLE:**

In connection with the Series B Preferred Stock offering, interest payable on certain debt was agreed to be paid over 33 months in installments of \$10,000 per month and a final payment of \$3,159 in the 34<sup>th</sup> month (October 2007). These payments are subordinate to the redemption rights of the Series B preferred stockholders. No additional interest accrues on this payable. The accrued interest repaid in the three- and nine-month periods ended September 30, 2007 was \$30,000 and \$90,000, respectively. The balance remaining unpaid was \$3,159 as of September 30, 2007.

**NOTE 4 - STOCKHOLDERS' EQUITY:**

*(a) Common Stock*

During the nine months ended September 30, 2007, the Company issued 200,000 shares of its Common Stock upon the execution of an employment agreement, of which 100,000 shares vested immediately, 50,000 shares will vest on March 5, 2008 and 50,000 shares will vest on March 5, 2009. These shares were valued at the market price on the date of grant and aggregated \$119,800 and are being expensed over the vesting periods.

During the nine months ended September 30, 2007 the Company issued 50,000 shares of its Common Stock upon the exercise of options and received cash of \$31,000.

During the nine months ended September 30, 2007 Series A Preferred shareholders converted 8.33092 shares of Series A Preferred Stock into 416,546 shares of Common Stock.

During the nine months ended September 30, 2007 Series B Preferred shareholders converted 2.25 shares of Series B Preferred Stock into 184,426 shares of Common Stock.

In the nine months ended September 30, 2007 the Company issued 897,896, 835,577 and 198,749 shares of its Common Stock as payment of dividends on its Series C Preferred Stock, Series B Preferred Stock and Series A Preferred Stock, respectively. These shares were valued, in the aggregate at \$1,072,157, using a volume weighted average price (VWAP) for the ten trading days immediately preceding the issue date.

*(b) Warrants*

During the nine months ended September 30, 2007, the Company issued warrants to purchase 33,381 shares of Common Stock at an exercise price of \$0.81 per share to a sales agent as payment for commissions accrued at year end 2006 (value \$20,000). These warrants have a five-year life.

The above warrants were valued using a Black-Scholes option pricing model based on assumptions for expected volatility of 104.8%, expected life of 5 years and expected risk-free interest rate of 4.54%.

*(c) Series A 8% Convertible Preferred Stock:*

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series A Preferred Stock. The Series A Preferred Stock is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its

redemption value. The liquidation preference is \$30,000 per share plus accrued and unpaid dividends, presently \$988 per share, an aggregate for all such shares of \$4,387,605. Accrued but unpaid dividends of \$139,897 are included in the preferred stock carrying value as of September 30, 2007.

Dividends: The 8% per annum dividend is payable semi-annually, in cash or, at the Company's option, in Common Stock, except as to Vicis Capital, which is to be paid in cash unless it opts to take its dividends in Common Stock. In June 2006, the Series A Preferred Stock was amended to provide, among other matters, that dividends paid in Preferred or Common Stock would be based on a 10-day volume-weighted average market price at the time of the dividend.

F - 10

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

***(d) Series B 9% Convertible Preferred Stock:***

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series B Preferred Stock. The Series B Preferred is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$1,151 per share, an aggregate for all such shares of \$5,712,830. Accrued but unpaid dividends of \$128,534 are included in the preferred stock carrying value as of September 30, 2007.

Dividends: The 9% Series B Preferred Stock accrues dividends at 9% per annum, payable semi-annually. Dividends are payable in Series B Preferred Stock, Common Stock or in cash. In June 2006, the Series B Preferred Stock was amended to provide, among other amendments, that the dividend could be paid in Common Stock (in addition to Preferred Stock or cash) and that dividends in Preferred or Common Stock would be based on a 10-day volume-weighted average market price at the time of the dividend. The majority investor in the Series B financing has the option as it pertains to its dividend payment to choose cash or Preferred or Common shares. The Company has the option to choose cash or Preferred or Common shares as to the balance of the dividends. To date all dividends have been paid in Preferred or Common Shares, except \$140,226 which was paid in cash at the option of the majority investor.

***(e) Series C 7% Convertible Preferred Stock:***

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series C Preferred Stock. The redemption value is the greater of (i) 130% of the stated value or \$65,000 or (ii) the product of (a) daily volume weighted average price of the Company's common stock and (b) a quotient of \$65,000 divided by the then existing conversion price, plus accrued and unpaid dividends and all liquidated damages. The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$894 per share, an aggregate for all such shares of \$8,397,583. Accrued but unpaid dividends of \$147,583 are included in the preferred stock carrying value as of September 30, 2007.

Dividends: Holders of Series C Preferred Stock are entitled to a 7% per annum dividend per share. The dividend accrues and is payable semi-annually in cash or in shares of common stock, at our option. Accrued but unpaid dividends are also payable upon the conversion or redemption of the shares of Series C Preferred Stock and upon a liquidation event.

The Company has accounted for the Series C Preferred Stock pursuant to the provisions of Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" and EITF 00-19: "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19"). The Company has determined that the redemption feature in the Series C Preferred Stock needed to be bifurcated and the liability for the value of the redemption feature will be "marked to market" in future accounting periods until such time as the redemption is exercised or the feature meets the criteria for equity classification, and has valued the same at \$228,644 as of September 30, 2007. Due to the contingent redemption feature, the Series C Preferred Stock is reflected as temporary equity.





**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

**NOTE5—COMMITMENTS AND CONTINGENCIES:**

*(a) Economic Dependency:*

The Company had sales to two customers in excess of 10% of total sales in the three months ended September 30, 2007. Sales to these customers approximated \$723,000 and \$628,000, respectively. This represents approximately 63% of total sales. Accounts receivable as of September 30, 2007 from these customers approximated \$411,000 and \$425,000, respectively.

The Company had sales to two customers in excess of 10% of total sales in the three months ended September 30, 2006. Sales to these customers approximated \$363,000 and \$232,000, respectively. This represents approximately 63% of total sales. Accounts receivable as of September 30, 2006 from these customers approximated \$360,000 and \$232,000, respectively.

The Company had sales to three customers in excess of 10% of total sales in the nine months ended September 30, 2007. Sales to these customers approximated \$1,933,000, \$1,581,000 and \$1,398,000, respectively. This represents approximately 74% of total sales. Accounts receivable as of September 30, 2007 from these customers approximated \$411,000, \$425,000 and none, respectively.

The Company had sales to three customers in excess of 10% of total sales in the nine months ended September 30, 2006. Sales to these customers approximated \$1,197,000, \$685,000 and \$640,000, respectively. This represents approximately 68% of total sales. Accounts receivable as of September 30, 2006 from these customers approximated \$232,000, \$360,000 and none, respectively.

The Company had purchases from two vendors in excess of 10% of total purchases for the three months ended September 30, 2007. Purchases from these vendors approximated \$143,000 and \$57,000, respectively. Accounts payable as of September 30, 2007 to these vendors approximated \$4,000 and \$18,000, respectively.

The Company had purchases from one vendor in excess of 10% of total purchases for the three months ended September 30, 2006. Purchases from this vendor approximated \$70,000. Accounts payable as of September 30, 2006 to this vendor approximated \$4,000.

The Company had purchases from one vendor in excess of 10% of total purchases for the nine months ended September 30, 2007. Purchases from this vendor approximated \$251,000. There was no accounts payable as of September 30, 2007 to this vendor.

The Company had purchases from one vendor in excess of 10% of total purchases for the nine months ended September 30, 2006. Purchases from this vendor approximated \$203,000. There was no accounts payable as of September 30, 2006 to this vendor.

*(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) Equipment Purchase Commitment:***

In August 2007, the Company entered into a commitment to purchase \$218,000 of fixed assets during the three months ended September 30, 2007. The Company believes the equipment will help improve the quality and efficiency of the manufacturing process and delivery is expected in the fourth quarter of 2007. The Company issued a deposit to the vendor in the amount of \$54,500, which is reflected in other assets.

F - 12

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

**NOTE 6 - SUBSEQUENT EVENTS:**

*Amendments to Preferred Stock and Warrants and Certain Options:*

In October 2007, the Company sent a letter to the holders of the Company's Series A, Series B and Series C Convertible Preferred Stock (collectively, the "Preferred Stock"), and the holders of certain of the Company's outstanding warrants and options, not including options or warrants issued to employees or directors in their capacity as such (collectively, such warrants and options, the "Warrants"), to consider amendments to the terms of the Preferred Stock and Warrants. These amendments and the related transactions are collectively referred to herein as the "Plan." As set forth below, the Plan will not be consummated unless certain conditions are satisfied, including a number of conditions that are in the sole discretion of the Company.

Pursuant to the terms of the Plan, all of the outstanding Series A and Series B Preferred Stock, other than the Series A Preferred and Series B Preferred held by the Company's Chief Executive Officer, Lawrence A. Siebert, would be converted into shares of the Company's \$.01 par value common stock (the "Common Stock") at a conversion rate of \$0.40 per share of Common Stock. The Series A Preferred and Series B Preferred held by Mr. Siebert would be converted at the rate of \$0.48 per share of Common Stock. The Plan would also convert all the outstanding Series C Preferred Stock into shares of Common Stock at the rate of \$0.48 per share of Common Stock. Any accrued but unpaid dividends on any shares of the Preferred Stock would be converted into shares of Common Stock.

The Plan would reduce, for a limited time period, the exercise price of all of the Warrants so that at the time of the initial closing of the Plan (the "Closing") (i) the Warrants would be exercisable for cash at \$0.40 per share; and (ii) the Warrants would be exercisable on a cashless basis (as described below) at an exercise price of \$0.45 per share. Warrant holders who exercise at least 25% of their Warrants for cash at \$0.40 per share at the Closing would be permitted, but not required, to exercise the remaining balance of their Warrants for cash or on a cashless basis at an exercise price of \$0.45 per share at any time on or before March 31, 2008. If a Warrant holder exercises at least 25% of its Warrants for cash at the Closing, but does not exercise the remaining balance of its Warrants for cash or on a cashless basis on or before March 31, 2008, then the exercise price of the unexercised Warrants would revert on April 1, 2008 to the original exercise price, subject to any applicable adjustment. For a Warrant holder that does not exercise at least 25% of its Warrants for cash at the Closing, the exercise price of its Warrants would revert to the original exercise price, subject to any applicable adjustment, on the first trading day after the Closing. Beginning April 1, 2008, in addition to being exercisable for cash, holders of all unexercised Warrants would be permitted to exercise their Warrants on a cashless basis based on the volume weighted average price (VWAP) for the ten-trading day period that ends on the first trading day immediately preceding the date of such Warrant exercise over the original exercise price. In addition to these amendments, the Warrants would be amended to provide that the anti-dilution provisions would not cause any adjustment to the exercise price or number of shares issuable based on any issuance or other action taken in connection with the Plan.

The cashless exercise provision under the Plan would permit a Warrant holder to use any excess of the market price of the Company's Common Stock over the exercise price of a Warrant under the Plan as part of the exercise price for another Warrant by submitting both warrants at the time of exercise. Pursuant to the Plan, at the Closing a Warrant holder would be entitled to use, as the value of the Common Stock, the greater of (i) \$0.53 or (ii) the VWAP for the ten-trading day period that ends on the second trading day prior to the Closing, so that each Warrant used as part of the exercise price payment would represent the difference between the greater of these two values and the \$0.45 Warrant exercise price. After the Closing, the value of a Warrant to be used as part of the exercise price payment in such cashless exercise would equal the excess of the VWAP for the ten-trading day period that ends on the first

trading day immediately preceding the date of such Warrant exercise over the exercise price of a Warrant.

F - 13

---

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

The Company will not consummate the Plan unless it obtains a minimum of \$2,000,000 in cash upon Warrant exercises. In this regard, certain Warrant holders have indicated that they intend to exercise all of their Series C Warrants for cash at Closing. In addition, Lawrence A. Siebert has indicated that he will exercise 250,000 of his Series A Warrants for cash at Closing. As a result of these transactions, the Company expects to receive at least \$787,500 in cash at Closing. One of these holders has also indicated that, to the extent necessary for the Company to obtain the \$2,000,000 minimum capital infusion, in addition to exercising 100% of its Series C Warrants (approximately 9% of its total Warrants) for cash at the Closing, it will agree to exercise up to \$1,000,000 of its Series B warrants on or before March 31, 2008, provided that all its other Series B warrants will be amended to provide that they can be exercised for \$0.45 cash or \$0.45 on a cashless basis at any time on or before March 31, 2008.

The Company is working with Collins Stewart LLC ("Collins Stewart"), an investment banking advisor, with respect to the Plan. As compensation for the services rendered by Collins Stewart, the Company will pay Collins Stewart at the Closing cash fees equal to \$250,000 (the "Advisory Fee"), plus two and one-half percent (2.5%) of the consideration up to \$5,000,000, and eight percent (8%) of any consideration above \$5,000,000 (the "Agent Fee"), less 5% of the Agent Fee if the warrant exercise price is less than \$0.45 per share and equal to or greater than \$0.40 per share. Collins Stewart also will be reimbursed, up to specified thresholds, for its reasonable counsel and out-of-pocket expenses related to the Plan.

The Plan will not be implemented, in part or whole, unless substantially all of the Plan is approved by the required number of holders of each of the Preferred Stock, the Warrants and the Non-Employee Options. The Company will use a portion of any new equity to pay certain expenses incurred in implementing the Plan, including fees payable to Collins Stewart, legal fees and other costs of the Plan, as well as for general working capital purposes.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS AND PLAN OF OPERATION

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an 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, 2006.

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," "will," "should," "expects," "intends," "plans," "anticipates," "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.

### Overview

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. These products all employ single path lateral flow technology. 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., which is the Company's exclusive marketing partner for its rapid HIV test products in the United States.

In October 2007, the Company sent a letter to the holders of the Company's Series A, Series B and Series C Convertible Preferred Stock (collectively, the "Preferred Stock"), and the holders of certain of the Company's outstanding warrants and options, not including options or warrants issued to employees or directors in their capacity as such (collectively, such warrants and options, the "Warrants"), to consider amendments to the terms of the Preferred Stock and Warrants. These amendments and the related transactions are collectively referred to herein as the "Plan." A description of the terms of the Plan is included in Note 6 to the condensed consolidated financial statements in Part I of this Form 10-QSB (Note 6). As set forth in Note 6, the Plan will not be consummated unless certain conditions are satisfied, including a number of conditions that are in the sole discretion of the Company. On October 19, 2007, the

Company filed a Form 8-K with the SEC concerning this matter.

**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, 2006, see our annual report on Form 10-KSB for the period ended December 31, 2006 which was filed with the SEC on March 29, 2007.

**RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2007 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2006**

**Revenues:**

Selected Product Categories:	For the three months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b>HIV</b>	\$ 1,975,120	\$ 547,398	\$ 1,427,722	260.82%
<b>Chagas</b>	31,060	259,146	(228,086)	-88.01%
<b>Other</b>	152,258	135,544	16,714	12.33%
<b>Net Sales</b>	<b>2,158,438</b>	<b>942,088</b>	<b>1,216,350</b>	<b>129.11%</b>
<b>Research grant income</b>	155,099	76,102	78,997	103.80%
<b>Total Revenues</b>	<b>\$ 2,313,537</b>	<b>\$ 1,018,190</b>	<b>\$ 1,295,347</b>	<b>127.22%</b>

Revenues for our HIV tests during the three months ended September 30, 2007 increased by \$1.4 million over the same period in 2006. This was primarily attributable to sales in Africa and to our distributor in the United States. Sales of our Chagas product declined because a \$1.2 million order received in 2006 was not repeated. The increase in grant and development income of \$79,000 was due to revenue generated from a grant and feasibility studies for our DPP™ Platform of which \$262,000 was received and \$155,000 was earned in the third quarter of 2007, the balance of \$107,000 was added to deferred revenue.

**Gross Margin:**

Gross Margin related to	For the three months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b>Net Product Sales:</b>				
<b>Gross Margin per Statement of Operations</b>	\$ 985,009	\$ 187,371	\$ 797,638	425.70%
<b>Less: Research grant income</b>	155,099	76,102	78,997	103.80%
<b>Gross Margin from Net Product Sales</b>	<b>\$ 829,910</b>	<b>\$ 111,269</b>	<b>\$ 718,641</b>	<b>645.86%</b>
<b>Gross Margin %</b>	<b>38.45%</b>	<b>11.81%</b>	<b>26.64%</b>	

Increased quantities of product sales and increased average unit prices on product sales to our U.S. distributor combined to increase our gross margins.





**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, 2007	September 30, 2006		
<b><u>Clinical &amp; Regulatory Affairs:</u></b>				
Wages and related costs	\$ 44,472	\$ 43,598	\$ 874	2.00%
Consulting	22,000	12,505	9,495	75.93%
Clinical Trials	21,415	14,110	7,305	51.77%
Other	3,026	676	2,350	347.63%
<b>Total Regulatory</b>	<b>\$ 90,913</b>	<b>\$ 70,889</b>	<b>\$ 20,024</b>	<b>28.25%</b>
<b><u>R&amp;D Other than Regulatory:</u></b>				
Wages and related costs	\$ 243,418	\$ 201,189	42,229	20.99%
Consulting	15,000	5,000	10,000	200.00%
Share-based compensation	28,669	6,286	22,383	356.08%
Materials and supplies	81,909	6,546	75,363	1151.28%
Other	23,279	28,138	(4,859)	-17.27%
<b>Total other than Regulatory</b>	<b>\$ 392,275</b>	<b>\$ 247,159</b>	<b>\$ 145,116</b>	<b>58.71%</b>
<b>Total Research and Development</b>	<b>\$ 483,188</b>	<b>\$ 318,048</b>	<b>\$ 165,140</b>	<b>51.92%</b>

Expenses for Clinical & Regulatory Affairs increased in the three months ended September 30, 2007 as compared with the same period in 2006 and were primarily related to an increase in the cost related to CLIA waiver studies for our barrel product marketed by our U.S. distributor.

Expenses other than Clinical & Regulatory Affairs increased in the three months ended September 30, 2007 as compared with the same period in 2006 and were primarily related to the additional work related to feasibility studies of our DPP™ platform and grant income which has resulted in an increase in our personnel and material costs. In addition, an increase in the cost of share-based compensation was related to the value of common stock and the employee stock options issued to an employee pursuant to a contract.

The Company entered into five externally funded research agreements during the second and third quarters of 2007 that accounted for total financial commitments of \$600,000, of which \$370,000 was received by the Company during 2007 (approximately \$155,000 of which was earned in the third quarter of 2007 on a percentage of completion basis) with clinical diagnostics, life science, companion animal, academic, and government-affiliated public health entities. These agreements all related to potential applications for point of care tests that would employ our Dual Path Platform (DPP™) technology.

Subject to cash availability, the Company currently plans to continue to increase its spending on research and development in the fourth quarter of 2007 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:

**R&D - Dual Path Platform (DPP™)**

During the third quarter we made significant progress in implementing our strategy for the deployment of our Dual Path Platform technology. We have further confirmed that this platform technology has potential application to a broad range of point-of-care/point-of-use products and markets. We believe that our DPP™ intellectual property, product development and regulated manufacturing know-how and experience are core strengths, but that significant additional resources would be required for the associated product development and marketing needed to adequately address such a wide range of opportunities. Our strategy is therefore to leverage our strengths in developing collaborations with premier organizations that have significant sales, marketing and distribution capabilities. We have received a substantial amount of interest in these kinds of collaborations. If successful, in each case we would be an exclusive development and long term manufacturing partner to these companies, and the companies would also acquire an exclusive license to our DPP™ intellectual property to market the product in the field of interest. Our focus is on opportunities with partners that can address large markets where the proposed product fills an unmet need. Those projects which have to date resulted in funding from third parties are described below:

**Externally Funded DPP™ R&D Projects**

Project	Short Description of the status of the R&D project
DPP™ Multiplex Antigen Detection Product	In August 2007 Chembio received \$150,000 in funding for the purpose of Chembio conducting a two phase, six month feasibility study to establish improved performance capabilities of DPP™ based upon agreed upon protocols to ascertain detection limits with respect to antigen detection in certain types of samples prior to development of a new multiplex point of care product. We are very satisfied with the progress to date and we also believe that progress thus far has been satisfactory to our partner Pall Corporation. If feasibility is established to the satisfaction of the funding partner then it is anticipated that a long term development, limited exclusive license to DPP™ for this field of application, and manufacturing contract would be negotiated between the parties. There can be no assurance that these activities will result in successful commercial products.
DPP™ Multiplex Antigen Detection POCT-Women's Health	In September 2007 Chembio received \$100,000 in funding for the purpose of Chembio conducting a three month feasibility study to establish performance capabilities including detection limits of DPP™ antigen detection in connection with a new point of care product in the women's health field. We are very satisfied with the progress to date and we also believe that progress thus far has been satisfactory to our funding partner. If feasibility is established then it is anticipated that a long term development, limited exclusive license to DPP™ for this field of use, and manufacturing contract would be negotiated between the parties. There can be no assurance that these activities will result in successful commercial products.
Public Health/Donor Funded DPP™ Antibody Detection Tests for Neglected Diseases (Leptospira Leishmaniasis, Leprosy)	We have completed prototypes of the Leishmania and Leprosy antibody detection tests on our DPP™ technology platform and we and our partner that funded some of this prototype development work, Infectious Disease Research Institute (IDRI), are pursuing procurement opportunities with public health entities and donor foundations for the acquisition of these products. Our collaborators on Leptospira include the National Institutes of Health, Infectious Disease Research Institute, Weill Medical College of Cornell University and Oswaldo Cruz Foundation in Brazil. The Leishmania product is nearest completion and the likeliest of these products to have significant revenue opportunities in 2008. There can be no assurance that these activities will result in any

DPP™ Companion Animal Screening Test	successful commercial products. In late September 2007, Chembio received \$20,000 for a one month; feasibility study to establish if Chembio can developing a screening test that would be marketed to veterinary practices for companion animals. If feasibility is established then it is anticipated that a long term development, limited exclusive license to DPP™ for this field of use, and manufacturing contract would be negotiated between the parties. There can be no assurance that these activities will result in successful commercial products.
DPP™ Auto-Immune Status Multiplex Test	In late September 2007, Chembio received \$15,000 for a one month feasibility study to establish if Chembio can develop a multiplex screening test for autoimmune diseases. If feasibility is established then it is anticipated that a long term development, limited exclusive license to DPP™ for this field of use, and manufacturing contract would be negotiated between the parties. There can be no assurance that these activities will result in successful commercial products.

We have a number of additional DPP™ feasibility and development projects under discussion with third parties. If we are successful with this business model, of which we have no assurance, we expect the expansion of our research and development organization to be partially funded with our chosen partners. There can be no assurance that either our current or pending DPP™ feasibility or product development activities will result in successful commercial products.

## Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10QSB

Other Research and Development activities that are being funded internally include the following:

### Other Research & Development Activities

DPP™ HIV 1/2	We have completed a prototype of our DPP™ HIV 1/2 test for whole blood, serum and plasma and are doing internal studies with various components to optimize the oral fluid feature pending commencement of pre-clinical studies. We are considering the various options with respect to bringing this product through regulatory approval and potential marketing and distribution strategies
Clearview® HIV 1/2 STAT PAK®	At the request of Inverness, we are investigating the possibility of adding additional features to our HIV STAT PAK that we manufacture for export and that is marketed by Inverness Medical in the United States.
DPP™ Syphilis	This product development activity is pursuant to a Cooperative Research and Development Agreement (CRADA) that we entered into with the United States Centers for Disease Control in November, 2006. The goal of the CRADA was to develop a DPP™ multiplex test that could be used to both screen for antibodies to Syphilis (known as treponomal) and confirm (known as non-treponomal) them. During the third quarter we completed validation work for the treponomal screening test and submitted several thousand treponomal tests for use in a large overseas CDC study for which we are waiting for reported results
Reader Technologies	We have made significant progress in employing reflectance and fluorescence reader devices that can measure, record and report results of DPP™ tests with greater consistency than interpretation through visual observation. This will be particularly important with the development of multiplex tests on DPP™, which is a significant advantage of DPP™ due to the independently controlled, direct, even and simultaneous delivery of sample material to the test zone area that is unique to DPP™. We have found that the DPP™ technology results in much improved membrane clearance as compared with conventional single path lateral flow technologies and this substantially increases the utility and accuracy of readers, and we have made significant progress in adapting these reading instruments to DPP™ using both colored and fluorescent conjugate labels
Fluorescence Technology	We have entered into a collaboration with a development stage company that has a patent-pending technology that could increase detection levels using a unique fluorescence labeling methodology

### Regulatory Activities

In July 2007, we submitted to the FDA the results of our untrained user studies in connection with our pending CLIA waiver application for the HIV barrel product marketed by Inverness under the name Clearview® Complete™ HIV 1/2. In October 2007, we announced that the FDA granted a CLIA waiver for this product. We believe that CLIA waiver for this product will create additional sales opportunities for Inverness with this product that were not available previously without the CLIA waiver.

In August 2007, we received ISO 13.485 certification. ISO 13.485 is a directive of the International Standards Organization (ISO) that is specifically related to manufacturers of in-vitro diagnostic products. This certification is necessary to obtain CE (Community European) Markings for our products which are required in order to sell in most European countries, as well as many other countries in the world. We have made progress in pursuing CE Markings for all of our rapid HIV tests, which we anticipate receiving during the first half of 2008. We have also made progress in pursuing CE Marking and FDA 510(K) clearance for our Chagas rapid test.

During the third quarter of 2007, we applied to the FDA for an Investigational Device Exemption (IDE) in connection with a study that we have agreed upon a protocol with FDA that, if successfully completed, would enable us and therefore Inverness to expand the age range of our two FDA approved rapid HIV tests beyond the current 18-64 year old range down to individuals 13 years of age and above. We believe the IDE will be granted and that this study and associated submission, which will be a supplement to our Pre-Marketing Approval (PMA), will be completed during the fourth quarter of 2007. However there is no assurance that this study will be completed successfully or that the FDA will approve these additional claims based upon our submission.

The Company received its first USDA approval during the second quarter of 2007 for manufacturing and marketing its Prima-TB STAT PAK™ test, a rapid test for the detection of active pulmonary tuberculosis in non-human primate whole blood samples. We anticipate that additional product licenses may be issued to Chembio by the USDA over the next six months for additional veterinary tuberculosis products. There is no assurance that commercialization of these products will be successful.

**Selling, General and Administrative Expense:**

Selected expense lines:	For the three months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b>Wages and related costs</b>	\$ 363,148	\$ 385,452	\$ (22,304)	-5.79%
<b>Consulting</b>	54,397	82,227	(27,830)	-33.85%
<b>Commissions, License and Royalties</b>	249,152	92,410	156,742	169.62%
<b>Options (per SFAS 123R)</b>	41,705	23,694	18,011	76.02%
<b>Marketing Materials</b>	15,698	25,137	(9,439)	-37.55%
<b>Investor Relations</b>	66,297	113,181	(46,884)	-41.42%
<b>Legal, Accounting and 404</b>	237,907	115,796	122,111	105.45%
<b>Travel, Entertainment and shows</b>	55,332	91,560	(36,228)	-39.57%
<b>Bad Debt Allowance</b>	-	7,945	(7,945)	-100.00%
<b>Other</b>	90,894	172,395	(81,501)	-47.28%
<b>Total S, G &amp; A</b>	<b>\$ 1,174,530</b>	<b>\$ 1,109,797</b>	<b>\$ 64,733</b>	<b>5.83%</b>

Selling, general and administrative expense increased for the three months ended September 30, 2007 as compared to the same period in 2006. This is primarily due to increased royalties on the increase in sales for the period. The increased cost of legal, accounting and section 404 (Sarbanes-Oxley) expenses were related to the added cost of DPP™ patent filings in many countries, legal expenses associated with the Plan (see Note 6) of approximately \$67,000, as well as additional section 404 related expenses of approximately \$66,000, which was offset by the settlement of litigation with Statsure Diagnostics Systems, Inc. in September of 2006 which contributed to a decrease in legal costs of approximately \$34,000. We reduced our spending on investor relations as compared to last year by approximately \$47,000.



As the Company's sales of its rapid test products increase, we will incur increased costs for commissions and royalties on intellectual property licenses.

**Other Income and Expense:**

<b>Other Income and Expense</b>	<b>For the three months ended</b>			
	<b>September 30, 2007</b>	<b>September 30, 2006</b>	<b>\$ Change</b>	<b>% Change</b>
<b>Other income (expense)</b>	\$ -	\$ 25,000	\$ (25,000)	-100.00%
<b>Interest income</b>	30,603	2,094	28,509	1361.46%
<b>Interest expense</b>	(6,408)	(360,606)	354,198	-98.22%
<b>Total Other Income and Expense</b>	\$ <b>24,195</b>	\$ <b>(333,512)</b>	\$ <b>357,707</b>	<b>-107.25%</b>

Interest income for the three months ended September 30, 2007 increased due to the additional availability of funds to invest. Other income (expense) in 2006 of \$25,000 was for a New York State marketing grant received in 2006. The absence of interest expense related to the bridge loan received in June 2006 and repaid in September 2006 accounts for most of the decrease in interest expense.

**RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2007 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2006****Revenues:**

Selected Product Categories:	For the nine months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b>HIV</b>	\$ 5,935,013	\$ 1,970,240	\$ 3,964,773	201.23%
<b>Chagas</b>	61,080	1,200,907	(1,139,827)	-94.91%
<b>Other</b>	607,883	512,452	95,431	18.62%
<b>Net Sales</b>	<b>6,603,976</b>	<b>3,683,599</b>	<b>2,920,377</b>	<b>79.28%</b>
<b>Research grant income</b>	250,655	209,494	41,161	19.65%
<b>Total Revenues</b>	<b>\$ 6,854,631</b>	<b>\$ 3,893,093</b>	<b>\$ 2,961,538</b>	<b>76.07%</b>

Revenues for our HIV tests during the nine months ended September 30, 2007 increased by \$3.96 million over the same period in 2006. This was primarily attributable to sales in Africa and to our distributor in the United States. Sales of our Chagas product declined because a \$1.2 million order received in 2006 was not repeated. The increase in grant and development income was due to revenue generated from a grant and feasibility studies for our DPP™ platform of which \$370,000 was received and \$203,000 was earned in 2007, the \$167,000 balance is reflected in deferred revenues.

**Gross Margin:**

Gross Margin related to	For the nine months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b>Net Product Sales:</b>				
<b>Gross Margin per Statement of Operations</b>	\$ 2,636,728	\$ 1,187,344	\$ 1,449,384	122.07%
<b>Less: Research grant income</b>	250,655	209,494	41,161	19.65%
<b>Gross Margin from Net Product Sales</b>	<b>\$ 2,386,073</b>	<b>\$ 977,850</b>	<b>\$ 1,408,223</b>	<b>144.01%</b>
<b>Gross Margin %</b>	<b>36.13%</b>	<b>26.55%</b>	<b>9.58%</b>	

Increased quantities of our product sales and increased average unit prices on product sales to our U.S. distributor combined to increase our gross margins.

**Research and Development:**

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

Selected expense lines:	For the nine months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b><u>Clinical &amp; Regulatory Affairs:</u></b>				
Wages and related costs	\$ 134,731	\$ 130,230	\$ 4,501	3.46%
Consulting	79,732	59,160	20,572	34.77%
Clinical Trials	33,355	59,427	(26,072)	-43.87%
Other	7,725	689	7,036	1021.19%
<b>Total Regulatory</b>	<b>\$ 255,543</b>	<b>\$ 249,506</b>	<b>\$ 6,037</b>	<b>2.42%</b>
<b><u>R&amp;D Other than Regulatory:</u></b>				
Wages and related costs	\$ 651,442	\$ 560,727	90,715	16.18%
Consulting	37,934	10,455	27,479	262.83%
Share-based compensation	161,174	54,261	106,913	197.03%
Materials and supplies	198,190	115,351	82,839	71.81%
Other	80,790	72,019	8,771	12.18%
<b>Total other than Regulatory</b>	<b>\$ 1,129,530</b>	<b>\$ 812,813</b>	<b>\$ 316,717</b>	<b>38.97%</b>
<b>Total Research and Development</b>	<b>\$ 1,385,073</b>	<b>\$ 1,062,319</b>	<b>\$ 322,754</b>	<b>30.38%</b>

Expenses for Clinical & Regulatory Affairs for the nine months ended September 30, 2007 remained similar as compared to the same period in 2006.

Expenses other than Clinical & Regulatory Affairs increased in the nine months ended September 30, 2007 as compared with the same period in 2006 and were primarily related to an increase in the cost of share-based compensation related to the value of common stock and employee stock options issued to an employee pursuant to a contract. The additional work related to feasibility studies of our DPP™ platform and grant income has resulted in an increase in our personnel and material costs.

The Company entered into five externally funded research agreements during the second and third quarters of 2007 that accounted for total financial commitments of \$600,000 of which \$370,000 was received by the Company during 2007 (approximately \$203,000 of which was earned in the second and third quarters of 2007 on a percentage of completion basis) with clinical diagnostics, life science, companion animal, academic, and government-affiliated public health entities. These agreements all related to potential applications for point of care tests that would employ our Dual Path Platform (DPP™) technology.

**Selling, General and Administrative Expense:**

Selected expense lines: For the nine months ended

	September 30, 2007	September 30, 2006	\$ Change	% Change
<b>Wages and related costs</b>	\$ 1,098,524	\$ 1,058,398	\$ 40,126	3.79%
<b>Consulting</b>	165,042	228,834	(63,792)	-27.88%
<b>Commissions, License and Royalties</b>	622,425	601,940	20,485	3.40%
<b>Options (per SFAS 123R)</b>	115,134	159,587	(44,453)	-27.86%
<b>Marketing Materials</b>	57,906	39,049	18,857	48.29%
<b>Investor Relations</b>	161,524	381,610	(220,086)	-57.67%
<b>Legal, Accounting and 404</b>	630,416	626,776	3,640	0.58%
<b>Travel, Entertainment and shows</b>	132,645	220,963	(88,318)	-39.97%
<b>Bad Debt Allowance</b>	(11,210)	14,824	(26,034)	-175.62%
<b>Other</b>	517,693	408,784	108,909	26.64%
<b>Total S, G &amp;A</b>	<b>\$ 3,490,099</b>	<b>\$ 3,740,765</b>	<b>\$ (250,666)</b>	<b>-6.70%</b>

Selling, general and administrative expense for the nine months ended September 30, 2007 decreased by 6.70 percent as compared with the same period in 2006. Reduction in spending on investor relations and decreased travel and entertainment were offset by increases in wages and other expenses. The increased cost of legal, accounting and section 404 (Sarbanes-Oxley) expenses were related to the added cost of DPP™ patent filings in many countries, legal expenses associated with the Plan (see Note 6) of approximately \$75,000, as well as additional section 404 related expenses of approximately \$87,000, which was offset by the settlement of litigation with Statsure Diagnostics Systems, Inc. in September of 2006 which contributed to a decrease in legal costs of approximately \$225,000. Our periodic review of our allowance for doubtful accounts resulted in a reduction of the allowance in the nine months ended September 30, 2007.

As the Company's sales of its rapid test products increase, it will incur increased costs for commissions and royalties on intellectual property licenses.

### **Other Income and Expense:**

Other Income and Expense	For the nine months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b>Other income</b>	\$ 120,862	\$ 30,000	\$ 90,862	302.87%
<b>Interest income</b>	125,513	2,980	122,533	4111.85%
<b>Interest expense</b>	(11,107)	(382,316)	371,209	-97.09%
<b>Total Other Income and Expense</b>	<b>\$ 235,268</b>	<b>\$ (349,336)</b>	<b>\$ 584,604</b>	<b>-167.35%</b>

Interest income for the nine months ended September 30, 2007 increased due to the additional availability of funds to invest. In addition the Company received \$133,000 in 2007, net of expenses, from New York State related to a program for qualified emerging technology companies, which was partially offset by the retirement of a fixed asset in 2007 of \$12,000 resulting in the increase in other income. The lack of interest expense related to a bridge loan in 2006 as well as the effect of several of our operating leases approaching the end of their terms, resulted in the decrease in interest expense in 2007 over 2006.

### **LIQUIDITY AND CAPITAL RESOURCES**

	For the nine months ended		\$ Change	% Change
	September 30, 2007	September 30, 2006		
<b>Net cash used in operating activities</b>	\$ (1,710,135)	\$ (2,004,682)	\$ 294,547	-14.69%
<b>Net cash used in investing activities</b>	(171,501)	(320,750)	149,249	-46.53%
<b>Net cash (used in) provided by financing activities</b>	(153,443)	5,567,314	(5,720,757)	-102.76%

<b>NET (DECREASE) INCREASE IN CASH</b>	<b>\$ (2,035,079)</b>	<b>\$ 3,241,882</b>	<b>\$ (5,276,961)</b>	<b>-162.77%</b>
--	-----------------------	---------------------	-----------------------	-----------------

The Company had a decrease in cash for the nine months ended September 30, 2007 as compared to an increase in cash for the same period in 2006. The decrease during the 2007 nine-month period is primarily attributable to the cash used in operations. The increase during the 2006 nine-month period was primarily due to cash from the sale of additional Series B Preferred of \$1,000,000, proceeds from a bridge loan of \$1,300,000 and proceeds from the sales of Series C Preferred of \$4,000,000, all received in 2006.

The Company had a working capital surplus of \$3,437,000 at September 30, 2007 and a working capital surplus of \$5,113,000 at December 31, 2006. The Company believes its resources are sufficient to fund its needs through the end of 2007 and into early 2008. 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; and (4) the Company's investment in capital equipment and the extent to which this investment improves cash flow through operating efficiencies.

The following table lists the future payments required on the Company's debt and certain other contractual obligations as of September 30, 2007:

OBLIGATIONS	Total	Less than 1 Year	1-3 Years	4-5 Years	Greater than 5 Years
Capital Leases (1)	\$ 150,216	\$ 42,153	\$ 85,717	\$ 22,346	\$ -
Operating Leases	202,920	128,160	74,760	-	-
Other Long Term Obligations(2)	987,083	523,083	383,000	27,000	54,000
<b>Total Obligations</b>	<b>\$ 1,340,219</b>	<b>\$ 693,396</b>	<b>\$ 543,477</b>	<b>\$ 49,346</b>	<b>\$ 54,000</b>

(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

In 2007 our business has been undergoing a significant shift as we begin to realize higher margins from revenues in the developed world markets (initially the US) from our FDA-approved rapid HIV tests and as we focus more of our business development efforts on leveraging our Dual Path Platform technology (DPP™) for which we were granted a U.S. patent in March, 2007 and for which we have recently filed for patent protection in many additional markets worldwide.

During the third quarter of 2007, we made significant progress in implementing our strategy for the deployment of our Dual Path Platform technology. We have confirmed, through our own studies and those that we are performing for prospective marketing partners, that this technology has potential application to a broad range of point-of-care/point-of-use products and markets. We believe that our DPP™ intellectual property, product development and regulated manufacturing know-how and experience are core strengths. Because significant additional resources would be required for the associated product development and marketing needed to adequately address such a wide range of opportunities, our DPP™ business development strategy is to develop collaborations with premier organizations that have significant sales, marketing and distribution capabilities. We have received a substantial amount of interest in these kinds of collaborations. In each case we would be an exclusive development and long term manufacturing partner with these companies, and the companies would also acquire an exclusive license to our DPP™ intellectual property to market the product in the field of interest. Our focus is on opportunities with partners that can address large markets where the proposed product fills an unmet need.

An initial step in achieving these long term opportunities is to establish a feasibility or proof of concept to demonstrate that the proposed product and its desired performance features can be achieved on our platform. Our priority is being placed on those projects where the proposed partner makes some initial financial commitment even at this stage. During the third quarter we entered into five externally funded DPP™ projects, four of which are from commercial partners including three with whom we have signed non-disclosure agreements that preclude our disclosing their identity; the fifth is a group of projects concerned with neglected diseases funded by non-profit donor and/or government-affiliated organizations.

As an adjunct to this principal strategy for our DPP™ technology, we plan to bring certain products that we are developing on the DPP™ platform through the regulatory approval under a Chembio brand. This should help us to

achieve manufacturing economies of scale for DPP™, showcase the features and benefits of DPP™ in the market, create Chembio brand equity, and generate additional revenues from product sales. Subject to the receipt of satisfactory clinical performance data, we believe that the syphilis rapid test product that we began work on less than one year ago pursuant to our Cooperative Research and Development Agreement with the United States Centers for Disease Control may be our first commercially available product that utilizes our DPP™ technology. There can be no assurance that this performance data will be satisfactory or that the product will be successfully commercialized.

On September 29, 2006, the Company executed several agreements by and among the Company, Inverness Medical Innovations, Inc. (“Inverness”) and StatSure Diagnostic Systems, Inc. (“StatSure”). Pursuant to these agreements, Inverness markets the Company’s then-existing FDA-approved rapid HIV tests, Chembio received a nonexclusive license to Inverness’ lateral flow patents, and the Company and StatSure settled their patent litigation. The distribution agreements contain gross margin sharing formulae among Inverness, the Company and StatSure. In addition, the Company has the exclusive right and duty to manufacture the products marketed by Inverness under all the agreements, and it has the right to subcontract manufacturing, but not sublicense or subcontract its rights or obligations. The specific terms of these agreements are available for review in the Company’s Current Report on Form 8-K filed with the Commission on October 5, 2006 (SEC Accession No. 000085), which is incorporated by reference herein.



Inverness launched marketing of the two rapid HIV tests in the United States during the first quarter of 2007 and we are pleased with the results of their efforts thus far. We believe that their distribution network in the point of care markets for HIV tests, namely hospital emergency departments, public health clinics, and physicians' offices, is outstanding and superior to the networks of the two other CLIA-waived competitive products, and that our products are beginning to successfully penetrate these market segments.

During the second quarter of 2007 we signed a contract with the Partnership for Supply Chain Management ("PSCM") based in Washington D.C. PSCM is the organization now charged with centralizing procurement, distribution, logistics and forecasting under the United States President's Emergency Plan for AIDS Relief ("PEPFAR") and other donor-funded relief programs in the developing world. Our sales to the PEPFAR program will increasingly be through this organization, and we believe that this is a positive development. However, sales into PEPFAR countries still largely depend upon being selected in national testing protocols. Currently our STAT-PAK test is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda, and in four of the eight parallel testing algorithms (two tests are used on each patient) adopted by the Nigerian Ministry of Health. In October 2007, we were also selected as the confirmatory test to be used in Ethiopia, and initial orders have been shipped to this market. Progress in being selected in additional countries is unpredictable and very price competitive.

Numerous other distribution opportunities are being pursued directly by Chembio for its HIV 1/2 STAT PAK® cassette and dipstick tests outside the United States, and progress is being made. However there can be no assurance that these efforts will result in successful distribution arrangements.

During the first nine months of 2007, we have continued to sell our HIV barrel product under our Sure Check® brand to our distributor in Mexico, a division of Bio-Rad Laboratories, Inc. In addition to the approximately 600,000 units we shipped during the first quarter of 2007, an additional 150,000 units were shipped during the second quarter of 2007, and no units were shipped during the third quarter of 2007. This distribution arrangement, which was the one exception to our otherwise global exclusive agreement with Inverness for this product, was to terminate as of the anniversary date of our agreement with Inverness on September 29, 2007. However, during the second quarter of 2007 Inverness agreed to extend this carve-out to at least September 2008. We believe that the program we announced in the fall of 2007 for the use of our test in a nationwide screening program in Mexico will be renewed, but there can be no assurance that it will be.

We also believe that our line of veterinary tuberculosis products ultimately will contribute to sales and improving margins. However, the introduction of our initial tuberculosis products in nonhuman primates has been slower than we anticipated and we will need to monitor these activities closely in the months ahead. We anticipate that we may receive additional veterinary tuberculosis product approvals in 2007 and 2008, although there can be no assurance that these approvals will be granted, or if granted, that the approved products will be successfully commercialized.

In October 2007, the Company sent a letter to the holders of the Company's Series A, Series B and Series C Convertible Preferred Stock (collectively, the "Preferred Stock"), and the holders of certain of the Company's outstanding warrants and options, not including options or warrants issued to employees or directors in their capacity as such (collectively, such warrants and options, the "Warrants"), to consider amendments to the terms of the Preferred Stock and the Warrants. These amendments and the related transactions are collectively referred to herein as the "Plan." A description of the terms of the Plan is included in Note 6 to the condensed consolidated financial statements in Part I of this Form 10-QSB (Note 6). As set forth in Note 6, the Plan will not be consummated unless certain conditions are satisfied, including a number of conditions that are in the sole discretion of the Company. On October 19, 2007, the Company filed a Form 8-K with the SEC concerning this matter.

**ITEM 3. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

As of the end of the period covered by this report, the Company conducted an evaluation under the supervision and with the participation of the principal executive officer and principal financial officer, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. There was no change in the Company's internal controls over financial reporting during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

13

---

## PART II. OTHER INFORMATION

### ITEM 6. EXHIBITS.

- 3.1 Articles of Incorporation, as amended. (3)
- 3.2 Bylaws. (1)
- 3.3 Amendment No. 1 to Bylaws dated May 3, 2004. (2)
- 4.1 Form of Warrant, dated June 29, 2006, issued pursuant to Company's sale of Secured Debentures. (4)
- 4.2 Registration Rights Agreement, dated June 29, 2006. (4)
- 4.3 Certificate of Designation of Preferences, Rights and Limitations of Series C 7% Convertible Preferred Stock of the Registrant. (6)
- 4.4 Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series C 7% Convertible Preferred Stock of the Registrant (6)
- 4.5 Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 4.6 Registration Rights Agreement, dated as of October 5, 2007 by and among the Registrant and the Purchases listed therein. (6)
- 4.7 Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement dated September 29, 2006. (6)
- 10.1 Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (5)
- 10.2 Securities Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (4)
- 10.3 Form of Secured Debenture, dated June 29, 2006. (4)
- 10.4 Security Agreement, dated June 29, 2006, among the Company, Chembio Diagnostic Systems, Inc., and purchasers of the Company's Secured Debentures. (4)
- 10.5 Subsidiary Guarantee, dated June 29, 2006, made by Chembio Diagnostic Systems, Inc., in favor of Purchasers of the Company's Secured Debentures. (4)
- 10.6 Securities Purchase Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (6)
- 10.7 Securities Purchase Agreement, dated as of October 5, 2006, by and among the Registrant and the Purchases listed therein. (6)
- 10.8 Letter of Amendment to Securities Purchase Agreements dated as of October 5, 2006 by and among the Registrant and the Purchasers listed therein. (6)
- 10.9 HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (7)
- 10.1 HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (7)
- 10.11 Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (7)
- 10.12 Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (7)
- 10.13 Settlement Agreement, dated September 29, 2006, between the Registrant and StatSure. (7)
- 10.14 Employment Agreement, dated April 23, 2007, with Javan Esfandiari (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.

Edgar Filing: CHEMBIO DIAGNOSTICS, INC. - Form 10QSB

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.
- (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 (SEC Accession No. 000083).
- (7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006 (SEC Accession No. 000085).
- (8) Incorporated by reference to the Registrant's Current Report on Form 8-K/A filed with the Commission on May 3, 2007.

**SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Chembio Diagnostics, Inc.

Date: November 1, 2007 By: /s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 1, 2007 By: /s/ Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)