

Chembio Diagnostics Inc.  
Form 10QSB  
November 15, 2004

**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, 2004.**

**000-30379**

*(Commission File Number)*

**Chembio Diagnostics, Inc.**

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

**Nevada**

*(State or other jurisdiction of  
incorporation)*

**88-0425691**

*(IRS Employer Identification Number)*

**3661 Horseblock Road**

**Medford, New York 11763**

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

**(631) 924-1135**

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

**Trading Solutions.com, Inc.**

*(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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of November 4, 2004, the Registrant had 6,417,908 shares outstanding of its \$.01 par value common stock.

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

**September 30, 2004**

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

	September 30, 2004 (Unaudited)	Dec. 31, 2003
<b>CURRENT ASSETS:</b>		
Cash	\$ 282,864	\$ -
Restricted Cash	250,000	-
Accounts receivable, net of allowance for doubtful accounts of \$18,034 and \$15,231 for September 30, 2004 and December 31, 2003, respectively	168,542	282,734
Inventories	688,325	466,498
Prepaid expenses and other current assets	140,229	23,448
<b>TOTAL CURRENT ASSETS</b>	<b>1,529,960</b>	<b>772,680</b>
<b>FIXED ASSETS, net of accumulated depreciation of \$698,791 and \$600,195 for September 30, 2004 and December 31, 2003, respectively</b>		
	<b>217,737</b>	<b>249,247</b>
<b>OTHER ASSETS:</b>		
Deposits	31,147	55,723
Other assets	-	9,095
	<b>\$ 1,778,844</b>	<b>\$ 1,086,745</b>

**- LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIENCY) -**

<b>CURRENT LIABILITIES:</b>		
Bank overdraft	\$ -	\$ 67,434
Accounts payable and accrued liabilities	880,897	1,361,547
Working capital loan	50,000	-
Current portion of obligations under capital leases	49,650	61,789
Accrued contingency	53,400	-
Other current liabilities	-	12,648
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,033,947</b>	<b>1,503,418</b>
<b>OTHER LIABILITIES:</b>		
Notes payable - net of current portion	361,559	1,693,851
Obligations under capital leases - net of current portion	88,877	107,885
Accrued interest	322,476	239,032
<b>TOTAL LIABILITIES</b>	<b>1,806,859</b>	<b>3,544,186</b>

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

Convertible - \$.01 par value; 10,000,000  
shares authorized: 151,57984 and 0 shares  
issued and outstanding as of September 30,  
2004 and December 31, 2003, respectively.  
Liquidation preference-see notes

<b>2,591,298</b>	-
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**STOCKHOLDERS EQUITY  
(DEFICIENCY)**

Common stock - \$.01 par value; 50,000,000  
shares authorized: 6,417,908 and 4,902,608  
shares issued and outstanding as of September  
30, 2004 and December 31, 2003, respectively

<b>64,179</b>	49,026
<b>2,311,871</b>	-
<b>4,416,201</b>	4,550,975
<b>(9,411,564)</b>	(7,057,442)
<b>(2,619,313)</b>	(2,457,441)
<b>\$ 1,778,844</b>	<b>\$ 1,086,745</b>

*See notes accompanying the financial statements.*

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

	Three months ended		Nine months ended	
	Sept. 30, 2004	Sept. 30, 2003	Sept. 30, 2004	Sept. 30, 2003
<b>REVENUES:</b>				
Net sales	\$ 440,371	\$ 566,559	\$ 1,681,291	\$ 2,007,087
Research grants and development income	125,875	12,000	465,332	110,170
<b>TOTAL REVENUES</b>	<b>566,246</b>	<b>578,559</b>	<b>2,146,623</b>	<b>2,117,257</b>
Cost of sales	674,402	519,817	1,765,412	1,670,375
<b>GROSS PROFIT (LOSS)</b>	<b>(108,156)</b>	<b>58,742</b>	<b>381,211</b>	<b>446,882</b>
<b>OVERHEAD COSTS:</b>				
Research and development expenses	396,836	80,140	896,282	241,700
Selling, general and administrative expenses	543,097	277,164	1,736,758	852,104
	<b>939,933</b>	<b>357,304</b>	<b>2,633,040</b>	<b>1,093,804</b>
<b>(LOSS) FROM OPERATIONS</b>	<b>(1,048,089)</b>	<b>(298,562)</b>	<b>(2,251,829)</b>	<b>(646,922)</b>
<b>OTHER INCOME (EXPENSES):</b>				
Forgiveness of Debt	-	-	209,372	-
Interest income	3,479	2	6,176	2
Interest (expense)	(13,819)	(52,139)	(169,337)	(150,965)
<b>(LOSS) BEFORE INCOME TAXES</b>	<b>(1,058,429)</b>	<b>(350,699)</b>	<b>(2,205,618)</b>	<b>(797,885)</b>
Income taxes	-	-	-	-
<b>NET LOSS BEFORE DIVIDENDS</b>	<b>\$ (1,058,429)</b>	<b>\$ (350,699)</b>	<b>\$ (2,205,618)</b>	<b>\$ (797,885)</b>
Preferred Dividend	91,694	-	148,504	-
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (1,150,123)</b>	<b>\$ (350,699)</b>	<b>\$ (2,354,122)</b>	<b>\$ (797,885)</b>
<b>Basic and diluted (loss) per share</b>	<b>\$ (0.18)</b>	<b>\$ (0.07)</b>	<b>\$ (0.41)</b>	<b>\$ (0.16)</b>
<i>Weighted number of shares outstanding, basic and diluted</i>	<b>6,417,908</b>	<b>4,915,883</b>	<b>5,754,835</b>	<b>4,924,674</b>

*See notes accompanying the financial statements.*

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003**  
**(UNAUDITED)**

	2004	2003
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,205,618)	\$ (797,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	98,596	75,005
Provision for doubtful accounts	(6,383)	10,245
Increase in accrued interest not paid	83,444	130,460
Stock issued as compensation	304,229	-
Stock issued as payment for fees	37,391	-
Options issued as compensation	969	-
Options amortized as payment - consultants	43,669	-
Warrants issued as interest for debt	60,650	-
Changes in:		
Accounts receivable	120,575	(82,272)
Restricted Cash	(250,000)	-
Inventories	(221,827)	68,195
Prepaid expenses and other current assets	(51,886)	(7,793)
Other assets and deposits	33,671	(2,935)
Accounts payable and accrued expenses	(480,650)	162,126
Accrued contingency	53,400	-
Grant and other current liabilities	(12,648)	648
<b>Net cash used in operating activities</b>	<b>(2,392,418)</b>	<b>(444,206)</b>
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Acquisition of fixed assets	(67,086)	-
<b>Net cash used in investing activities</b>	<b>(67,086)</b>	<b>-</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Changes in bank overdraft	(67,434)	54,359
Change of capital lease obligation	(31,147)	26,012
Proceeds from Shareholder Loans	-	335,664
Proceeds from Working Capital loan	50,000	-
Proceeds from Bridge loan and converted interest, net the cost of financing of \$83,770.	926,035	-
Sale of Series A Preferred Stock, net the cost of financing of \$335,086.	1,864,914	-
<b>Net cash provided by financing activities</b>	<b>2,742,368</b>	<b>416,035</b>
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>282,864</b>	<b>(28,171)</b>
Cash - beginning of the period	-	28,171

<b>CASH - end of the period</b>	<b>\$</b>	<b>282,864</b>	<b>\$</b>	<b>-</b>
<b>Supplemental disclosure of cash flow information:</b>				
Cash paid during the period for interest	\$	1,976	\$	-
<b>Supplemental disclosures for non-cash investing and financing activities:</b>				
Fixed assets acquired under capital leases	\$	-	\$	31,071
Stock issued as payment for financing fees		39,400		-
Options issued as payment for consulting services		108,564		-
Options issued as payment for financing fees		337,973		-
Warrants issued as interest for existing debt		60,650		-
Warrants issued for Chembio Diagnostics Systems, Inc. shareholder consent		144,643		-
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		-

*See notes accompanying the financial statements.*

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**UNAUDITED**

**NOTE 1- DESCRIPTION OF BUSINESS:**

Chembio Diagnostics, Inc. ( the Company ) was formerly known as Trading Solutions.com, Inc. (see Merger and Other Related Transactions below). The historical information presented for 2003 is based on the wholly owned subsidiary of the Company, Chembio Diagnostic Systems, Inc. prior to the merger, as discussed below. The equity sections of the balance sheets for 2003 have been restated to reflect the shares outstanding as if the merger had taken place as of the first date of 2003, the earliest period presented.

Chembio Diagnostics, Inc (formerly Trading Solutions.com) issued 4,000,000 shares to acquire all the outstanding common stock of Chembio Diagnostic Systems, Inc. as well as assuming all outstanding options and warrants on May 5<sup>th</sup> 2004. For accounting purposes the acquisition has been treated as a recapitalization of Chembio Diagnostics, Inc with Chembio Diagnostic Systems, Inc as the acquirer (reverse acquisition).

Trading Solutions.com, Inc. had no assets, liabilities or transactions (other than the 1:17 reverse split) for the current year periods prior to the reverse merger. Trading Solutions.com, Inc. had a fiscal year ending September 30. After the merger Chembio Diagnostics, Inc. (formerly Trading Solutions.com) fiscal year was changed to December 31, which was the year end of Chembio Diagnostic Systems, Inc.

Chembio Diagnostic Systems, Inc., which was originally incorporated in New York on December 15, 1985 and re-incorporated in Delaware on November 5, 1991, develops, manufactures, and markets rapid point of care medical diagnostic tests. These tests are ultimately sold in the U.S. and/or internationally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and/or retail establishments. Sales are primarily through distributors and are made under Chembio Diagnostic Systems, Inc. s and/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.

On April 8, 2004 we approved: a) An amendment to our articles of incorporation to increase the authorized number of shares of common stock from 20,000,000 to 50,000,000; b) Authorization of 10,000,000 shares of undesignated preferred stock, par value \$0.01 per share; and c) Change of our name to Chembio Diagnostics, Inc.

**MERGER AND OTHER RELATED TRANSACTIONS:**

On May 5, 2004, pursuant to the Agreement and Plan of Merger (the Merger Agreement ), dated as of March 3, 2004, as amended on May 3, 2004 by and among privately-held Chembio Diagnostic Systems Inc. ( Chembio Diagnostic Systems ), a Delaware corporation, Chembio Diagnostics, Inc. (formerly, Trading Solutions.com, Inc.), a publicly traded Nevada corporation ( the Company ) and New Trading Solutions, Inc., a wholly owned subsidiary of the Company ( Merger Sub ), the Merger Sub merged with and into Chembio Diagnostic Systems, with Chembio Diagnostic Systems remaining as the surviving corporation (the Merger ). Pursuant to the Merger, the Company issued 4,000,000 shares of its restricted common stock, 704,000 options and warrants to purchase 690,000 shares of its common stock to the stockholders of Chembio Diagnostic Systems in exchange for 100% of their common stock in Chembio Diagnostic Systems and 100% of their options and warrants to purchase Chembio Diagnostic Systems common stock. The Company relied on Regulation D promulgated under Section 4(2) of the Act and on Section 4(2) of the Act as the basis for its exemption from registration of this offering. 44 accredited and only 3 non-accredited investors received securities of the Company in the Merger. All of the stockholders of Chembio Diagnostic Systems, including the non-accredited investors, were provided with an information statement meeting the informational requirements of Rule 502 (b)(2) of the Securities Act.

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**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONSOLIDATED STATEMENTS  
UNAUDITED**

At or about the time of the Merger, the Company consummated three private placements of its 8% Series A Convertible Preferred Stock as follows: (i) shares of series A preferred and warrants were sold for cash (the Cash Offering ); (ii) shares of series A preferred and warrants were exchanged, as described herein, for conversion of the Bridge Notes described below (the Bridge Conversion Offering ), and (iii) shares of series A Preferred and warrants were exchanged, as described herein, for conversion of the Existing Debt (as defined below) of Chembio Diagnostic Systems (the Existing Debt Exchange Offering ). These placements are described below:

- a) The Cash Offering. A total of 73,333,330 shares of series A preferred stock and warrants to acquire 4,400,000 shares of common stock at \$.90 per share were issued pursuant to the Cash Offering in May 2005 for total consideration of \$2,200,000.
- b) The Bridge Conversion Offering. On March 22, 2004, Chembio Diagnostic Systems completed a private placement (the Bridge Financing ) of \$1,000,000 in face amount of Convertible Notes (the Bridge Notes ). The Bridge Financing provided for the Bridge Note holders to elect whether to convert the Bridge Notes into shares of the Company s series A preferred stock (together with warrants to acquire shares of the Company s common stock) or into shares of the Company s common stock at the effective time of the Merger. As a result, \$672,000 in principal amount of the Bridge Notes, together with accrued and unpaid interest, was converted into 33,836,82 shares of the Company s series A preferred stock (together with warrants to acquire an additional 2,030,217 shares of the Company s common stock at \$.90 per share). The balance of the Bridge Financing, or \$328,000, was converted into 826,741 shares of the Company s common stock.
- c) The Existing Debt Exchange Offering. Per the merger agreement a minimum of \$1,300,000 of existing debt of Chembio diagnostic Systems, Inc. was required to be converted to series A preferred stock, any balances not converted will, if not paid by December 31, 2004, automatically be converted to series A preferred stock as of December 31, 2004. Pursuant to the Existing Debt Exchange Offering, which was consummated at the effective time of the Merger, the Company issued 44,409,72 shares of series A preferred stock and warrants to acquire 2,664,584 shares of common stock at \$.90 per share in exchange for the conversion of \$1,332,292 of Chembio Diagnostic Systems debt existing on its balance sheet as of December 31, 2003.

On May 5, 2004 the Company issued warrants to designees of H.C. Wainright & Co., Inc. and Wellfleet Partners, Inc., our placement agents in the series A preferred stock private placement, to purchase 751,667 shares and 183,333 shares of our common stock at exercise prices of \$0.72 and \$1.08. In addition, designees of Wellfleet Partners received 59,000 shares of common stock and an individual finder received 6,667 shares of common stock.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY  
NOTES TO CONSOLIDATED STATEMENTS  
UNAUDITED**

**OPERATIONS:**

We anticipate that we will have additional capital requirements in the near future. The amount of additional capital we may need to raise will depend on a number of factors. These factors primarily include (1) receipt of orders from Bio-Manguinhos in 2004 and 2005 in accordance with contractual commitments; (2) whether we can generally achieve revenue growth and 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 availability and cost of raising additional capital and potential dilution to shareholders.

Our cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of new products, and effective management of inventory levels in response to sales forecasts. We expect to devote capital resources to continue our product development, expand manufacturing capacity and continue research and development activities. We will examine other growth opportunities, including strategic alliances, and we expect any such activities will be funded from existing cash and cash equivalents, as well as issuance of additional equity or additional borrowings, subject to market and other conditions. We believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations through the end of 2004. We therefore expect that we will be required to sell additional equity or obtain additional credit facilities in the near term. We further expect that cash generated from operations will not be sufficient to satisfy our working capital and capital expenditure requirements over the next twelve months, so we expect that we will be required to sell additional equity or obtain additional credit facilities during that period. We cannot be certain that this financing will be available or that we will be able to complete financing on satisfactory terms, if at all.

Beyond twelve months out, it is likely that we will have additional financing requirements to finance our expected growth and/or to fund continuing operating deficits. The amount of additional capital we may need to raise will depend on a number of factors. These factors primarily include the extent to which we can achieve revenue growth, the profitability of such revenues, operating expenses, research and development expenses, and capital expenditures. Given the number of product development programs that we have ongoing and not complete, and the dependence we have on factors outside of our control such as government and other donor funding for HIV rapid tests, as well as the success of our marketing partners such as Prionics and Ivoclar-Vivadent, it is not possible to predict the extent or cost of these expected additional financing requirements.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company's significant operating losses and significant capital requirements, however, raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We are currently attempting to raise \$1.5 million to \$2.5 million of equity and/or debt financing. Although at least one party has indicated a preliminary interest, there are no commitments at this time.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**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, 2004, 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 obtained in any future interim period or for the entire year.

For a summary of significant accounting policies (which have not changed from December 31, 2003) and additional financial information, see the Company's registration statement on Amendment No. 3 to Form SB-2 filed October 26, 2004, including the consolidated financial statements and notes thereto, for the year ended December 31, 2003 which should be read in conjunction with these financial statements.

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.

***Inventory:***

Inventory consists of the following at:

	<b>September 30, 2004</b>	<b>December 31, 2003</b>
<b>Raw Materials</b>	\$ 489,590	\$ 379,079
<b>Work in Process</b>	48,322	73,319
<b>Finished Goods</b>	150,413	14,100
	\$ 688,325	\$ 466,498

**Reclassifications**

Certain reclassifications have been made to the December 31, 2003 balance sheet to conform to the 2004 presentation.

***Earnings Per Share***

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

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>Sept. 30, 2004</b>	<b>Sept. 30, 2003</b>	<b>Sept. 30, 2004</b>	<b>Sept. 30, 2003</b>
<b>Basic</b>	6,417,908	4,915,883	5,754,835	4,924,674
<b>Diluted</b>	6,417,908	4,915,883	5,754,835	4,924,674



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**UNAUDITED**

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 months and nine months ended 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:

	<b>Three Months Ended Sept. 30,</b>		<b>Nine Months ended Sept. 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Stock Options	1,304,000	365,000	1,304,000	365,000
Warrants	11,569,803	140,000	11,569,803	140,000
Preferred Stock	7,578,985	-	7,578,985	-

**EMPLOYEE STOCK OPTION PLAN:**

As part of the merger, the Company adopted the 1999 Stock Option Plan (the Plan) of Chembio Diagnostic Systems, Inc. Under the terms of this plan, the Company's option committee is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and key individuals. The option committee has been authorized to grant options to purchase up to 1,500,000 shares of common stock. The options become exercisable at such times and under such conditions as determined by the option committee.

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 earnings and earnings 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. The effect of the fair value method allowed under SFAS 123 is shown below.

**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**UNAUDITED**

	Three months ended		Nine months ended	
	Sept. 30, 2004	Sept. 30, 2003	Sept. 30, 2004	Sept. 30, 2003
Net (loss) available to common stockholders, as reported	\$ (1,150,123)	\$ (350,699)	\$ (2,354,122)	\$ (797,885)
Add: Stock-based compensation included in reported net loss	-	-	969	-
Deduct: Total stock based employee compensation expense determined under the fair value based method for all awards, net of tax	(14,221)	-	(467,540)	-
Pro forma (loss)	\$ (1,164,344)	\$ (350,699)	\$ (2,820,693)	\$ (797,885)
Income (loss) per share:				
Basic and diluted (loss) per share - as reported	\$ (0.18)	\$ (0.07)	\$ (0.41)	\$ (0.16)
Basic and diluted (loss) per share - pro forma	\$ (0.18)	\$ (0.07)	\$ (0.49)	\$ (0.16)

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 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.

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

**NOTE****3****GEOGRAPHIC INFORMATION:**

In June 1997, FASB issued SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information . SFAS 131 establishes standards for the way that business enterprises report information about operating segments in annual 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.

Chembio Diagnostics Systems, Inc. believes that they operate in a single business segment, however, attributes revenues to different geographic areas on the basis of the location of the customer. Net sales by geographic area are as follows:



**CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED STATEMENTS**  
**UNAUDITED**

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2004	2003	2004	2003
BRAZIL	\$ 1,430	\$ -	\$ 362,586	\$ -
USA	147,170	150,605	321,379	450,119
CANADA	99,390	86,642	283,945	315,907
COSTA RICA	16,846	16,950	138,544	102,450
SAUDI ARABIA	17	14,016	56,643	43,934
JAPAN	44,290	37,000	81,290	78,649
INDIA	-	11,790	34,009	68,501
KOREA	-	45,187	27,132	103,246
SWITZERLAND	5,334	618	35,851	2,273
AUSTRIA	7,700	22,352	27,733	53,091
ISRAEL	16,096	8,064	32,900	32,464
PUERTO RICO	13,935	7,500	25,703	22,500
BELGIUM	7,300	2,000	22,593	26,955
FRANCE	5,947	10,680	20,492	34,073
AUSTRALIA	5,527	5,885	20,491	18,763
OTHER	69,389	147,270	190,000	654,162
	<b>\$ 440,371</b>	<b>\$ 566,559</b>	<b>\$ 1,681,291</b>	<b>\$ 2,007,087</b>

**NOTE 4 ACCOUNTS PAYABLE AND ACCRUED LIABILITIES**

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

	as of	
	Sept. 30, 2004	December 31, 2003
Accounts Payable - Suppliers	\$ 660,135	\$ 1,027,252
Accrued Payroll	55,067	119,236
Accrued Commissions and Royalties	87,915	80,927
Accrued Payroll and other taxes	11,317	41,737
Accrued Legal and Accounting	49,861	81,315
Accrued Expenses - other	16,602	11,080
<b>TOTAL</b>	<b>\$ 880,897</b>	<b>\$ 1,361,547</b>

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

**a) Long-term debt is comprised of the following:**

\$707,914 of Senior Notes bearing interest at 11% was issued in 1999 in connection with a debt restructuring. The Senior Notes are collateralized by a first lien on all of the assets of the Company. Holders of these Notes were also granted warrants to purchase an aggregate of 140,000 shares of common stock at \$1.80 per share. The aggregate fair value of the warrants was \$10,000, of which \$7,000 was related to the debt refinancing and is being amortized over the term of the loan. \$3,000 of the fair value of the warrants are related to the conversion of debt to equity.

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Per a waiver agreement dated July 10, 2002, the senior note holders agreed to extend the Company's required first principal payment until July 31, 2003 provided that the Company pay the balance of accrued and unpaid interest on or before August 31, 2002 and remain current on interest payments due during the period from September 1, 2002 through July 31, 2003. Current interest payments were not maintained nor was the first principal payment made when it became due on July 31, 2003. However, no acceleration or event of default has been claimed on these Notes and, as described below, this debt will be converted to equity unless the Board of Directors chooses to refinance or otherwise retire this debt. Accordingly the entire amount of this debt has been classified as long term.

Per a line of credit agreement dated April 2001, the President who is also a major shareholder agreed to advance the Company up to a maximum principal amount of \$350,000. This amount was later increased to \$1,200,000. The line of credit is collateralized by a subordinated security interest in all of the assets of the Company. In consideration for the above, the Company agreed to repay such borrowed funds on a quarterly basis with accrued interest at 12% per annum, starting September 30, 2003, with a final payment due March 31, 2005, at a maximum quarterly payment of \$43,750. As of December 31, 2003 the principal amount of the advance was \$985,937 with additional accrued interest of \$146,653. Current payments were not being made however, no acceleration or event of default has been claimed on these Notes and as described below, the entire amount of this debt has been classified as long term.

Long-term debt was originally comprised of \$1,693,851, of which \$707,914 was attributable to senior notes bearing interest at 11% issued in 1999 in connection with a debt restructuring of Chembio Diagnostic Systems, Inc., as described above and \$985,937 of which was attributable to a line of credit bearing interest at 12%, as described above.

As a result of the merger (see Note 1), \$1,332,292 of debt (\$580,417 of senior notes and \$751,875 of the line of credit) was converted into series A preferred stock. The total debt remaining as of September 30, 2004 totaled \$361,559.

There is an additional amount due of \$322,476 which represents interest on the entirety of the debt prior to the conversion.

As part of the merger agreement this debt, along with the unpaid interest must be paid or converted into series A preferred stock by the end of December 2004. The remaining debt and unpaid interest is not expected to be paid before the end of December 2004 and therefore the expectation is it will be converted on December 31, 2004 and accordingly it has been reflected as long-term.

**b) Working Capital Loan and Restricted Cash:**

The Company opened a \$250,000 certificate of deposit with HSBC Bank USA which was used as collateral for a working capital line of credit. The line of credit provides for advances of up to \$250,000 at the banks prime rate. The agreement provides for advances up to June 30, 2005, with option to renew for another year. The company borrowed \$50,000 during the quarter ended September 30, 2004. An Addendum modifies the interest rate for the first six months to 0.9%, which expires on December 10, 2004.

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**NOTE 6 CONDITIONALLY REDEEMABLE CONVERTIBLE PREFERRED STOCK:**

The series A preferred stock was issued at a face value of \$30,000 per share and came with detachable warrants. Partial shares can be issued. The value of the preferred was calculated using a fair value allocation between the preferred shares and detachable warrants. The series A preferred stock contains provisions whereby it can be redeemed outside of the control of management, accordingly per EITF #D-98 it has been classified outside of permanent equity. Some key features include:

- Dividends: Holders are entitled to an 8% per annum dividend accrued monthly and payable semi-annually. This dividend can be paid in either cash or common stock at the option of the board of directors.
- Conversion: Series A preferred stock is convertible, at the option of the holders, into shares of common stock at an initial 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 initially convertible into 50,000 shares of common stock.
- Redemption: The holders have the right based on certain events to redeem all or a portion of such holder's shares of series A preferred stock. As the series A preferred is not currently redeemable and there is no certainty that it will be redeemable, no accretion has been made to bring the value up to its redemption value (currently \$30,000 per share plus accrued and unpaid dividends of \$979.71 per share). Accrued but unpaid dividends of \$148,504 are included in the preferred stock carrying value.

In connection with the merger, 151.57984 shares of 8% series A preferred stock convertible into 50,000 shares of common stock per preferred share, were issued and outstanding at September 30, 2004 as follows:

- i) 73.33330 shares were issued in connection with the cash offering of \$2,200,000, along with warrants to purchase 4,400,000 shares of common stock at an exercise price of \$0.90. Cash offering costs associated with this transaction were \$335,086 and were charged against Additional Paid in Capital.
- ii) 33.83682 shares were issued upon the conversion of \$672,000 of convertible debt and related interest thereon. Warrants to purchase 2,030,217 shares of common stock at an exercise price of \$0.90 were issued in connection with these shares. Cash offering costs associated with this transaction were \$83,770 and were charged against Additional Paid in Capital.
- iii) 44.40972 shares were issued upon the conversion of \$1,332,292 of existing debt. Along with warrants to purchase 2,664,584 shares of common stock at an exercise price of \$0.90.

The total amount received or converted into series A preferred stock was \$4,211,399. This value has been allocated between preferred stock at a value of \$2,442,794 and warrants issued at a value of \$1,768,605.

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**NOTE 7 STOCKHOLDERS EQUITY:**

The stockholders equity section on the balance sheet as of December 31, 2003 has been restated to reflect its recapitalization as a result of the consummated merger transaction (see Note 1).

**(a) COMMON STOCK**

As of March 1, 2004, Chembio Diagnostic Systems, Inc. issued 160,573 shares of its common stock to employees as compensation prior to the completion of the merger (see note 1) at a price of \$0.40 per share. These shares are included in i) below.

As a result of the merger on May 5, 2004;

i) Stockholders of 40,000 shares of existing common stock in Chembio Diagnostic Systems, Inc. were issued 4,000,000 shares of common stock in the Company.

ii) Convertible Note holders converted \$328,000 of debt along with interest into 826,741 shares of common stock of the Company.

iii) An employee was issued 400,000 shares of common stock pursuant to an employment contract. The value of the shares was recorded at \$240,000 and since there was no vesting period it has been expensed in the quarter ended June 30, 2004. In addition this employee received warrants to purchase 850,000 shares of common stock at exercise prices from \$0.60 to \$0.90. These warrants had no intrinsic value

iv) As compensation for the financing of the convertible debt and the series A financing, 65,667 shares of common stock were issued. The fair value of these shares was recorded as \$39,400 and reflected as deferred financing costs in the equity section of the balance sheet.

In addition during the second quarter 25,000 shares of common stock were issued to a consultant; the fair value of these shares was recorded as \$15,000 and reflected as an expense. Payables to an attorney were paid with 37,319 shares of common stock, valued at \$22,391 and reflected as a reduction of payables and a gain on settlement.

This results in 6,417,908 shares of common stock issued and outstanding as of September 30, 2004.

**(b) Options**

On March 13, 2004 (prior to the merger - see note 1) Chembio Diagnostic Systems, Inc. issued 24,000 options as part of a consulting agreement. The exercise price for these options is \$0.60 per share. These options were part of the assumed options noted below. The fair value of \$11,089 was expensed.

Prior to the merger (see note 1) Chembio Diagnostic Systems, Inc. issued 315,000 options to existing option holders as part of the employee stock option plan (see note 2). The exercise price for these options ranged from \$0.543 to \$1.00 per share. These options were part of the assumed options noted below. 32,500 options had an intrinsic value of \$929 and were expensed as they became fully vested at the time of merger. The remaining 282,500 options had no intrinsic value.



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The company assumed options of Chembio Diagnostic Systems, Inc. during the merger. The options assumed were to purchase a total of 704,000 shares of common stock of the Company.

Employee options were issued during the quarter ended June 30, 2004 as per the employee stock option plan (see note 2). Options to purchase an aggregate of 375,000 shares of common stock at exercise prices from \$0.60 to \$1.50 were granted. These options had no intrinsic value.

Options were issued to consultants during the quarter ended June 30, 2004 to purchase a total of 225,000 shares of common stock at exercise prices from \$0.60 to \$1.50. The fair values of these options were \$108,564 as of September 30, 2004 and are treated as prepaid expense and are being amortized over the life of their contracts. For the quarter and nine months ended September 30, 2004 amortization of these options were \$15,981 and \$43,669 respectively. As per EITF 96-18 these options will continually be revalued until the measurement date for each option has been reached.

As of September 30, 2004 total options are outstanding to purchase 1,304,000 shares of common stock.

*(c) Warrants*

In May 2004, prior to the merger, Chembio Diagnostic Systems, Inc. issued 140,000 warrants to existing debt holders to compensate for the valuation of the company in the merger and issued 400,002 to existing stockholders in consent of the merger. The warrants issued to debt holders had a fair value of \$60,650 and were expensed for the quarter ended June 30, 2004. The warrants issued to existing stockholders had a fair value of \$144,643 and were charged to Additional Paid in Capital.

The Company assumed warrants of Chembio Diagnostic Systems, Inc. during the merger. The warrants assumed were to purchase a total of 690,002 shares of common stock of the Company (This number includes the 140,000 and 400,002 warrants noted above).

9,094,801 warrants were issued along with the series A preferred stock offering. These warrants were assigned a value of \$1,768,605, see Note 6.

850,000 warrants were issued in connection with an employment agreement see Note 7 (a).

Warrants were issued to placement agents in connection with the series A preferred stock financing to purchase a total of 935,000 shares of common stock at exercise prices from \$0.72 to \$1.80. The fair values of these warrants are \$337,973 and reflected as deferred financing costs, included within paid in capital, in the equity section of the balance sheet.

As of September 30, 2004 total warrants are outstanding to purchase 11,569,803 shares of common stock.

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**NOTE 8 COMMITMENTS AND CONTINGENCIES:**

***Economic Dependency:***

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 aggregated approximately \$70,080 and \$64,881, respectively. Accounts receivable from these customers were \$0 and \$0, respectively at September 30, 2004.

The Company had sales to two customers in excess of 10% of total sales in the three months ended September 30, 2003. Sales to these customers aggregated approximately \$77,102 and \$70,386, respectively. Accounts receivable from these customers were \$0 and \$805, respectively at September 30, 2003

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 aggregated approximately \$362,586 and \$237,877, respectively. Accounts receivable from these customers were \$0 and \$0, respectively at September 30, 2004.

The Company had sales to two customers in excess of 10% of total sales in the nine months ended September 30, 2003. Sales to these customers aggregated approximately \$283,932 and \$278,983, respectively. Accounts receivable from these customers were \$0 and \$805, respectively at September 30, 2003.

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

The Company had one purchase from a vendor in excess of 10% of total purchases for the three months ended September 30, 2003. The purchase value was \$30,143. Accounts Payable to this vendor was \$14,209 at September 30, 2003

The Company had no purchases from any vendor in excess of 10% of total purchases for the nine months ended September 30, 2003.

***Litigation:***

The Company filed a complaint in the United States District Court for the Eastern District of New York against Saliva Diagnostic Systems, Inc. Saliva Diagnostic is the assignee of patent #5,935,864 ( the 864 patent ) that describes a method for collecting samples. The complaint asks the court for declaratory and other relief that the Company's Sure Check HIV test does not infringe the 864 patent, that the 864 patent is invalid, and that the 864 patent is unenforceable due to inequitable procurement. In 2001 and 2002, pursuant to various agreements it had entered into with Saliva Diagnostic, the Company developed, manufactured and sold an HIV rapid test that Saliva Diagnostic had represented incorporates the sample collection method described in the 864 patent. Saliva Diagnostic also represented that the 864 patent is valid. During 2001-2003, the Company paid royalties to Saliva Diagnostic and took several other actions based upon Saliva Diagnostic's representations. In 2003, Saliva Diagnostic sought to abrogate the agreements between the companies and alleged that the Company was infringing the 864 patent. The Company has received opinions from its patent counsel that the product manufactured by the Company is in fact not covered by this patent, that the patent is invalid, and that the patent was obtained through inequitable procurement.





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On March 17, 2004, Saliva Diagnostic made further allegations of patent infringement against Chembio Diagnostic Systems Inc. In connection with the foregoing, Chembio Diagnostic Systems Inc. filed a complaint against Saliva Diagnostic in the United States District Court for the Eastern District of New York on March 18, 2004 (Civil Action No. 04-1149-JS-ETB). The complaint asks the court for declaratory and other relief that our Sure Check HIV test does not infringe the Saliva Diagnostic patent, that the Saliva Diagnostic patent is invalid, and that the Saliva Diagnostic patent is unenforceable due to inequitable procurement. On April 8, 2004, Saliva Diagnostic filed its answer and counterclaim, alleging that we were infringing on the Saliva Diagnostic Patent. We filed our Reply to Counterclaim on May 3, 2004, denying the allegation of infringement of the Saliva Diagnostic Patent. A pretrial scheduling conference was held on September 8, 2004. The scheduling conference set March 15, 2005 as the date for the close of all discovery on liability issues and stipulated that a pre-motion conference or summary judgment motion must be requested by April 1, 2005.

**NOTE**

**9**

**SUBSEQUENT EVENTS**

- a) In November the Company's Board of Directors voted to pay the \$181,896 dividend due on the 8% series A preferred stock in the form of Common Stock. The number of shares issued for this transaction was 303,145.
- b) In October of 2004 the Company issued a voluntary recall of approximately 100,000 pregnancy tests. As a precautionary measure, the recall was expanded on November 3, 2004 to include approximately 215,000 additional pregnancy tests.

These recalls result from a determination that we made that the seals on some of the pouches that were used for packaging pregnancy tests during a certain period from March through August were in many cases deficient, resulting in product degradation in certain cases. Although our investigation has established that some of the lots pouched within this time period remain within specification, we have decided, as a precautionary measure, to recall all of them.

The problem has been corrected, we have revalidated our entire pouching operation, and we increased final product testing as well. We do not anticipate any further problems, but are continuing to monitor all lots of material.

As of the filing date of this report, the estimated cost to the Company to replace the product for these recalls ranges from \$10,000 to \$110,000. Because information relating to the recall is still being gathered, an exact estimate cannot be made as of the filing date of this report due to the fact that most of these tests have already been sold to the end user and therefore, the Company is not responsible to replace them. An amount of \$60,000 (\$6,600 to Inventory and \$53,400 to liability) has been reserved in the three months ended September 30, 2004

## **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 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.

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 following management discussion and analysis relates to the business of Chembio Diagnostic Systems, Inc., our 100% wholly-owned subsidiary. Prior to our merger with Chembio Diagnostics Systems, Inc. in early May 2004, we had no assets or liabilities and no operations. As a result of the merger, we added the assets, liabilities and business and operations of Chembio Diagnostics Systems, Inc. We are now de-emphasizing the manufacturing of private label pregnancy tests and focusing on developing products and then obtaining applicable clearances or approvals in the areas of rapid tests for HIV, tuberculosis, mad cow disease and dental disease. We either have or are pursuing collaborative agreements that may include distribution arrangements in each of these areas. We believe that our research and development, manufacturing overhead, selling, marketing and general and administrative costs will increase as we create the necessary infrastructure to focus in these new areas.

The de-emphasis of the private label pregnancy tests will not impair any assets of Chembio Diagnostic Systems, Inc. This is primarily due to the gradual nature of this move. Chembio Diagnostic Systems, Inc. will continue to produce component parts, while transferring technology to another manufacturer.

### **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. These policies, and

our procedures related to these policies, are described in detail below.

*Revenue Recognition -*

We sell our products directly through our sales force and through distributors. Revenue from direct sales of our product is recognized upon shipment to the customer. We recognize income from research grants when earned. Grants are invoiced after expenses are incurred. Some grants are funded up front; these funds are then deferred until earned.

*Research & Development Costs -*

Research and development activities consist primarily of new product development and continuing engineering for existing products. Costs related to research and development efforts on existing or potential products are expensed as incurred.

*Valuation of Inventories -*

Inventories are stated at the lower of cost or market, using the first-in, first-out method (FIFO) to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete.

*Valuation of Long-Lived Assets -*

We assess the realizable value of long-lived assets for potential impairment at least annually or when events and circumstances warrant such a review. The carrying value of a long-lived asset is considered impaired when the anticipated fair value is less than its carrying value. In assessing the recoverability of our long-lived assets, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. In addition, we must make assumptions regarding the useful lives of these assets.

*Income Taxes -*

We account for income taxes under SFAS No. 109, Accounting for Income Taxes. SFAS No. 109 requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered.

SFAS 109 also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits.

Forming a conclusion that a valuation allowance is not needed is difficult when there is negative objective evidence such as cumulative losses in recent years. Cumulative losses weigh heavily in the overall assessment. As a result, we determined that it was appropriate to establish a 100% valuation allowance.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles, generally accepted in the United States of America, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any viable alternative would not produce a materially different result. See our audited financial statements (included in our SB-2 filing) and notes thereto which contain accounting policies and other disclosures required by accounting principles, generally accepted in the United States of America.

**RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2004 AS COMPARED WITH THE THREE MONTHS ENDED SEPTEMBER 30, 2003**

Revenues were \$566,246 for the three months ended September 30, 2004 as compared with \$578,559 for the three months ended September 30, 2003, representing a decrease of \$12,313, or 2.1%. Revenues are comprised of \$440,371 in net sales and \$125,875 in grants and development income for the three months ended September 30, 2004 as

compared with \$566,559 in net sales and \$12,000 in grant and development income for the three months ended September 30, 2003. The decrease in sales is attributable to decreased income from sales of our HIV product of \$24,585, sales of our pregnancy test kit of \$34,498 and other product sales of \$67,105. These decreases were offset by an increase in contracts and grants of \$113,875. A substantial portion of the grant-related income will recur for the balance of 2004 and in 2005.

Cost of goods sold for the three months ended September 30, 2004 was \$674,402, or 153.1% of net sales, as compared to \$519,817, or 91.8% of net sales, for the three months ended September 30, 2003. The resulting decrease in gross margin is primarily attributable to underutilization of manufacturing capacity as sales volume for the quarter decreased. \$60,000 of this is attributable to a reserve for a voluntary recall of pregnancy tests. We also had increased costs due to the creation of separate quality assurance and quality control departments and the hiring of a new manager to head up the quality assurance department. In addition, we started the transfer of our pregnancy test business in the third quarter to a third party; this included the transfer of automated assembly and packaging equipment. However, technicalities prevented the third party from producing test until October of 2004. This resulted in the Company having to produce tests without the benefit of the automated equipment for this line of product which resulted in higher costs of manufacture.

Research and development expenses for the three months ended September 30, 2004 were \$396,836, or 70.1% of revenues, compared with \$80,140, or 13.9% of revenues, for the three months ended September 30, 2003. Clinical & Regulatory Affairs, which totaled \$242,099 for the three months ended September 30, 2004, accounted for most of this increase. This cost category includes costs incurred for regulatory approvals, clinical studies, product evaluations and registrations. These costs are expected to continue in the 4<sup>th</sup> quarter of 2004 when the HIV rapid test clinical studies will be completed and then return to substantially reduced levels in the first quarter of 2005. The balance of the increase in expense and associated percentage of revenues is due primarily to increased salaries and wages and related costs of each of the members of the R&D group since the September 30, 2003 period as new grants and development contracts were awarded and also due to the addition of an R&D Technician hired in late 2003 for the purpose of fulfilling obligations under grants from the National Institute of Health and World Health Organization as well as other product development contracts.

Selling, general and administrative expense increased \$265,933 to \$543,097 in the three months ended September 30, 2004 compared with the same period in 2003. This increase was attributable to \$48,650 of recruiting expenses incurred in the hiring of quality, manufacturing and regulatory personnel, \$59,200 for marketing consultants (\$15,900 non-cash amortization of options issued to consultants), \$59,400 in salary increases to employees (the addition of a new Chief Financial Officer as well as general increased salary to administrative and marketing personnel) as well as increased legal and accounting expenses of \$68,387 relating to the registration process and required quarterly filings. The balance of the increase or \$30,296 was attributable to increased travel costs related to HIV rapid test marketing efforts, increase cost for Directors and Officers insurance and increased costs for computer and software maintenance.

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

Project	Rapid Test for Mad Cow Disease
Current status	The technology transfer from Prionics AG has commenced. We are waiting for it to be completed in order to begin production scale-up, validation and regulatory submission
Nature, timing and estimated costs of the efforts necessary to complete	The timing of production scale-up and validation is anticipated to be approximately three to six months from the date of the completion of the technology transfer. Thereafter, we will incur costs to establish the production capacity required for this product, which we presently anticipate to be approximately \$100,000.
Anticipated completion date	Not Known

<p>Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely</p>	<p>We are relying on technology developed by Prionics and so there is a risk that the product validation will encounter difficulties that at present are not known or foreseeable. The risks associated with the product involve regulatory and technology risks.</p>
<p>Timing of commencement of expected material net cash inflows</p>	<p>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 the nature and timing of Prionics' distribution network</p>



<b>Project</b>	<b>Dental Bacteria Test</b>
Current status	During the balance of 2004, we expect to complete Phase 2 of the Project Plan (Optimization of Test) and move into Phase 3 (Scale Up of Production and validation).
Nature, timing and estimated costs of the efforts necessary to complete	In April 2004, we received 80% of the Phase 2 project cost of \$65,000, or \$52,000, and this reflects the estimate of the costs anticipated to be incurred to complete Phase 2 during a three to five month period. We expect to complete Phase 2 in December. Upon completion of Phase 2 we will provide a report to Ivoclar-Vivadent. If the report is acceptable, we will receive the \$13,000 balance from Phase 2 and 80% of the Phase III project cost, also \$65,000. Phase 3 is also estimated to take three to five months to complete
Anticipated completion date	Assuming the project plan is achieved, the anticipated completion date of the product is first quarter 2005. It is not known at this time how long it will take to 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	Technical challenges remain that must be overcome in order for this product to meet the performance specifications that Ivoclar Vivadent has set forth in the Agreement. If we do not achieve the performance specifications, the product will not be completed.
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 the nature and timing of Ivoclar-Vivadent's distribution network and strategy.

<b>Project</b>	<b>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	Not known
Anticipated completion date	Not known

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<p>Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely</p>	<p>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.</p>
<p>Timing of commencement of expected material net cash inflows</p>	<p>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.</p>

The other tuberculosis products that are under development, as well as the combination HIV/tuberculosis rapid test and the New Generation Rapid HIV Test, are either at an early stage of research and development, have a limited amount of resources being applied, and/or involve a substantial amount of uncertainty as to the completion of the product. There is no expectation of material revenues in 2004 and 2005 from any of these products.

**RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AS COMPARED WITH THE NINE MONTHS ENDED SEPTEMBER 30, 2003**

Revenues were \$2,146,623 for the nine months ended September 30, 2004 as compared with \$2,117,257 for the nine months ended September 30, 2003, representing an increase of \$29,366, or 1.4%. Revenues are comprised of \$1,681,291 in net sales and \$465,332 in grants and development income for the nine months ended September 30, 2004 as compared with \$2,007,087 in net sales and \$110,170 in grant and development income for the nine months ended September 30, 2003. The increase in sales is primarily attributable to increased income from contracts and grants (\$355,162 increase) as well as increased sales of our HIV product (\$126,835 increase). The increases were partially offset by reduced pregnancy test kit sales (\$284,821 decrease). A substantial portion of the grant-related income will recur for the balance of 2004 and in 2005.

Cost of goods sold for the nine months ended September 30, 2004 was \$1,765,412, or 105.0% of net sales, as compared with \$1,670,375, or 83.2% of net sales, for the nine months ended September 30, 2003. The resulting decrease in gross margin is primarily attributable to underutilization of manufacturing capacity, especially in the third quarter with low sales volume. \$60,000 of this is attributable to a reserve for a voluntary recall of pregnancy tests. We also had increased costs due to the creation of separate quality assurance and quality control departments and the hiring of a new manager to head up the quality assurance department. In addition, the initial order, in the second quarter, with Bio-Manguinhos for HIV related product resulted in overtime to meet customer demand. We also started the transfer of our pregnancy test business in the third quarter to a third party; this included the transfer of automated assembly and packaging equipment. However, technicalities prevented the third party from producing test until October of 2004. This resulted in the Company having to produce tests without the benefit of the automated equipment for this line of product which resulted in higher costs of manufacture.

Research and development expenses for the nine months ended September 30, 2004 were \$896,282, or 41.8% of revenues, compared with \$241,700, or 11.4% of revenues, for the nine months ended September 30, 2003. Clinical & Regulatory Affairs, which totaled \$471,735 for the nine months ended September 30, 2004, accounted for most of this increase. This cost category includes costs incurred for regulatory approvals, clinical studies, product evaluations and registrations. These costs are expected to continue in the 4<sup>th</sup> quarter of 2004 when the HIV rapid test clinical studies will be completed and then return to substantially reduced levels in the first quarter of 2005. The balance of the increase in expense and associated percentage of revenues is due primarily to increased salaries and wages and related costs of each of the members of the research and development group subsequent to September 30, 2003, as new grants and development contracts were awarded and also due to the addition of an R&D Technician hired in late 2003 for the purpose of fulfilling obligations under grants from the National Institute of Health and World Health Organization as well as other product development contracts.

Selling, general and administrative expense increased \$884,654 to \$1,736,758 for the first nine months of 2004 compared with the same period in 2003. This increase is primarily attributable to \$304,229 of non-cash expenses reflecting the fair value of common stock issued to key employees, \$60,450 for recruiting expenses incurred in the hiring of quality, manufacturing and regulatory personnel and \$145,000 in marketing consultants (\$43,600 of which is non-cash expenses reflecting the amortized fair value of options to purchase common stock that were issued to consultants). Also driving this increase were \$84,900 in cash salary increases to employees (the addition of a new Chief Financial Officer as well as general increased salary to administrative and marketing personnel), and increased legal and accounting expenses of \$131,500 relating to the merger, registration process and required quarterly filings. The balance of the increase, or \$158,575, is primarily attributable to increased travel costs related to HIV rapid test marketing efforts and increased commissions relating to the Bio-Manguinhos contract.

Other income and expenses changed by \$197,174. This was attributable to an increase of \$18,372 in interest expense, which was comprised of \$60,650 for a non-cash beneficial conversion feature on 140,000 warrants issued to existing debt holders of Chembio Diagnostic Systems, Inc. and a reduction of \$42,278 primarily attributable to the conversion

of \$1,332,292 of existing debt of Chembio Diagnostic Systems, Inc, at the time of the merger. In addition, approximately \$210,000 is attributable to settlements of old outstanding payables due that were settled during the second quarter of 2004 are reflected in other income as forgiveness of debt.

## LIQUIDITY AND CAPITAL RESOURCES

We began to improve our liquidity and capital resources position during the first quarter of 2004 as a result of the completion of a \$1,000,000 convertible bridge note offering in March in anticipation of our merger. As a result of the completion of the merger, \$328,000 of the \$1,000,000 of convertible bridge notes was converted into 826,741 shares of common stock at \$.40 per share, and the balance of \$672,000 was converted into 33.83682 shares of series A preferred stock. Simultaneous with that conversion, 73.33330 shares of series A preferred stock were issued for \$2,200,000 in cash, and an additional \$1,332,292 of debt to our note holders was converted into 44.40972 additional shares of the series A preferred stock. The values mentioned above for the series A preferred stock have been allocated between the series A preferred stock and the detachable warrants. Together, before accounting for costs and expenses associated with these transactions, these events resulted in recording new redeemable preferred stock and equity capital of approximately \$4,532,292 (\$2,200,000 cash, \$1,000,000 from converted bridge debt and \$1,332,292 from converted existing debt) since December 31, 2003.

During the nine months ended September 30, 2004, we used \$2,392,418 cash in operations, \$67,086 to acquire fixed assets, \$31,147 to fund capital lease payments, and \$67,434 to fund the bank overdraft existing as of December 31, 2003. The cash was funded primarily from the \$1,000,000 of convertible notes issued during March, the accrual of interest on all debt due for both term debt and convertible debt, discounts from the settlement of accounts payable of \$210,000, the sale of \$2,200,000 of series A preferred stock and the funding of \$305,198 of compensation expense by the issuance of common stock and options to some of our key employees.

Accordingly, we had a working capital deficiency of \$730,738 at December 31, 2003 and a working capital surplus of \$496,013 at September 30, 2004. This increase in working capital is due to the completion of the convertible note offering as well as the completion of the series A offering and options to consultants being amortized. Our current assets increased 98.0% to \$1,529,960 at September 30, 2004 from \$772,680 at December 31, 2003. This increase is also primarily attributable to the completion of the convertible note offering in March and the series A preferred offering in May.

Compared with corresponding balances at December 31, 2003, current liabilities as of September 30, 2004 decreased 31.2% to \$1,033,947, long-term liabilities decreased 62.1% to \$772,912, and total liabilities decreased 49.0% to \$1,806,859. The decrease in long-term liabilities is attributable to the completion of the merger where \$1,332,292 of debt was converted into series A preferred stock.

We know that we will have additional capital requirements in the immediate future. The amount of additional capital we may need to raise will depend on a number of factors. These factors primarily include (1) receipt of orders from Bio-Manguinhos in 2004 and 2005 in accordance with contractual commitments; (2) whether we can generally achieve revenue growth and 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 availability and cost of raising additional capital and potential dilution to shareholders. We are currently attempting to raise \$1.5 million to \$2.5 million of equity and/or debt financing. Although at least one party has indicated a preliminary interest, there are no commitments at this time.

The following table lists the future payments required on our debt and any other contractual obligations as of September 30, 2004:

OBLIGATIONS	Total	Less than			Greater than	
		1 Year	1-3 Years	4-5 Years	5 Years	
Working Capital Line	\$ 50,000	\$ 50,000	-	-	-	
Long Term Debt(1)	\$ 684,035	-	-	-	\$ 684,035	
Capital Leases (2)	\$ 138,527	\$ 49,650	\$ 79,206	\$ 9,671	-	

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Operating Leases	\$	50,568	\$	50,568	-	-	-
Other Long Term Obligations(3)	\$	257,500	\$	12,500	\$	95,000	\$ 25,000 \$ 125,000
Total Obligations	\$	1,180,630	\$	162,718	\$	174,206	\$ 34,671 \$ 809,035

(1) This represents existing debt and accrued interest which if not paid by the end of 2004 must convert into series A preferred stock. It is currently expected that the Company will not be able to repay this debt and it will be converted.

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

(3) This represents contractual obligations for licenses.

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

Clinical trials for our HIV rapid tests have begun, and we believe that they will be completed during the fourth quarter of 2004. The trials will be used to support a pre-marketing approval application to the FDA. Simultaneous with this regulatory approval process, we are actively involved in increasing distribution of our HIV rapid tests through a variety of distribution channels and partners. We have engaged Bio-Equity Partners, a company that specializes in helping small biotech firms in the HIV field, to assist in these efforts. Several other marketing and business development efforts are ongoing that are aimed toward participating in the various initiatives publicly announced for the implementation of voluntary counseling and testing (VCT), pre-natal testing for mother to child transmission, and other programs that are taking root globally. A significant portion of the capital currently available to us is being used to obtain US regulatory approval of our HIV rapid tests and to provide the marketing and business development resources to achieve wider distribution of our products in the global market.

We also are working on completing the development of the mad cow, dental bacteria and tuberculosis rapid tests that are under product development agreements and/or research grants. We believe that these products will begin to produce revenues in 2005.

Our cash requirements depend on numerous factors, including product development activities, penetration of the direct sales market, market acceptance of new products, and effective management of inventory levels in response to sales forecasts. We expect to devote capital resources to continue our product development, expand manufacturing capacity and continue research and development activities. We will examine other growth opportunities, including strategic alliances, and we expect any such activities will be funded from existing cash and cash equivalents, as well as issuance of additional equity or additional borrowings, subject to market and other conditions. We believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations through the end of 2004. We therefore will be required to sell additional equity or obtain additional credit facilities in the near term. We further expect that cash generated from operations will not be sufficient to satisfy our working capital and capital expenditure requirements over the next twelve months, so we expect that we will be required to sell additional equity or obtain additional credit facilities during that period. We cannot be certain that this financing will be available or that we will be able to complete financing on satisfactory terms, if at all. We are currently attempting to raise \$1.5 million to \$2.5 million of equity and/or debt financing. Although at least one party has indicated a preliminary interest, there are no commitments at this time

Beyond twelve months out, it is likely that we will have additional financing requirements to finance our expected growth and/or to fund continuing operating deficits. The amount of additional capital we may need to raise will depend on a number of factors. These factors primarily include the extent to which we can achieve revenue growth, the profitability of such revenues, operating expenses, research and development expenses, and capital expenditures. Given the number of product development programs that we have ongoing and not complete, and the dependence we have on factors outside of our control such as government and other donor funding for HIV rapid tests, as well as the success of our marketing partners such as Prionics and Ivoclar-Vivadent, it is not possible to predict the extent or cost of these expected additional financing requirements.

Notwithstanding the numerous factors that our cash requirements depend on, and the uncertainties associated with each of the major revenue opportunities that we have, we believe that our plan of operation can build long term value if we are able to demonstrate clear progress toward our objectives, particularly FDA approval of our HIV rapid tests. We expect to complete the clinical testing portion related to our HIV rapid test FDA submission in the fourth quarter of this year (2004), and we believe that if the results of these tests are at the level required for FDA approval, these results will provide strong evidence of our progress. We also have other important international evaluations pending of our HIV rapid tests which, if favorable, would result in additional independent proof of the quality of our products and the accretion of long term value to our shareholders. We believe that our international sales efforts for our HIV tests will succeed based upon the market need, the performance of our products, their competitive pricing, the

distribution and marketing channels we are pursuing, and the quality of our professional staff. Based upon our agreement with Bio-Manguinhos alone, we expect to receive orders for our HIV rapid tests that will more than offset the net cash flow that we will no longer have from the private label manufacturing of pregnancy tests.

Our attendance at the XVth World AIDS Conference recently in Bangkok, Thailand has generated potential new revenue opportunities for our HIV rapid tests.



Progress in our other major product groups, particularly those for the mad cow disease and dental bacteria test, as well as the non-human primate tuberculosis test, are also likely to lend credibility to our plan to become profitable. In this regard, we have hired a director of regulatory affairs who will be directing the regulatory activities related to the veterinary products (e.g., mad cow and non-human primate tuberculosis) as well as the dental bacteria test, provided that each of the projects progresses to the point where a regulatory submission is appropriate. This individual will eventually absorb some of the responsibilities that have been performed by our outside regulatory consultant. We have also added one person to our solutions manufacturing group and have hired an assembly supervisor. These three positions will add at least \$250,000 in annual costs. We have not decided at this juncture whether to add to our research and development team, though it is under consideration. If such a position is added, the annual cost would be at least \$100,000.

If we are not successful in obtaining additional financing, then we would not be able to pursue our current plan of operation.

### **ITEM 3. CONTROLS AND PROCEDURES**

#### *Evaluation of Disclosure Controls and Procedures*

As of the end of the periods 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 date of the evaluation 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 1. LEGAL PROCEEDINGS**

For information concerning our legal proceedings, please see the LEGAL PROCEEDINGS section of our final Prospectus filed with the U.S. Securities and Exchange Commission on November 9, 2004 and also Note 8 to the financial statements accompanying this quarterly report on Form 10-QSB.

### **ITEM 2. CHANGES IN SECURITIES**

In November the Company's Board of Directors voted to pay the dividends on the Company's 8% series A preferred stock due on November 5, 2004 in the form of shares of common stock. As a result, a total of 303,145 shares of common stock were issued to the holders of the 8% series A preferred stock. The issuance was made pursuant to Section 4(2) of the Securities Act of 1933, as amended, and pursuant to Regulation D promulgated thereunder.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None

**ITEM 5. OTHER INFORMATION**

In October 2004, the Company issued a voluntary recall of approximately 100,000 pregnancy tests. As a precautionary measure, the recall was expanded in early November to include approximately 215,000 additional pregnancy tests. As of the filing date of this report, the estimated cost to the Company to replace the product for these recalls ranges from \$10,000 to \$110,000. Because information relating to the recall is still being gathered, an exact estimate cannot be made as of the filing date of this report due to the fact that most of these tests have already been sold to the end user and therefore, the Company is not responsible to replace them. An amount of \$60,000 (\$6,600 to Inventory and \$53,400 to liability) has been reserved in the three months ended September 30, 2004.

**ITEM 6. EXHIBITS.**

Exhibits.

- 3.1 Articles of Incorporation. (1)
- 3.2 Certificate of Amendment to Articles of Incorporation. (1)
- 3.3 Bylaws. (1)
- 3.4 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.**

**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 15, 2004  
Lawrence A. Siebert  
Chief Executive Officer

By: /s/ Lawrence A. Siebert

Date: November 15, 2004  
Richard J. Larkin  
Chief Financial Officer

By: /s / Richard J. Larkin

