CHEMBIO DIAGNOSTICS, INC. Form 10QSB May 13, 2005

#### 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 March 31, 2005.

#### 000-30379

(Commission File Number)

#### Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

#### Nevada

(State or other jurisdiction of incorporation)

88-0425691

(IRS Employer Identification Number)

#### 3661 Horseblock Road Medford, New York 11763

(Address of principal executive offices including zip code)

#### (631) 924-1135

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of th
Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file suc
reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes <u>X</u> No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes \_\_\_\_ No <u>X</u>

As of May 12, 2005, the Registrant had 7,108,086 shares outstanding of its \$.01 par value common stock.

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

#### March 31, 2005

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#### PART I

#### **Item 1. FINANCIAL STATEMENTS**

TOTAL CURRENT LIABILITIES

## CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS AS OF:

#### - ASSETS -

	March 31, 2005	<u>December 31, 2004</u>
CUIDDENIT ACCETC.	(Unaudited)	
CURRENT ASSETS: Cash	\$ 3,696,581	\$ 34,837
Restricted Cash	\$ 3,090,301	250,000
Accounts receivable, net of allowance for doubtful	-	230,000
accounts of \$14,017 and \$16,367 for March 31, 2005		
and December 31, 2004, respectively	268,770	165,056
Inventories	622,859	538,647
Prepaid expenses and other current assets	178,540	222,520
TOTAL CURRENT ASSETS	4,766,750	1,211,060
FIXED ASSETS, net of accumulated depreciation of		
\$477,160 and \$460,720 for March 31, 2005 and		
December 31, 2004, respectively	257,704	188,399
OTHER ASSETS:		
Deposits and other assets	110,636	26,990
-		
	\$ 5,135,090	\$1,426,449
- LIABILITIES AND COMMON	STOCKHOLDERS (DEF	FICIT) -
CURRENT LIABILITIES:		
Working capital loan	\$ -	\$ 45,000
Accounts payable and accrued liabilities	860,783	1,102,428
Current accrued interest payable	120,000	120,000
Current portion of obligations under capital leases	46,868	51,029
Accrued contingency	48,217	60,264
Payable to related parties	202,323	284,475

1,278,191

1,663,196

#### **OTHER LIABILITIES:**

Obligations under capital leases - net of current		
portion	64,575	74,267
Accrued interest, net of current portion	183,160	212,950
TOTAL LIABILITIES	1,525,926	1,950,413
COMMITMENTS AND CONTINGENCIES		
PREFERRED STOCK -Series A 8% Convertible - \$.01 par value; 10,000,000 shares authorized: 159.28688 and 162.37241 shares issued and outstanding as of March 31, 2005 and December 31, 2004, respectively. Liquidation preference \$4,874,313	2,730,715	2,427,030
<b>PREFERRED STOCK</b> -Series B 9% Convertible - \$.01 par value; 10,000,000 shares authorized: 106.33 and 0 shares issued and outstanding as of March 31, 2005 and December 31, 2004, respectively. Liquidation preference \$5,317,365	3,053,078	-
COMMON STOCKHOLDERS (DEFICIT)		
Common stock - \$.01 par value; 50,000,000 shares authorized 7,048,086 and 6,907,143 shares issued and outstanding as of March 31, 2005 and December 31,		
2004, respectively	70,481	69,071
Additional paid-in capital	13,355,161	9,079,341
Accumulated deficit	(15,600,271)	(12,099,406)
TOTAL COMMON STOCKHOLDERS (DEFICIT)	(2,174,629)	(2,950,994)
	\$ 5,135,090	\$ 1,426,449

See notes accompanying the financial statements.

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

March 31, 2005

182,178

2,698,701

\$ (3,500,865)

**Three months ended** 

March 31, 2004

\$ (429,888)

	1/141 CH 01, 2000	<u>March 31, 2001</u>
REVENUES:		
Net sales	\$ 346,125	\$ 493,970
License revenue	250,000	-
Research grants and development income	135,760	91,342
TOTAL REVENUES	731,885	585,312
Cost of sales	464,550	465,402
GROSS PROFIT	267,335	119,910
OVERHEAD COSTS:		
Research and development expenses	334,750	138,329
Selling, general and administrative expenses	556,061	355,723
	890,811	494,052
(LOSS) FROM OPERATIONS	(623,476)	(374,142)
OTHER INCOME (EXPENSES):		
Interest income	9,468	97
Interest (expense)	(5,978)	(55,843)
(LOSS) BEFORE INCOME TAXES	(619,986)	(429,888)
Income taxes	-	-
NET LOSS	(619,986)	(429,888)

Dividends payable to preferred stockholders

Dividend accreted to preferred stock for associated costs and a beneficial conversion

feature

## NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS

Basic and diluted (loss) per share	\$ (0.50)	\$ (0.09)
Weighted number of shares outstanding, basic		
and diluted	6,945,849	4,957,340

See notes accompanying the financial statements.

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CHANGES IN PREFERRED STOCK AND COMMON STOCKHOLDE (DEFICIT)

#### FOR THE THREE MONTHS ENDED MARCH 31, 2005

	PREFEI STO	RRED A OCK		FERRED B FOCK	COMI STO		Additional	Accumulated	TOTAL COI STOCKHOI
Balance at	Shares	Amount	Shares	Amount	Shares	Amount	Additional paid in capital		(DEFIC
December 31, 2004	162.37241	2,427,030	-	-	6,907,143	69,071	9,079,341	(12,099,406)	(2,950,99
Preferred stock:									
For cash	-	-	100.95	502,777	-	-	4,223,084	-	4,223,0
For Fees	-	-	4.98	24,803	-	-	(24,803)	, -	(24,8
Exchange from series A to series									
B	(0.66666)	(11,600)	0.40	1,992	, <u>-</u>	-	9,608	-	9,6
Accretion of preferred dividend Accretion of	-	95,707		86,471		-	-	(182,178)	
beneficial conversion	-	261,666	-	2,437,035	-	-	-	(2,698,701)	(2,698,7
Common stock issued Common converted from									
Preferred	(2.41887)	(42,088)	) -	-	120,943	3 1,210	40,878	-	42,0
Common stock issued		. , ,			·	ŕ	·		Í
for services	-	-	-	-	20,000	200	14,800	-	15,0
Warrants and options:									
	-	-	-	-	-	-	12,253	-	12,2

Marketing consultants

Net loss to March 31, 2005 - - - - - - - - (619,986) (619,588)

Balance at March 31, \$
2005 159.28688 \$2,730,715 106.33 \$3,053,078 7,048,086 70,481 \$ 13,355,161 \$(15,600,271) \$(2,174,60)

See notes accompanying the financial statements.

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

	<b>Three months ended</b>		
	March 31, 2005	March 31, 2004	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (619,986)	\$ (429,888)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	16,440	18,150	
Provision for doubtful accounts	(2,350)	1,803	
Stock issued as compensation	-	64,229	
Changes in:			
Accounts receivable	(101,364)	2,726	
Restricted cash	250,000	-	
Inventories	(84,212)	(33,322)	
Prepaid expenses and other current assets	71,232	(28,677)	
Other assets and deposits	(83,646)	(124,678)	
Accounts payable and accrued expenses	(241,645)	76,803	
Payable to related parties	(82,152)	-	
Accrued contingency	(12,047)	-	
Net cash used in operating activities	(889,730)	(452,854)	
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of fixed assets	(85,745)	(13,900)	
Net cash used in investing activities	(85,745)	(13,900)	
CASH FLOWS FROM FINANCING ACTIVITIES:			
Changes in obligations to bank	-	(67,434)	
Payment of capital lease obligation	(13,852)	(18,512)	
Payment of accrued interest	(29,790)	-	
Proceeds from working capital loan	161,917	-	
Payment of working capital loan	(206,917)	-	
Proceeds from bridge loan	-	1,000,000	
Sale of Series B Preferred Stock and associated warrants,			
net of cash cost of financing of \$321,639	4,725,861	-	
Net cash provided by financing activities	4,637,219	914,054	

NET INCREASE IN CASH	3,661,744	447,300
Cash - beginning of the period	34,837	-
CASH - end of the period	\$3,696,581	\$ 447,300
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 5,978	\$ -
Supplemental disclosures for non-cash investing and financing activities:		
Stock issued as payment for consulting services	\$ 15,000	\$ -
Warrants issued as payment for financing fees	364,268	-
Preferred B issued as payment for financing fees	249,000	-
Preferred A and associated warrants exchanged for Preferred B and associated warrants	20,000	-
Preferred A converted to common stock	42,088	-
Accreted dividend to preferred stock	2,880,879	-

See notes accompanying the financial statements.

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED STATEMENTS

#### UNAUDITED

NOTE

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#### **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<sup>th</sup> 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.

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 Chembio Diagnostics, Inc. 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 related to certain long term debt totaling \$332,950 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 enough to fund our needs at least through the third quarter of 2005. We anticipate this based upon our current operating budget which assumes significant new expenditures this year that are intended to help us increase revenues and cash flow, and to achieve a variety of other corporate objectives that are aimed to increase shareholder value. The Company is considering alternatives to provide for its capital requirements for late 2005 and beyond. There are no assurances that it will be successful in raising sufficient capital and accordingly we may have to curtail certain of the new expenditures.

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED STATEMENTS

#### **UNAUDITED**

NOTE

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#### 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 March 31, 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 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, 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 contain provisions whereby, under certain conditions outside of the control of management, the holders can require redemption; accordingly, they have not been classified as permanent equity.

#### Inventory:

Inventory consists of the following at:

	March 31,	December 31	
	<u>2005</u>	2004	
<b>Raw Materials</b>	\$321,315	\$ 289,204	
<b>Work in Process</b>	72,124	156,063	
<b>Finished Goods</b>	229,420	93,380	

#### Earnings Per Share:

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

	For the three months ended			
	March 31, 2005 March 31, 2004			
Basic	6,945,849	4,957,340		
Diluted	6,945,849	4,957,340		

## 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 ended March 31, 2005 and March 31, 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:

	For the three months ended					
	March 31, 2005	March 31, 2004				
<b>Stock Options</b>	1,142,250	389,000				
Warrants	21,204,316	140,000				
<b>Preferred Stock</b>	16,680,717	-				

#### 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 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 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 (loss) and earnings (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.

For the three	months ended
March 31,	
<u>2005</u>	March 31, 2004

Net (loss) available to common stockholders, as reported Add: Stock-based compensation included in reported net loss

**\$ (3,500,865) \$ (429,888)** 

Deduct: Total stock based employee compensation expense determ	nined	
under the fair value based method for all awards (net of tax effect)	60,719	-
Pro forma (loss)	\$ (3,561,584)	\$ (429,888)
Income (loss) per share:		
Basic and diluted (loss) per share as reported	\$ (0.50)	\$ (0.09)
Basic and diluted (loss) per share pro forma	\$ (0.51)	\$ (0.09)

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 months ended March 31, 2005: expected volatility of 114.9%; risk-free interest rate of 3.96% to 4.26%; and expected lives of 3 to 7 years.

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED STATEMENTS

#### **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 investments 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 public 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 public entity will initially measure the cost of employee services received in exchange for an award of a liability instrument 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 compensation over that period.

The grant-date for 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 with periods beginning after December 15, 2005.

During the first quarter ended March 31, 2005, 225,000 options under the plan expired. Also during the quarter ended March 31, 2005, the Company issued options to purchase 72,000 shares of Common Stock to two of the Company s new outside Directors. These options were not issued as a part of the plan. The exercise price for these options is \$0.80 per share.

Subsequent to the balance sheet date the Company issued options to purchase 36,000 shares of Common Stock to the third new outside Director, these options were not issued as a part of the plan. The exercise price for these options is \$0.79 per share.

#### **NOTE**

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#### 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, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED STATEMENTS

#### **UNAUDITED**

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

	Three Months Ended March 31,		
	<u>2005</u>	<u>2004</u>	
ASIA and MIDDLE EAST	\$ 112,206	\$ 66,672	
NORTH AMERICA	75,213	178,933	
SOUTH AMERICA	71,555	204,156	
AFRICA	41,070	9,894	
EUROPE	34,458	22,577	
AUSTRALIA	11,623	11,738	
	\$ 346,125	\$ 493,970	

#### **NOTE**

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#### **ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:**

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

	as of			
	March 31,	December 31,		
	<u>2005</u>	2004		
Accounts Payable Suppliers	\$ 420,557	\$ 453,839		
Accrued Payroll	53,918	49,888		
Accrued Commissions and Royalties	167,036	383,630		
Accrued Payroll and other taxes	14,741	30,540		
Accrued Legal and Accounting	68,562	81,005		
Accrued Expenses other	135,969	103,526		
TOTAL	\$ 860,783	\$ 1,102,428		

#### **NOTE**

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#### 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**

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#### **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.

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.

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## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED STATEMENTS

#### UNAUDITED

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 \$600.85 per share, an aggregate for all such shares of \$4,874,313). Accrued but unpaid dividends of \$95,707 are included in the preferred stock carrying value as at March 31, 2005.

Series A shareholders converted 2.41886 shares into 120,943 shares of Common Stock during the three month period ended March 31, 2005.

As per EITF 00-27 Application of Issue 98-5 to Certain Convertible Instruments the Company evaluated the preferred stock transactions and accordingly found that there was an associated beneficial conversion feature. The cash purchase and existing debt conversions were found to contain a beneficial conversion totaling \$1,635,416 and 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 period ended March 31, 2005.

#### **NOTE**

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#### **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. Dividend 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 their 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.

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

\$813.23 per share, an aggregate for all such shares of \$5,317,365). Accrued but unpaid dividends of \$86,471 are included in the preferred stock carrying value as at March 31, 2005.

As per EITF 00-27 Application of Issue 98-5 to Certain Convertible Instruments the Company evaluated the preferred stock transactions and accordingly found that there was an associated beneficial conversion feature. The cash purchase and existing debt conversions were found to contain a beneficial conversion totaling \$2,437,035 and 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. The total amount accreted back to the preferred and charged to dividends was \$2,437,035 for the three month period ended March 31, 2005.

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED STATEMENTS

#### **UNAUDITED**

NOTE
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COMMON STOCKHOLDERS (DEFICIT):
(a)
COMMON STOCK
On March 9, 2005, the Company issued 20,000 shares of its Common Stock to a consultant as compensation. These shares were valued at \$0.75 per share and are being expensed over the three month life of the contract.
On March 7, 2005, series A shareholders converted 2.41886 shares into 120,943 shares of Common Stock.
(b)
Warrants
In association 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, (See Note 7).
Warrants were issued 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.
On March 18, 2005, the Company s Board of Directors approved the re-pricing of existing warrants to purchas 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.
NOTE
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COMMITMENTS AND CONTINGENCIES:

Economic Dependency:

The Company had sales to one customer in excess of 10% of total sales in the three months ended March 31, 2005. Sales to this customer aggregated \$64,520.

The Company had sales to one customer in excess of 10% of total sales in the three months ended March 31, 2004. Sales to this customer aggregated approximately \$120,000.

The Company had no purchases from any vendor in excess of 10% of total purchases for the three months ended March 31, 2005 and March 31, 2004.

#### Litigation:

The Company is involved in a patent litigation with Saliva Diagnostic Systems, Inc. (Saliva), the assignee of patent related to a method for collecting samples. The Company has requested relief from the court that its Sure Check<sup>TM</sup> 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. The parties to the litigation are presently awaiting the judge s ruling on certain issues before proceeding with the discovery phase. The Company s patent counsel has opined that the product manufactured by the Company is not in fact covered by Saliva s patent, that said patent is invalid and that it was obtained through inequitable procurement.

## CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY NOTES TO CONSOLIDATED STATEMENTS

#### **UNAUDITED**

NOTE

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#### SUBSEQUENT EVENTS:

Subsequent to the balance sheet date the Company s board of directors elected to pay the Series A Preferred Stock dividend due on May 5<sup>th</sup> 2005 in the form of Common Stock. The dividend payment equates to 312,773 shares of Common Stock.

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#### 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, 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 the Company s 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 MARCH 31, 2005 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2004

Revenues are comprised of \$346,125 in net sales, \$250,000 in license revenue and \$135,760 in grants and development income for the three months ended March 31, 2005 as compared with \$493,970 in net sales, no license revenue and \$91,342 in grant and development income for the three months ended March 31, 2004. The decrease in sales is attributable to decreased sales of our HIV product of \$86,022, decreased sales of our pregnancy test kit of \$67,696 and increased other product sales of \$5,873. The increase in license revenue was \$250,000 and is due to a technology transfer agreement. The Company does not expect that this revenue will continue in the future. The increase in grant and development income was \$44,418 and was due to increased activity in our non-human primate project. A substantial portion of the grant-related income is expected to recur until the third quarter of 2005.

Cost of goods sold for the three months ended March 31, 2005 was \$464,550, or 134.2% of net sales, as compared to \$465,402, or 94.2% of net sales, for the three months ended March 31, 2004. The decrease in gross margin is primarily attributable to underutilization of manufacturing capacity as sales volume for the quarter decreased. 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. Decreased sales of our HIV products, which were at a higher margin than our other product lines, contributed to the decreased gross margin. We anticipate that we will receive significant orders from our customer in Brazil to be delivered over the next three quarters. These additional sales of our HIV product should generate increased gross margins for the balance of 2005.

Research and development expenses for the three months ended March 31, 2005 were \$334,750compared with \$138,329 for the three months ended March 31, 2004. Expenses for Clinical & Regulatory Affairs, totaled \$138,767 for the three months ended March 31, 2005, an increase of \$125,701 over the three months ended March 31, 2004, and accounted for most of this increase. This category includes costs incurred for regulatory approvals, clinical studies, product evaluations and registrations. These costs are expected to continue in the 2nd quarter of 2005 when the HIV rapid test applications and review will be completed. We expect this category to be reduced in the third quarter of 2005. Increased salaries and wages and related costs of the R&D group and recruitment charges to hire additional staff has contributed to the increase in R&D costs and the balance is due to hiring of a vice-president of regulatory affairs.

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

#### **Project**

#### **Rapid Test for Mad Cow Disease**

Current status

We are waiting for technology transfer from Prionics AG in order to begin production scale-up, validation and regulatory submission. In February 2005 we entered into a license agreement with Prionics AG related to our licensing certain technology that Prionics desired in order for Prionics to complete the technology transfer to Chembio. The agreement provides for additional contingent payments based upon our attainment of certain milestones relating to product performance specified in the agreement. If the milestones are not achieved, there may be a significant reduction or complete elimination of any additional payments under this license agreement. Moreover, the manufacturing agreement we signed with Prionics AG in 2004 would be of no further force or effect.

Nature, timing and estimated costs of the efforts necessary to complete We should know by the end of the second quarter of this year whether our technology can overcome changes to the product formulation that Prionics AG implemented last year. Initial results were unfavorable, though we have continued to work on this project and have an additional opportunity to meet the specifications under the agreement. Testing to determine whether these modifications can meet the agreed-upon specifications will commence in late May. Assuming a favorable outcome of these tests (Milestone 2), one additional milestone (training) would be required before the maximum payments under the agreement will be due and payable and before the Manufacturing & Supply Agreement would remain in effect. Assuming that to be the case, 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

Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely

We are relying on technology and product specifications developed by Prionics, including certain changes they have made to their formulation since the product underwent a successful evaluation. As stated above, there is therefore a risk that the technology transfer from Chembio will not be completed and that the Manufacturing agreement will be of no further force and effect. The risks associated with the product involve regulatory and technology risks. We had anticipated that we would start to see revenues form this program in 2005. This is now in substantial doubt. The Manufacturing Contract provides for a minimum purchase of one million units during the first year following approval in the EU. We understand that the product has in fact been approved in the EU based upon the above-referenced evaluation but because of the problems described herein, Prionics has been unable to complete the production specifications for this product.

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 Prionics distribution network

#### **Project**

#### **Dental Bacteria Test**

Current status

We expected to complete Phase 2 of the Project Plan (Optimization of Test) and move into Phase 3 (Scale Up of Production and validation) in 2005. However, one of the monoclonal antibodies has sensitivity and specificity problem with lateral flow test system. We are therefore discussing strategies in order to overcome this technical problem. We are also considering another detection system, which could be applied instead of the lateral flow system. Such a system could be based on antibodies labeled with fluorescence markers. However, a correspondent reader would have to be used for an analysis of the risk of caries (dental decay).

efforts necessary to complete

Nature, timing and estimated costs of the In April 2004, Chembio received 80% of the Phase 2 project funding of \$65,000, or \$52,000 and this reflected the estimate of the costs anticipated to be incurred to complete Phase 2 during a three to five month period. It is now assumed that Phase 2 will not be satisfactorily completed and that any additional funding from Ivoclar-Vivadent will be pursuant to a new development contract, which is under discussion. Chembio has completed the level of effort needed to earn the 80% funded.

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,

Technical challenges remain that must be overcome in order for this product to meet the performance specifications that Ivoclar-Vivadent had

and the consequences to operations, financial position and liquidity if not completed timely

Timing of commencement of expected material net cash inflows

set forth in the Agreement. If we do not achieve the performance specifications, the product will not be completed.

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.

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Danid Tast for the detection of antihodies to active

Project	pulmonary tuberculosis in non-human primate whole blood samples
Current status	Product validation completed.
Nature, timing and estimated costs of the efforts necessary to complete	We submitted the initial documentation required to commence our application to the United States Department of Agriculture (USDA) for the approval of the product and of our facility where it will be manufactured.
Anticipated completion date	We anticipate that we could have USDA approval by the end of 2005.
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.

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 2005 from any of these products.

Selling, general and administrative expense increased \$200,338 to \$556,061 in the three months ended March 31, 2005 compared with the same period in 2004. This increase was attributable to \$15,000 of recruiting expenses incurred in the hiring of sales and marketing personnel, \$34,550 for marketing consultants (including \$17,986 non-cash amortization of options issued to consultants), costs relating to investor relations of \$50,000 (including \$15,000 non-cash Common Stock issued to consultant), insurance coverage for Directors & Officers of \$10,812 and increased legal and accounting expenses of \$103,780 relating to patent applications, patent litigation, the filling of a registration statement and other required year-end filings.

#### LIQUIDITY AND CAPITAL RESOURCES

We had a working capital surplus of \$3,488,559 at March 31, 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 will be 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.

Subsequent to March 31, 2005 we currently have paid for or committed to purchasing fixed assets aggregating \$26,600. This equipment will allow us to save labor cost and improve efficiencies. In addition, we are considering additional fixed asset purchases for the future, but we have no firm commitments at this time.

We anticipate that the funds from the Series B Offering will be enough to fund our needs at least through the third quarter of 2005. We anticipate this based upon our recently completed operating budget which assumes significant new expenditures this year that are intended to help us increase revenues and cash flow, and to achieve a variety of other corporate objectives that are aimed to increase shareholder value. The Company is considering alternatives to provide for its capital requirements for late 2005 and beyond. There are no assurances that it will be successful in raising sufficient capital.

Our liquidity will ultimately depend on several factors. These factors primarily include (1) whether we can generally achieve 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.

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 improve our sales and marketing efforts, 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 utilization of the funds provided from the Series B Offering.

The following table lists the future payments required on our debt and any other contractual obligations as of March 31, 2005:

<b>OBLIGATIONS</b>	OBLIGATIONS		Less than 1 Year		1-3 Years		4-5 Years		Greater than 5	
		Total								Years
Long Term Debt(1)	\$	303,160	\$	120,000	\$	183,160	\$	-	\$	-
Capital Leases (2)		111,443		46,868		64,575		-		-
Operating Leases		198,450		98,000		100,450		-		-
Other Long Term										
Obligations(3)		863,250		478,167		247,583		25,000		112,500
<b>Total Obligations</b>	\$	1,476,303	\$	743,035	\$	595,768	\$	25,000	\$	112,500

(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.

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

During 2004 and to date in 2005, we successfully completed several important milestones that we believe were fundamental to our being able to achieve significant growth from our HIV products. These milestones include:

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Completion of clinical trials for our HIV rapid tests in the United States and submission of this data with our Pre-Marketing Approval application to the United States Food and Drug Administration.

.

Grant of waiver status by the United States Agency for International Development for our rapid HIV tests for procurements being made under the Presidential Emergency Plan for AIDS Relief which enables our products to be procured pending FDA approval.

.

Qualification under the World Health Organization Bulk Procurement Scheme for our HIV rapid tests. This provides United Nations funded programs and their beneficiary countries with the ability to purchase our products.

•

Submission of our initial application documentation for our Non-Human primate TB test to the USDA.

•

Completion of the License and Technology Transfer Agreement with Prionics AG.

.

Completion of the Series B Five Million Dollar Private Placement of Convertible Preferred Stock.

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Appointment of three independent members to our Board of Directors who will stand for election to our board at our annual meeting.

Our efforts are focused on one or more of our three rapid HIV tests becoming part of the testing protocols used by various governmental and non-governmental organizations in 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 will be used to provide the marketing and business development resources needed to achieve wider distribution of our products for these programs.

We also are working on our non-human primate Tuberculosis test which we expect will begin to produce revenues in 2006, and we are investing additional resources to improve our human Tuberculosis test.

Our license to Prionics AG of certain of our technology has not resulted in their being able to complete for us the specifications for the manufacture of their rapid test for Mad Cow Disease, and this development will likely result in their being unable to complete this product which we were to manufacture for them.

As stated above, we believe that our current cash balances, and cash generated from future operations, will be sufficient to fund operations at least through the end of the third quarter of 2005. Therefore, we do expect that we will be required to sell additional equity or obtain additional credit facilities during the fourth quarter of 2005. Our financing requirements will depend on our progress in growing our product revenues and on our expense levels, and are expectations for those same factors in 2006 as well.

We believe that our plan of operation will build long-term value if we are able to demonstrate clear progress toward our objectives, particularly penetrating international markets with our HIV rapid tests. We also expect to obtain FDA approval of our Sure check<sup>TM</sup> and HIV Stat Pak products by the end of 2005 and we believe that this will represent significant value. 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.

USDA approval of our non-human primate tuberculosis test, and results from new research and development would also likely lend credibility to our plan to become profitable. We anticipate that we will hire several new members to our sales, marketing, research and development, regulatory and administrative staff during the course of 2005 in order to fully implement our plans for growth.

#### 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 December 9, 2004, the Company entered into a contract with an investor relations company, as part of the terms of this contract the Company issued 56,250 shares of common stock. No cash was exchanged in this issuance. The Company issued an additional 20,000 shares of common stock to the investor relations company on March 9, 2005. 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 investor in the issuance was an accredited investor of the Company.

On March 18, 2005, the Company granted to each of the Company s two new non-employee directors, Dr. Gary Meller and Gerald A. Eppner, an option to purchase 36,000 shares of the Company s common stock at an exercise price of \$0.80, as a part of their compensation for their service on the Company s Board of Directors. One-third of the options granted vest immediately, one-third of the options vest one year after the date of grant, and one-third of the options vest two years after the date of grant. Each of these options expire on March 18, 2010.

#### 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
- (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.

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#### **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:
May 13, 2005
By: <u>/s/ Lawrence A. Siebert</u>
Lawrence A. Siebert
Chief Executive Officer
Date:
May 13, 2005
By: <u>/s / Richard J. Larkin</u>
Richard J. Larkin

Chief Financial Officer