

CHEMBIO DIAGNOSTICS, INC.  
Form 10QSB  
November 14, 2005

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

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**FORM 10 - QSB**

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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, 2005.**

**000-30379**

*(Commission File Number)*

**Chembio Diagnostics, Inc.**

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

**Nevada      88-0425691**

*(State or other  
jurisdiction of  
incorporation)*      *(IRS  
Employer  
Identification  
Number)*

**3661 Horseblock Road**

**Medford, New York 11763**

*(Address of principal executive offices including zip code)*

**(631) 924-1135**

*(Registrant's telephone number, including area code)*

*(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

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Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

As of November 11, 2005, the Registrant had 8,148,570 shares outstanding of its \$.01 par value common stock.

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**Quarterly Report on FORM 10-QSB For The Period Ended**  
**September 30, 2005**  
**Table of Contents**  
**Chembio Diagnostics, Inc.**

	<b>Page</b>
<b>Part I. FINANCIAL INFORMATION:</b>	
Item 1. Financial Statements:	
<u>Consolidated Balance Sheets as of September 30, 2005 (unaudited) and December 31, 2004.</u>	F-2
<u>Consolidated Statements of Operations (unaudited) for the Three and Nine Months ended September 30, 2005 and 2004.</u>	F-3
<u>Consolidated Statement of Changes in Stockholders' Equity (unaudited) for the Nine Months ended September 30, 2005.</u>	F-4
<u>Consolidated Statements of Cash Flows (unaudited) for the Nine Months ended September 30, 2005 and 2004.</u>	F-5
<u>Notes to Consolidated Financial Statements (unaudited)</u>	F-6 F-13
Item 2. <u>Management's Discussion and Analysis and Plan of Operation</u>	1
Item 3. <u>Controls and Procedures</u>	7
<b>Part II. OTHER INFORMATION:</b>	

Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	7
Item 6. <u>Exhibits</u>	8
<u>SIGNATURES</u>	9
<u>EXHIBITS</u>	

Table of Contents**PART I****Item 1. FINANCIAL STATEMENTS****CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARY**  
**CONSOLIDATED BALANCE SHEETS****AS OF:****- ASSETS -**

	September 30, 2005		December 31, 2004
	(Unaudited)		
<b>CURRENT ASSETS:</b>			
Cash	\$ 1,353,375	\$	34,837
Restricted Cash	-		250,000
Accounts receivable, net of allowance for doubtful accounts of \$12,089 and \$16,367 for September 30, 2005 and December 31, 2004, respectively	729,212		165,056
Inventories	570,862		538,647
Prepaid expenses and other current assets	134,622		222,520
<b>TOTAL CURRENT ASSETS</b>	<b>2,788,071</b>		<b>1,211,060</b>
<b>FIXED ASSETS</b> , net of accumulated depreciation of \$539,876 and \$460,720 for September 30, 2005 and December 31, 2004, respectively			
	433,612		188,399
<b>OTHER ASSETS:</b>			
Deposits and other assets	127,202		26,990
	\$ 3,348,885	\$	1,426,449
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>			
<b>CURRENT LIABILITIES:</b>			
Working capital loan	\$ -	\$	45,000
Accounts payable and accrued liabilities	884,682		1,102,428
Current accrued interest payable	120,000		120,000
Current portion of obligations under capital leases	42,487		51,029
Accrued contingency	13,674		60,264
Payable to related parties	183,485		284,475
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,244,328</b>		<b>1,663,196</b>
<b>OTHER LIABILITIES:</b>			
Obligations under capital leases - net of current portion	54,407		74,267
Accrued interest, net of current portion	123,160		212,950
<b>TOTAL LIABILITIES</b>	<b>1,421,895</b>		<b>1,950,413</b>

**COMMITMENTS AND  
CONTINGENCIES****PREFERRED STOCK -Series A 8%**

Convertible - \$.01 par value; 10,000,000  
shares authorized: 162.37241 shares  
issued and outstanding as of December  
31, 2004. Liquidation preference  
\$4,929,286.

- 2,427,030

**STOCKHOLDERS' EQUITY**

Preferred Stock - 10,000,000 shares  
authorized:

Series A 8% Convertible - \$.01 par value:  
158.68099 shares issued and outstanding  
as of September 30, 2005. Liquidation  
preference \$4,917,682

2,723,603 -

Series B 9% Convertible - \$.01 par value:  
102.19760 shares issued and outstanding  
as of September 30, 2005. Liquidation  
preference-\$5,220,061

3,051,404 -

Common stock - \$.01 par value;  
100,000,000 shares authorized 8,148,570  
and 6,907,143 shares issued and  
outstanding as of September 30, 2005 and  
December 31, 2004, respectively

81,486 69,071

Additional paid-in capital

13,797,733 9,079,341

Accumulated deficit

(17,727,236) (12,099,406)

**TOTAL STOCKHOLDERS' EQUITY**

**1,926,990 (2,950,994)**

\$ 3,348,885 \$ 1,426,449

*See notes accompanying the financial statements.*

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE PERIODS ENDED:**

(UNAUDITED)

	Three months ended		Nine months ended	
	September 30, 2005	September 30, 2004	September 30, 2005	September 30, 2004
<b>REVENUES:</b>				
Net sales	\$ 843,435	\$ 440,371	\$ 2,003,868	\$ 1,681,291
License revenue	-	-	250,000	-
Research grants and development income	101,277	125,875	328,419	465,332
<b>TOTAL REVENUES</b>	<b>944,712</b>	<b>566,246</b>	<b>2,582,287</b>	<b>2,146,623</b>
Cost of sales	669,817	719,239	1,770,747	1,858,402
<b>GROSS PROFIT (LOSS)</b>	<b>274,895</b>	<b>(152,993)</b>	<b>811,540</b>	<b>288,221</b>
<b>OVERHEAD COSTS:</b>				
Research and development expenses	292,198	446,486	1,053,731	962,286
Selling, general and administrative expenses	822,010	448,610	2,109,030	1,577,764
	<b>1,114,208</b>	<b>895,096</b>	<b>3,162,761</b>	<b>2,540,050</b>
<b>(LOSS) FROM OPERATIONS</b>	<b>(839,313)</b>	<b>(1,048,089)</b>	<b>(2,351,221)</b>	<b>(2,251,829)</b>
<b>OTHER INCOME (EXPENSES):</b>				
Interest income	10,135	3,479	33,456	6,176
Interest (expense)	(2,804)	(13,819)	(11,269)	(169,337)
Other	-	-	400	209,372
<b>(LOSS) BEFORE INCOME TAXES</b>	<b>(831,982)</b>	<b>(1,058,429)</b>	<b>(2,328,634)</b>	<b>(2,205,618)</b>
Income taxes	-	-	-	-
<b>NET LOSS</b>	<b>(831,982)</b>	<b>(1,058,429)</b>	<b>(2,328,634)</b>	<b>(2,205,618)</b>
Dividends payable in stock to preferred stockholders	206,256	91,694	600,495	148,504
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	-	486,592	2,698,701	1,216,480
	<b>\$ (1,038,238)</b>	<b>\$ (1,636,715)</b>	<b>\$ (5,627,830)</b>	<b>\$ (3,570,602)</b>

**NET LOSS  
ATTRIBUTABLE TO  
COMMON  
STOCKHOLDERS**

<b>Basic and diluted (loss) per share</b>	<b>\$ (0.13)</b>	<b>\$ (0.25)</b>	<b>\$ (0.75)</b>	<b>\$ (0.62)</b>
<i>Weighted number of shares outstanding, basic and diluted</i>	<b>8,137,727</b>	6,417,908	<b>7,500,167</b>	5,754,835

*See notes accompanying the financial statements.*



Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

	Preferred A Stock		Preferred B Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	paid in capital	Deficit	Stockholders' Equity
<b>Balance at December 31, 2004</b>	-	-	-	\$ -	6,907,143	\$69,071	\$ 9,079,341	\$(12,099,406)	\$(2,950,994)
Adjustment to reflect reclassification of Preferred A Stock	162.37241	\$2,427,030	-	-	-	-	-	-	2,427,030
<b>Preferred stock issued:</b>									
For cash	-	-	100.95000	5,047,500	-	-	(321,639 )	-	4,725,861
For fees	-	-	4.98000	249,000	-	-	(249,000 )	-	-
For dividends	-	-	4.06988	203,493	-	-	(203,493 )	-	-
Exchange from series A to series B	(0.66666)	(11,600)	0.40000	20,000	-	-	(8,400 )	-	-
Allocate fair value to warrants	-	-	-	(2,349,893 )	-	-	2,349,893	-	-
Allocate value for beneficial conversion	-	-	-	(2,437,035 )	-	-	2,437,035	-	-
Accretion of preferred dividend	-	286,821	-	313,674	-	-	-	(600,495)	-
Accretion of beneficial conversion	-	261,666	-	2,437,035	-	-	-	(2,698,701)	-
Payment of dividends	-	-	-	(203,493 )	-	-	203,493	-	-
<b>Common stock issued</b>									
Common converted from Preferred	(3.02476)	(52,631)	(8.20228)	(228,877 )	823,654	8,237	273,271	-	-
For services	-	-	-	-	70,000	700	41,800	-	42,500
Payment of dividend on	-	(187,683)	-	-	312,773	3,128	184,551	-	(4)

preferred A  
(includes cash  
payments for  
partial shares)

**Warrants and  
options:**

Issued for services	-	-	-	-	-	-	51,963	-	51,963
Exercised	-	-	-	-	35,000	350	24,850	-	25,200
Continuing valuation / cancellations	-	-	-	-	-	-	(65,932)	-	(65,932)

<b>Net loss for the nine months ended September 30, 2005</b>	-	-	-	-	-	-	-	(2,328,634)	(2,328,634)
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<b>Balance at September 30, 2005</b>	<b>158.68099</b>	<b>\$2,723,603</b>	<b>102.19760</b>	<b>\$ 3,051,404</b>	<b>8,148,570</b>	<b>\$ 81,486</b>	<b>\$ 13,797,733</b>	<b>\$ (17,727,236)</b>	<b>\$ 1,926,990</b>
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*See notes accompanying the financial statements.*

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE PERIODS ENDED:**  
**(UNAUDITED)**

	Nine months ended	
	September 30, 2005	September 30, 2004
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,328,634)	\$ (2,205,618)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	79,429	98,596
Provision for doubtful accounts	(4,278)	(6,383)
Increase in accrued interest	-	83,444
Warrants issued to existing debt holders, prior to the merger, recorded as interest expense	-	60,650
Stock issued as compensation	-	304,229
Stock issued as payment for fees	42,500	37,391
Options issued as compensation	-	969
Options/warrants issued as payment for fees and cancellation of options/warrants	(16,260)	43,669
Changes in:		
Accounts receivable	(559,878)	120,575
Restricted cash	250,000	(250,000)
Inventories	(32,215)	(221,827)
Prepaid expenses and other current assets	90,189	(51,886)
Other assets and deposits	(100,212)	33,671
Accounts payable and accrued expenses	(217,746)	(480,650)
Grant and other current liabilities	-	(12,648)
Payable to related parties	(100,990)	-
Accrued contingency	(46,590)	53,400
<b>Net cash used in operating activities</b>	<b>(2,944,685)</b>	<b>(2,392,418)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(324,642)	(67,086)
<b>Net cash used in investing activities</b>	<b>(324,642)</b>	<b>(67,086)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Changes in obligations to bank	-	(67,434)
Payment of capital lease obligation	(28,402)	(31,147)
Payment of accrued interest	(89,790)	-
Proceeds from working capital loan	161,917	50,000
Payment of working capital loan	(206,917)	-
Proceeds from bridge loan and converted interest, net of the cost of financing of \$83,770	-	926,035
Exercise of warrants	25,196	-
	-	1,864,914

Sale of Series A Preferred Stock, net of the cost of financing of \$335,086		
Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing of \$321,639	4,725,861	-
<b>Net cash provided by financing activities</b>	<b>4,587,865</b>	2,742,368
<b>NET INCREASE IN CASH</b>	<b>1,318,538</b>	282,864
Cash - beginning of the period	34,837	-
<b>CASH - end of the period</b>	<b>\$ 1,353,375</b>	<b>\$ 282,864</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	\$ 28,531	\$ 1,976
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Stock issued as payment for financing fees	\$ -	\$ 39,400
Warrants/Options issued as payment for consulting services/cancellations	2,291	108,564
Warrants issued for shareholder consent	-	144,643
Warrants issued as payment for financing fees	364,268	337,973
Bridge debt and converted interest into Common Stock	-	330,698
Bridge debt and converted interest into Series A Preferred Stock	-	679,107
Long term debt converted to Preferred Series A Preferred Stock	-	1,332,292
Preferred B issued as payment for financing fees	249,000	-
Preferred A and associated warrants exchanged for Preferred B and associated warrants	20,000	-
Accreted dividend to preferred stock	3,299,196	1,216,481
Preferred B stock issued as payment of Series B dividend	203,493	-
Stock issued as payment of Series A dividend	187,679	-

*See notes accompanying the financial statements.*

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

**NOTE 1—DESCRIPTION OF BUSINESS:**

Chembio Diagnostics, Inc. (“the Company”) was formerly known as Trading Solutions.com, Inc. On May 5, 2004, New Trading Solutions, Inc., a wholly owned subsidiary of the Company merged with and into Chembio Diagnostic Systems, Inc. (“CDS”) with CDS remaining as the surviving corporation (the “Merger”). The historical information presented for periods prior to the merger is based on the activities of CDS. The earnings per share presented in the statement of operations for periods prior to 2005 have been presented to reflect the shares outstanding as if the merger had taken place as of January 1, 2004.

On May 5, 2004, Chembio Diagnostics, Inc. issued 4,000,000 shares of its Common Stock to acquire all the outstanding Common Stock of CDS and assumed all outstanding options and warrants of CDS. For financial reporting purposes, the acquisition has been treated as a recapitalization of Chembio Diagnostics, Inc. with CDS, as the acquirer. CDS is a wholly owned subsidiary of the Company.

Trading Solutions.com, Inc. had no assets, liabilities or transactions (other than a 1:17 reverse split of its Common Stock) in the fiscal year preceding the merger. Prior to the merger, Trading Solutions.com, Inc.’s fiscal year ended September 30. After the merger, Chembio Diagnostics, Inc. adopted a fiscal year ending on December 31, the fiscal year-end of CDS.

CDS develops, manufactures, and markets rapid point of care medical diagnostic tests. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of CDS or the private labels of its distributors or their customers. The products aid in the diagnosis of infectious diseases and other conditions in humans and animals.

**SERIES B FINANCING:**

On January 28, 2005, the Company completed a private placement of 9% Series B Convertible Preferred Stock and associated warrants for \$5,047,500. The purchase price per unit (one share plus associated warrants) was \$50,000 and a total of 100.95 shares and warrants to purchase 7,860,846 shares of Common Stock were issued in the transaction. In addition one Series A Preferred stockholder exercised its right to exchange \$20,000 worth of Series A 8 % Preferred Stock and associated warrants for .40 shares of 9% Series B Preferred Stock and warrants to purchase 31,146 shares of Common Stock.

As part of the terms of the Series B purchase agreement, accrued but unpaid interest totaling \$332,950 related to certain long term debt is repayable commencing in January 2005 over 33 months at installments of \$10,000 per month and a final payment of \$2,950 in the 34th month.

Placement Agents were paid a commission in cash of 5% of the gross cash proceeds and received 5% of the gross cash proceeds in the form of 9 % Series B Preferred Stock and associated warrants. In addition, they received warrants to purchase 737,712 shares of Common Stock at an exercise price of \$0.80 per share. The warrants may not be exercised until the majority investor in the Series B financing has given notice of its intent to exercise its warrants.

**PLAN OF OPERATIONS:**

We anticipate that the funds from the Series B Offering will be sufficient to fund our needs at least through the fourth quarter of 2005, and we are considering alternatives to provide for our capital requirements for early 2006 and beyond. There are no assurances that we will be successful in raising sufficient capital.

F-6

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Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

***Basis of Presentation:***

In the opinion of management, the accompanying unaudited Consolidated Financial Statements include all adjustments (consisting of normal recurring accruals or adjustments only) necessary to present fairly the financial position at September 30, 2005, and the results of operations and the cash flows for all periods presented. The results of operations for the interim periods are not necessarily indicative of the results to be achieved in any future interim period or for the entire year.

For a summary of significant accounting policies (which have not changed from December 31, 2004) and additional financial information, see the Company's annual report on Form 10-KSB filed March 31, 2005.

The accompanying unaudited interim financial statements have been prepared in accordance with instructions to Form 10-QSB and, therefore, do not include all information and footnotes required to be in conformity with accounting principles generally accepted in the United States of America.

***Preferred Stock:***

Both the Series A and Series B Preferred Stock contained provisions whereby, under certain conditions outside of the control of management, the holders could have required redemption; accordingly, they were initially classified outside of permanent equity. At September 30, 2005, such conditions no longer exist; accordingly, the Series A and Series B Preferred have been reclassified to permanent equity at September 30, 2005.

***Inventory:***

Inventory consists of the following at:

	<b>September</b>	December
	<b>30, 2005</b>	31, 2004
<b>Raw</b>		
<b>Materials</b>	<b>\$ 288,174</b>	\$ 289,204
<b>Work in</b>		
<b>Process</b>	<b>87,708</b>	156,063
<b>Finished</b>		
<b>Goods</b>	<b>194,980</b>	93,380
	<b>\$ 570,862</b>	\$ 538,647

***Earnings Per Share:***

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

<b>For the three</b>		<b>For the nine months</b>	
<b>months ended</b>		<b>ended</b>	
<b>September</b>	September	<b>September</b>	September
<b>30, 2005</b>	30, 2004	<b>30, 2005</b>	30, 2004

**Basic** 8,137,727 6,417,908 7,500,167 5,754,835

**Diluted** 8,137,727 6,417,908 7,500,167 5,754,835

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 months ended September 30, 2005 and September 30, 2004 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:

F-7

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Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>September 30, 2005</b>	September 30, 2004	<b>September 30, 2005</b>	September 30, 2004
<b>Stock</b>	<b>1,401,125</b>	1,304,000	<b>1,401,125</b>	1,304,000
<b>Options</b>				
<b>Warrants</b>	<b>21,263,966</b>	11,569,803	<b>21,263,966</b>	11,569,803
<b>Preferred Stock</b>	<b>16,311,602</b>	7,578,985	<b>16,311,602</b>	7,578,985

***Employee Stock Option Plan:***

As part of the merger (see note 1), the Company adopted the 1999 Stock Option Plan (the "Plan") of CDS covering 1,500,000 shares of common stock. Under the terms of this plan, the compensation committee of the Company's board is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and key individuals. The options become exercisable at such times and under such conditions as determined by the compensation committee. The Plan was amended at the Company's annual stockholder meeting on June 17, 2005. The number of options under the Plan was increased to cover 3,000,000 shares of common stock. It was also amended to allow independent directors to be eligible for grants under the portion of the Plan concerning non-qualified options.

The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related Interpretations to account for the options issued to employees and or directors using the intrinsic value method. Had compensation cost for the options been determined using the fair value based method, as defined in Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), the Company's net (loss) and (loss) per share would have been adjusted to the pro forma amounts indicated below. The Company adopted Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123" requiring interim period disclosure for the years ending after December 15, 2002. The effect of the fair value method allowed under SFAS 123 is shown below.

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>September 30, 2005</b>	September 30, 2004	<b>September 30, 2005</b>	September 30, 2004
Net (loss) attributable to common stockholders, as reported	\$ (1,038,238)	\$ (1,636,715)	\$ (5,627,830)	\$ (3,570,602)
Add: Stock-based compensation included in reported net loss	-	-	-	969
Deduct: Total stock based compensation expense determined under the fair value based method for all awards (net of tax effect)	<b>(59,435)</b>	(14,221)	<b>(130,906)</b>	(467,540)

Pro forma net (loss) attributable to common stockholders	\$	<b>(1,097,673)</b>	\$	(1,650,936)	\$	<b>(5,758,736)</b>	\$	(4,037,173)
Net (loss) per share:								
Basic and diluted (loss) per share - as reported	\$	<b>(0.13)</b>	\$	(0.25)	\$	<b>(0.75)</b>	\$	(0.62)
Basic and diluted (loss) per share - pro forma	\$	<b>(0.13)</b>	\$	(0.26)	\$	<b>(0.77)</b>	\$	(0.70)

The fair value of each option grant was estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

- For the three and nine months ended September 30, 2005: expected volatility of 89.82%; risk-free interest rate of 3.84% to 4.18%; and expected lives of 3 to 5 years.
- For the three and nine months ended September 30, 2004: expected volatility of 82.6%; risk-free interest rate of 3.31%; and expected lives of 4 to 7 years.

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

The effects of applying SFAS 123 in the above pro forma disclosures are not indicative of future amounts since future amounts will be affected by the number of grants awarded and additional awards are generally expected to be made at varying prices.

In December 2004, the FASB issued a revision of SFAS No. 123 "Share-Based Payment" 123(R). The statement establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods and services. It also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. The statement does not change the accounting guidance for share-based payments with parties other than employees.

The statement requires a publicly-traded entity to measure the cost of employee service received in exchange for an award of equity instruments based on the grant-date fair value of the award (with limited exception). That cost will be recognized over the period during which an employee is required to provide service in exchange for the award (usually the vesting period). A publicly-traded entity will initially measure the cost of employee services received in exchange for an award based on its current fair value; the fair value of that award will be re-measured subsequently at each reporting date through the settlement date. Changes in fair value during the requisite service period will be recognized as changes in compensation over that period.

The grant-date fair value of employee share options and similar instruments will be estimated using option-pricing models adjusted for the unique characteristics of these instruments. The Company will be required to comply with this pronouncement beginning January 1, 2006.

The Company granted 436,500 options under the plan for the nine months ended September 30, 2005 at exercise prices ranging from \$0.57 per share to \$0.80 per share.

Stock incentive plan activity is summarized as follows:

	<b>Number of shares</b>	<b>Weighted Average Exercise Price</b>
Options outstanding at December 31, 2004	1,105,000	\$ 1.55
Granted	436,500	0.78
Canceled	(275,000)	1.86
Exercised	-	-
Options outstanding at September 30, 2005	1,266,500	\$ 1.22

**NOTE 3—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.

SFAS 131 further states that enterprises report “Information about Products and Service”. The Company produces only one group of similar products known collectively as “rapid medical tests”. We do not produce any further breakdown in our general-purpose statements and it would be impracticable for us to do so.

Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

The Company believes that it operates in a single business segment. Net sales by geographic area are as follows:

	<b>ended</b>		<b>For the nine months ended</b>	
	<b>September 30, 2005</b>	September 30, 2004	<b>September 30, 2005</b>	September 30, 2004
Africa	<b>\$ 95,550</b>	\$ 17,719	<b>\$ 313,261</b>	\$ 51,965
Asia	<b>37,640</b>	66,733	<b>113,729</b>	177,466
Australia	<b>520</b>	5,652	<b>13,598</b>	21,980
Europe	<b>20,460</b>	30,925	<b>75,303</b>	108,010
Middle East	<b>8,720</b>	1,982	<b>106,036</b>	64,753
North America	<b>138,452</b>	292,351	<b>374,132</b>	773,293
South America	<b>542,093</b>	25,009	<b>1,007,809</b>	483,824
	<b>\$ 843,435</b>	\$440,371	<b>\$2,003,868</b>	\$1,681,291

**NOTE 4—ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:**

The following tables detail the component parts of accounts payable and accrued liabilities:

	<b>as of</b>	
	<b>September 30, 2005</b>	December 31, 2004
Accounts Payable - Suppliers	<b>\$ 328,820</b>	\$ 453,839
Accrued Payroll and related liabilities	<b>88,289</b>	80,428
Accrued Commissions and Royalties	<b>317,648</b>	383,630
Accrued Legal and Accounting	<b>15,000</b>	81,005
Accrued Expenses - other	<b>134,925</b>	103,526
<b>TOTAL</b>	<b>\$ 884,682</b>	\$ 1,102,428

**NOTE 5—LONG-TERM DEBT AND WORKING CAPITAL LINE OF CREDIT:**

At December 31, 2004, the Company had a \$250,000 line of credit with a bank collateralized by a certificate of deposit in an equivalent amount with that bank.

As part of the requirements of the Series B Offering (see note 1), this line of credit was repaid and closed in February of 2005 and the collateral was released.

**NOTE 6—STOCKHOLDERS' EQUITY:**

**(a) Common Stock**

During the three month period ended September 30, 2005 there were no issuances of Common Stock. During the nine month period ended September 30, 2005 the Company issued 70,000 shares of its Common Stock to consultants as compensation. One consultant received 20,000 shares in the first quarter which were valued at \$0.75 per share and were expensed over the three month life of the contract. The other consultants received an aggregate of 50,000 shares in the second quarter which were valued at \$.55 per share and are being expensed over the lives of their respective contracts.

F-10

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Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

For the three and nine month periods ended September 30, 2005 Series A Preferred shareholders converted 0.60589 shares and 3.02476 shares into 30,294 shares and 151,237 shares of Common Stock, respectively.

For the three and nine month periods ended September 30, 2005 Series B Preferred shareholders converted 1.12228 shares and 8.20228 shares into 91,990 shares and 672,417 shares of Common Stock, respectively.

During the nine months ended September 30, 2005 warrants were exercised to purchase 35,000 shares of Common Stock at an exercise price of \$0.72 per share. The cash received was \$25,200.

On May 14, 2005 the Company issued 312,773 shares of its Common Stock as payment of dividends on its series A preferred stock.

(b) *Warrants*

In connection with the Series B offering, warrants to purchase 8,280,550 shares of Common Stock were issued. These warrants were assigned a value of \$2,349,893.

Warrants were issued in January 2005 to placement agents in connection with the Series B Preferred Stock financing to purchase a total of 737,712 shares of Common Stock at an exercise price of \$0.80. The fair values of these warrants are \$364,268. The effect of this transaction was netted in Additional Paid in Capital.

On March 18, 2005, the Company's Board of Directors approved the re-pricing of existing warrants to purchase 425,000 shares of Common Stock held by a former Director. The exercise price was changed from \$0.90 per share to \$0.75 per share. The Company is accounting for these warrants as variable from the date of the modification to the date the award is exercised, is forfeited, or expires unexercised. At September 30, 2005 the stock price was less than the exercise price; therefore there was no intrinsic value.

In May of 2005 warrants to purchase 100,000 shares of Common Stock were issued to a consultant as payment for services at exercise prices from \$1.20 to \$1.60 per share. The fair value (\$23,120) of these warrants was being amortized over the life of the contract. The contract has been terminated and these warrants were cancelled. The aforementioned \$23,120 was reversed in the third quarter of 2005.

In August 2005, the Company issued warrants to purchase 94,650 shares of Common Stock, with the right to purchase 63,018 shares at an exercise price of \$0.70 per share and the right to purchase 31,632 shares at an exercise price of \$0.66 per share to a distributor as payment for commissions of \$73,617 accrued at June 30, 2005. The value (\$51,963) of these warrants was calculated on a fair value basis.

(c) *Non-Plan Options*

On July 1, 2005 the Company issued options to purchase 10,000 shares of Common Stock to an advisory board member. These options were valued at \$3,840 and are being expensed over the vesting periods.

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

The Series A Preferred Stock was issued at a face value of \$30,000 per share and came with detachable warrants. The recorded amount of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants. Some key features include:

Dividends: Holders are entitled to an 8% per annum dividend payable semi-annually, in cash or, at the Company's option, in Common Stock.

F-11

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Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

Conversion: Series A preferred stock is convertible, at the option of the holders, into shares of Common Stock at a conversion price of \$0.60 per share. Based on its original purchase price of \$30,000 per share, each share of Series A Preferred Stock is convertible into 50,000 shares of Common Stock.

Redemption: The Series A Preferred Stock is not currently redeemable and there is no certainty 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 \$990.99 per share, an aggregate for all such shares of \$4,917,682). Accrued but unpaid dividends of \$157,252 are included in the preferred stock carrying value as at September 30, 2005.

As per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments" the Company evaluated the series A preferred stock transaction and found that there was an associated beneficial conversion feature totaling \$1,635,416; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 20% to be converted immediately and 100% after the earlier of ten months from the merger or 6 months after the registration statement registering the underlying common shares was effective. The total amount accreted back to the preferred and charged to dividends was \$261,666. Likewise, costs associated with the offering were charged to dividends over the same period. This amount totaled \$62,728 for the nine month period ended September 30, 2005.

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

The Series B Preferred Stock was issued at a face value of \$50,000 per share and came with detachable warrants. The recorded amount of the preferred shares was calculated using a fair value allocation between the preferred shares and detachable warrants. Some key features of the Series B Preferred Stock (see note 1) are as follows:

Dividends: The 9% Series B Preferred Stock accrues dividends at 9% per annum, payable semi-annually. Dividends are payable in either Series B Preferred Stock (plus associated warrants) or cash. The majority investor in the Series B financing has the option as it pertains to its dividend payment to choose cash or preferred shares. The Company has the option to choose cash or preferred shares as to the balance of the dividends.

Conversion: The Series B Preferred Stock is convertible, at the option of the holders, into shares of Common Stock at a conversion price of \$.61 per share. Based on the original purchase price of \$50,000 per share, each share of Series B Stock is convertible into 81,968 shares of Common 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 certainty 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 \$1,078.12 per share, an aggregate for all such shares of \$5,220,061). Accrued but unpaid dividends of \$110,181 are included in the preferred stock carrying value as at September 30, 2005.

On July 1, 2005, the Company issued 4.06988 shares of Series B Preferred Stock as payment of dividends on the Company's Series B Preferred Stock. No cash was exchanged in this issuance.

As per EITF 00-27 "Application of Issue 98-5 to Certain Convertible Instruments" the Company evaluated the series B preferred stock transactions and found that there was an associated beneficial conversion feature totaling \$2,437,035;

the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately.

F-12

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Table of Contents

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**  
**(UNAUDITED)**

**NOTE 7—COMMITMENTS AND CONTINGENCIES:**

***Economic Dependency:***

The Company had sales to one customer in excess of 10% of total sales in the three months ended September 30, 2005. Sales to this customer aggregated \$509,913.

The Company had sales to two customers in excess of 10% of total sales in the three months ended September 30, 2004. Sales to these customers were \$70,080 and \$64,881, respectively.

The Company had sales to one customer in excess of 10% of total sales in the nine months ended September 30, 2005. Sales to this customers aggregated \$862,413.

The Company had sales to two customers in excess of 10% of total sales in the nine months ended September 30, 2004. Sales to these customers were \$362,586 and \$237,877, respectively.

The Company had no purchases from any vendor in excess of 10% of total purchases for the three months or nine months ended September 30, 2005 and September 30, 2004.

***Litigation:***

The Company is involved in a patent litigation with Saliva Diagnostic Systems, Inc. (“Saliva”), the assignee of a patent related to a method for collecting samples. The Company has requested relief from the court that its Sure Check(R) HIV test does not infringe Saliva’s patent, that such patent is invalid, and that it is unenforceable due to inequitable procurement. Saliva has answered and counterclaimed, alleging that the Company has infringed the patent, which the Company has denied. In the years 2001 through 2003, the Company paid royalties to Saliva and took several other actions based upon Saliva’s representations regarding its alleged patent.

In response to the Company’s aforementioned request for relief the court has decided that it is not yet prepared to rule on the significant issues in the cases. The discovery phase of the litigation is proceeding pursuant to a scheduling order; trial is presently expected to convene in late 2006. The Company does not believe that the Court’s decision adversely affects the strength of its position. Accordingly, it is not presently appealing such decision, although it believes it has a meritorious basis for a future appeal.

Table of Contents

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

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 as set forth in Note 2 in the Notes to Consolidated Statements. The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, reported amounts of revenue and expenses during the reporting period, and disclosure of any contingent liabilities at the financial statement date. 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.

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," "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.

**OVERVIEW**

The Company, through its wholly owned subsidiary, Chembio Diagnostic Systems, Inc. ("CDS"), develops, manufactures, and markets rapid point of care medical diagnostic tests. These tests are sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments. The products are made under the label of CDS or the private labels of its distributors or their customers. The products aid in the diagnosis of infectious diseases and other conditions in humans and animals

**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 and income taxes. For a summary of our significant accounting policies (which have not changed from December 31, 2004), see our annual report on Form 10-KSB for the period ended December 31, 2004 filed March 31, 2005.

**RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2005 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2004**

Revenues are comprised of \$843,435 in net sales, and \$101,277 in grants and development income for the three months ended September 30, 2005 as compared with \$440,371 in net sales, and \$125,875 in grant and development income for the three months ended September 30, 2004. The increase in sales is attributable to increased sales of our HIV product of \$551,397, decreased sales of our pregnancy test kit of \$141,378, which is a product line that the Company is deemphasizing, and decreases in other product sales of \$6,955. The decrease in grant and development income of \$24,598 was due to grants and development income received in the third quarter of 2004 that did not recur in 2005. A substantial portion of the grant-related income in the third quarter of 2005 is expected not to recur beyond the third quarter of 2005.

Table of Contents

Cost of goods sold for the three months ended September 30, 2005 was \$669,817, or 79.4% of net sales, as compared to \$719,239, or 163.3% of net sales, for the three months ended September 30, 2004. The increase in gross margin percentage is primarily attributable to the increased sales for our HIV products, which were at a higher margin than our other product lines; in addition, the low sales volume in 2004 was not enough to cover fixed overhead expenses.

Research and development expenses for the three months ended September 30, 2005 were \$292,198, compared with \$446,486 for the three months ended September 30, 2004. Included in this category are expenses for Clinical & Regulatory Affairs which totaled \$72,340 for the three months ended September 30, 2005, a decrease of \$206,009 compared to the three months ended September 30, 2004. This category includes costs incurred for regulatory approvals, clinical studies, product evaluations and registrations. We had a decrease in our clinical trial costs, fees paid to outside sites which preformed the trials which were completed in 2004, of almost \$145,000, a decrease in regulatory consulting, also related to our clinical trials, of \$30,000 and a decrease in recruiting costs of \$36,000 which was paid in July 2004 in connection with the hiring of a VP of Regulatory Affairs. We expect costs in this category to continue at the third quarter 2005 levels in the fourth quarter of 2005. Increased salaries and wages-related costs of \$37,000 for new hires in the R&D group partially offset the decrease in R&D expenses.

The status of each of our major research and development projects is as follows:

<b>Project - New Generation Rapid Tests Based Upon Patent Pending Platform</b>	
Current status	We have done an extensive amount of preliminary laboratory work on prototypes of a our new patent pending lateral flow rapid test platform with a new generation rapid HIV test using our current reagents as the initial application. This preliminary work has confirmed the advantages of this new platform in terms of sensitivity to weak and early sero-conversion samples. We also believe that this platform may provide us the level of sensitivity that we will need in order to complete development of our human TB rapid test with which we could not achieve sufficient sensitivity based upon the existing platform. Based upon additional work planned on this project over the balance of this year and input from our marketing department, we will determine which of these or other applications to focus on for this new platform.
Nature, timing and estimated costs of the efforts necessary to complete	Will depend on decisions regarding applications and other features to be incorporated into this platform, and as such cannot be anticipated at this time
Anticipated completion date	It is not known at this time whether or how long it will take to develop the product or obtain regulatory approvals in the US, Europe, Japan and other potential markets.
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The requirements for clinical testing and the outcomes of such clinical testing can not be known at this time, and this information poses substantial risk and uncertainty as to whether or when this product will contribute to the operations, financial position and liquidity.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and without further progress on a distribution

strategy.

<b>Project - Rapid Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples</b>	
Current status	Product validation completed.
Nature, timing and estimated costs of the efforts necessary to complete	An amended outline of Chembio's production protocols, as requested, was submitted in early September to the USDA. These production protocols were reviewed and Chembio is proceeding with preparing to submit to the USDA its clinical study protocol. Three sites need to be selected and confirmed, the clinical study protocol reviewed by the USDA and three serial lots of product produced to be used in the clinical trials; all must be completed prior to our commencing the clinical trial data collection phase of the project. A USDA facility inspection needs to be scheduled in parallel with the agency's review of the final clinical study data results before full commercialization of the product can commence. A marketing plan for the product is scheduled to be completed in Q4'05. Both US & PCT patent applications have been filed together with Sequella as of August 2005.
Anticipated completion date	We anticipate conditional approval by Q3'06 and full commercial market clearance in Q1'07.
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The requirements to initiate clinical testing and the outcomes of such clinical testing are not yet fully known. Recent changes in the USDA reviewer may require additional time for him to come up to speed with the current status of the project. The facility inspection and its outcome is not yet fully known as it is yet to be scheduled which may adversely affect commercial release of the product. Substantial risk and uncertainty remain as to when this product will contribute to the operations, financial position, and liquidity.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and without further progress on a distribution strategy.

Table of Contents

<b>Project - Rapid Test for the detection of antibodies to active pulmonary tuberculosis in multiple host species</b>	
Current status	<p>Chembio has developed a rapid lateral-flow test for TB in multiple host species including cattle, deer, badgers, and potentially other animals. This is an antibody detection assay that employs a cocktail of carefully selected recombinant antigens of <i>Mycobacterium bovis</i> and <i>Mycobacterium tuberculosis</i>. The test can use serum, plasma, or whole blood samples and provides results within 20 minutes. Also, as was recently shown at Chembio, the test can use “meat juice” (diaphragm extract) as a sample for antibody detection in cattle and white-tailed deer. This may be important for introducing rapid TB testing for cattle in slaughterhouses as well as surveillance studies in captive and free-ranging cervids.</p> <p>VET TB STAT-Pak has been recently validated at Chembio. Three lots of 3,000 to 10,000 units have been produced and passed the established QC performance specifications using a panel of TB positive and negative sera from badgers, cattle and white-tailed deer. The use of whole blood samples from cattle and deer is being currently evaluated in comparison with serum and plasma samples in collaboration with USDA. The use of VET TB STAT-Pak for other host species, such as elephants, reindeer, and elk, is in progress and shows very promising results. This feature makes the test particularly attractive for testing wildlife and zoo animals.</p>
Nature, timing and estimated costs of the efforts necessary to complete	<p>A US patent application for the VET TB STAT-Pak was filed in August 2005. Several publications related to bovine, cervids (deer), badger, and elephant on the performance of the assay as compared to more traditional and generally less sensitive and specific test procedures are due to be submitted to peer review journals by Q1’06. In Q4’05, presentations at the USAHA (United States Animal Health Association) annual meeting by Chembio R&amp;D personnel are scheduled on the overall performance of the assay for earlier detection of TB in cattle, badgers, deer and elephants. A positive recommendation from this influential organization to the USDA for approval of the product is expected to assist in expediting the product’s approval cycle within the USDA.</p>
Anticipated completion date	<p>Anticipate conditional approval by Q3’06 with full commercial clearance by Q1’07.</p>
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position	<p>The requirements for clinical study protocol (i.e., by species) and the outcomes of such clinical testing are not fully known at this time. This information poses substantial</p>



and liquidity if not completed timely	risk and uncertainty as to when the product will begin contributing to the operations, financial position, and liquidity.
Timing of commencement of expected material net cash inflows.	It is not known or estimable when net cash inflows from this project will commence due to the uncertainties associated with the completion of the product, regulatory submissions, and without further progress on a distribution strategy.

<b>Project - Rapid Test for Mad Cow Disease</b>	
Anticipated completion date	This project has been suspended indefinitely

<b>Project - Dental Bacteria Test</b>	
Anticipated completion date	This project has been suspended indefinitely

Table of Contents

We believe we have made substantial progress toward our FDA approval of our Sure Check(R) HIV and HIV 1/2 Stat-Pak (TM) products. A pre-approval inspection of our facility was conducted in the third quarter of 2005 and based upon communications we have had with the agency during this latest quarter, we believe we will complete remaining documentation requested by the FDA in order to have an “approvable” Pre-Marketing Approval (PMA) application for two of our HIV products during the first quarter of 2006 and we expect to complete the full process during the first half of 2006. We have amended our PMA application to include an HIV-2 claim, as we believe this will further differentiate and enhance our product offering, and we are pursuing acquisition of intellectual property rights associated with incorporating an HIV-2 product claim

Selling, general and administrative expense increased \$373,400 to \$822,010 in the three months ended September 30, 2005 compared with the same period in 2004. This increase was primarily attributable to increased staff in the accounting, administration and sales and marketing departments of \$93,000 and related recruiting expenses of \$80,000. Increased sales resulted in an increase in commissions and royalty expenses of \$160,000. In addition, there was an increase in investor relations expenses of \$42,000, consulting costs associated with 404 compliance (Sarbanes-Oxley) of \$13,000 and a decrease in legal fees of \$25,000.

**RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2004**

Revenues are comprised of \$2,003,868 in net sales, \$250,000 in license revenue and \$328,419 in grants and development income for the nine months ended September 30, 2005 as compared with \$1,681,291 in net sales, no license revenue and \$465,332 in grant and development income for the nine months ended September 30, 2004. The increase in sales is attributable to increased sales of our HIV product of \$680,476 which was offset by decreased sales of our pregnancy test kit of \$355,194 and decreases in other product sales aggregating \$2,705. The increase in license revenue was \$250,000 and is primarily due to a technology transfer agreement. The Company does not expect that this revenue will continue in the future. The decrease in grant and development income was \$136,913 and was due to grants received in the nine months ended September 30, 2004 that weren't awarded or earned in 2005. A substantial portion of the grant-related income is not expected to continue into the fourth quarter of 2005.

Cost of goods sold for the nine months ended September 30, 2005 was \$1,770,747, or 88.4% of net sales, as compared to \$1,858,402, or 110.5% of net sales, for the nine months ended September 30, 2004. The increase in gross margin percentage is primarily attributable to the increased sales of our HIV products, which were at a higher margin than our other product lines; in addition the low sales volume in 2004 was not enough to cover fixed overhead expenses.

Research and development expenses for the nine months ended September 30, 2005 were \$1,053,731 compared with \$962,286 for the nine months ended September 30, 2004. Expenses for Clinical & Regulatory Affairs, totaled \$381,484 for the nine months ended September 30, 2005, a decrease of \$126,501 over the nine months ended September 30, 2004. This category includes costs incurred for regulatory approvals, product evaluations and registrations, clinical studies which decreased \$138,000, a reduction in outside regulatory consultants of \$51,000 and a reduction in regulatory recruitment of \$25,000 partially offset by an increase of \$86,000 due to the hiring in July 2004 of a Vice-President of Regulatory Affairs. These costs are expected to continue at the third quarter level in the 4th quarter of 2005. Increased salaries and wage-related costs of \$113,000 for new hires in the R&D group, increased travel and entertainment of \$46,000 and grant payments to a university of \$45,000 also contributed to the increases in R&D expenses.

Selling, general and administrative expense increased \$531,266 to \$2,109,030 in the nine months ended September 30, 2005 compared with the same period in 2004. This increase was attributable to increased staff in the accounting, administration and sales and marketing departments of \$164,000 and related recruiting expenses of \$84,000. Increased sales resulted in an increase in royalties and commissions of \$190,000. In addition there was an increase in costs

related to investor relations of \$120,000, \$39,000 resulting from an increase in the number of members of our board of directors, increased insurance liability coverage for directors and officers of \$20,000, costs related to 404 compliance of \$30,000 and increased legal and accounting expenses of \$74,000 relating to patent applications, patent litigation, the filing of a registration statement and other required year-end and quarterly filings. These increases were partially offset by a reduction in officer's salaries of \$240,000, mostly due to the inclusion in the 2004 period of the cost of common stock issued to a former officers' at the time of the merger.

Interest income increased in both the three and nine months ended September 30, 2005. This was due to funds received in the Series B Offering which were invested in certificates of deposit. Interest expense decreased in both the three and nine months ended September 30, 2005 as existing debt was converted into Series A Preferred Stock in May and December of 2004.

**LIQUIDITY AND CAPITAL RESOURCES**

We had a working capital surplus of \$1,543,743 at September 30, 2005 and a working capital deficiency of \$452,136 at December 31, 2004. On January 28, 2005, we completed a private placement offering which raised \$5,047,500 before costs in the form of 9% Convertible Series B Preferred Stock and associated warrants (“Series B Offering”). The proceeds from the Series B Offering are being used primarily for general corporate purposes including for sales and marketing, research and development, and intellectual property, and also for working capital, investor relations, and capital expenditures.

The following table lists the future payments required on our debt and any other contractual obligations as of September 30, 2005:

<b>OBLIGATIONS</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>Greater than 5 Years</b>
Long Term Debt					
(1)	\$ 243,160	\$ 120,000	\$ 123,160	\$ -	\$ -
Capital Leases					
(2)	\$ 96,894	\$ 42,487	\$ 54,407	-	-
Operating Leases	\$ 149,450	\$ 99,225	\$ 50,225	-	-
Other Long Term					
Obligations (3)	\$ 752,467	\$ 427,792	\$ 193,425	\$ 25,000	\$ 106,250
<b>Total Obligations</b>	<b>\$ 1,241,971</b>	<b>\$ 689,504</b>	<b>\$ 421,217</b>	<b>\$ 25,000</b>	<b>\$ 106,250</b>

(1) This represents accrued interest which is currently being paid out at the rate of \$10,000 per month.

(2) This represents capital leases used to purchase capital equipment.

(3) This represents contractual obligations for licenses and employment contracts.

We anticipate that the funds remaining from the Series B Offering will be enough to satisfy our needs at least through the fourth quarter of 2005. Our 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) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies.

The Company is considering alternatives to provide for its capital requirements for early 2006 and beyond in order to continue as a going concern. There are no assurances that it will be successful in raising sufficient capital.

**CHEMBIO’S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS**

During the third quarter of 2005, we established an office in Nigeria which we believe will be significant in our continuing efforts to become part of the national testing algorithms in many countries in Africa. We are designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda. We have registered our products and have established distribution partners in certain of these countries and are in negotiations to do so in other countries. We believe that our strategy of establishing full time company-owned sales offices in our markets of focus is the most effective way to establish sustainable and supportable business in these challenging markets. We are also actively looking at several opportunities for establishing marketing, distribution and local assembly programs for our rapid HIV tests with partners in South America (in addition to our contract in Brazil), Southeast Asia, and China. However we have no commitments or other assurance that they will materialize into meaningful programs.

Our technology transfer and supply agreement in Brazil is moving forward. We shipped 220,000 tests in the third quarter, and received an order for 210,000 tests to be delivered in the fourth quarter of 2005. We expect to receive an order to deliver 120,000 additional tests during the fourth quarter. This would result in a total of 700,000 test units shipped in 2005 up from 450,000 units last year. We expect that this program will continue to increase in 2006, although there is no assurance that it will.

5

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Table of Contents

We also believe that our Chagas Disease rapid test will begin to produce meaningful revenue early in 2006.

We recently hired a senior diagnostics marketing executive to substantially enhance our marketing ability for our Tuberculosis products, particularly for use in veterinary TB applications. Our Non-human primate Tuberculosis product is currently under review by the USDA; we are considering submitting additional complementary products to the USDA. We anticipate marketing these products in 2006 subject, as to certain products to USDA approval.

During the second quarter of 2005 we filed a patent application for a new lateral flow device and method which we believe will provide us with proprietary intellectual property to develop a pipeline of products that we believe will have improved performance over currently available lateral flow technologies. We are continuing to refine this device and we believe it will be the basis for new product developments that can address significant needs for screening of tuberculosis and other infectious diseases that occur in markets that we are already serving with our HIV rapid tests.

We anticipate that the funds remaining from the Series B Offering will be enough to satisfy our needs at least through the fourth quarter of 2005. The Company is considering alternatives to provide for its capital requirements for early 2006 and beyond in order to continue as a going concern. There are no assurances that it will be successful in raising sufficient capital.

Table of Contents

**ITEM 3. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

As of the end of the period covered by this report, we have evaluated, under the supervision and with the participation of management, including our chief executive officer and the chief financial officer, the effectiveness of the design and operation of our “disclosure controls and procedures” (as defined in Security Exchange Act of 1934, Rules 13a - 15(e) and 15d - 15(e)). Based on this evaluation, our management, including our chief executive officer and chief financial officer, have concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective to ensure that all material information required to be filed in this report has been made known to them.

*Changes In Internal Controls Over Financial Reporting*

There have been no changes in internal controls over financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**PART II.**

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

On July 1, 2005, the Company granted its new non-employee advisory board member, James Koziar, options to purchase 10,000 shares of the Company’s common stock at an exercise price of \$0.61, as a part of his compensation for his service on the Company’s Advisory Board. One-half of the options granted vest immediately, and one-half of the options vest one year after the date of grant. Each of these options expires on July 1, 2010. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

On July 1, 2005, the Company issued 4.06988 shares of series B preferred stock as payment of dividends on the Company’s series B preferred stock. No cash was exchanged in this issuance. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The investors in the issuance were accredited investors of the Company

On August 3, 2005, the Company issued to Bio-Business Science & Development LTDA, in payment of a liability for commissions, warrants to purchase an aggregate of 94,650 shares of the Company’s common stock, with warrants to purchase 63,018 shares having an exercise price of \$0.70 per share and warrants to purchase 31,632 shares having an exercise price of \$0.66 per share. These warrants are exercisable immediately and expire on August 3, 2010. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance. The sole investor in the issuance was an accredited investor.

On August 29, 2005, in accordance with the terms of the Company’s 1999 Equity Incentive Plan, the Company granted to an employee options to purchase 20,000 shares of the Company’s common stock. The exercise price for each of these options is \$.63 per share. Unexercised options will expire upon the earlier to occur of (a) 30 days after termination of the employee’s employment with the Company or (b) the fifth anniversary of the date of grant. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

On September 19, 2005, in accordance with the terms of the Company's 1999 Equity Incentive Plan, the Company granted to an employee options to purchase 20,000 shares of the Company's common stock. The exercise price for each of these options is equal to \$.57 per share. Unexercised options will expire upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the date of grant. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.



Table of Contents

**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)

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.**

**(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 registration statement on Form 10-KSB filed with the Commission on March 31, 2005.**

Table of Contents

**SIGNATURES**

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

Chembio Diagnostics, Inc.

Date: November 14, 2005 By: /s/ Lawrence A. Siebert  
Lawrence A. Siebert  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 14, 2005 By: /s/ Richard J. Larkin  
Richard J. Larkin  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

