

CHEMBIO DIAGNOSTICS, INC.
Form 10QSB
May 12, 2006

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

FORM 10 - QSB

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

For the quarterly period ended March 31, 2006.

000-30379

(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada 88-0425691

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

3661 Horseblock Road

Medford, New York 11763

(Address of principal executive offices including zip code)

(631) 924-1135

(Registrant's telephone number, including area code)

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

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

Yes No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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

As of May 10, 2006, the Registrant had 10,022,729 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-QSB For The Period Ended

March 31, 2006

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PART I**Item 1. FINANCIAL STATEMENTS**

CHEMBIO DIAGNOSTIC SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

- ASSETS -		
	March 31, 2006	December 31,
	(Unaudited)	2005
CURRENT ASSETS:		
Cash	\$ 882,432	\$ 232,148
Accounts receivable, net of allowance for doubtful accounts of \$20,140 and \$20,488 for 2006 and 2005, respectively	946,889	1,255,073
Inventories	918,164	687,983
Prepaid expenses and other current assets	212,575	292,989
TOTAL CURRENT ASSETS	2,960,060	2,468,193
FIXED ASSETS , net of accumulated depreciation of \$596,372 and \$559,228 for 2006 and 2005, respectively	584,771	438,632
OTHER ASSETS:		
Deposits and other assets	391,541	109,581
	\$ 3,936,372	\$ 3,016,406
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,660,404	\$ 1,477,925
Current accrued interest payable	120,000	120,000
Current portion of obligations under capital leases	39,435	38,368
Payable to related parties	182,181	182,181
TOTAL CURRENT LIABILITIES	3,002,020	1,818,474
OTHER LIABILITIES:		
Obligations under capital leases - net of current portion	34,149	44,417
Accrued interest, net of current portion	93,767	100,812
TOTAL LIABILITIES	3,129,936	1,963,703
COMMITMENTS AND CONTINGENCIES		

STOCKHOLDERS' EQUITY		
Preferred Stock - 10,000,000 shares authorized:		
Series A 8% Convertible - \$.01 par value: 155.92903 and 158.68099 shares issued and outstanding as of 2006 and 2005 , respectively. Liquidation preference \$4,833,101	2,673,697	2,628,879
Series B 9% Convertible - \$.01 par value: 119.28877 and 102.19760 shares issued and outstanding as 2006 and 2005, respectively. Liquidation preference-\$6,086,550	3,569,024	3,173,239
Common stock - \$.01 par value; 100,000,000 shares authorized 9,187,097 and 8,491,429 shares issued and outstanding as of 2006 and 2005, respectively	91,871	84,914
Additional paid-in capital	15,280,343	14,034,099
Accumulated deficit	(20,808,499)	(18,868,428)
TOTAL STOCKHOLDERS' EQUITY	806,436	1,052,703
	\$ 3,936,372	\$ 3,016,406

See notes accompanying the financial statements.

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

	Three months ended	
	March 31, 2006	March 31, 2005
REVENUES:		
Net sales	\$ 1,169,070	\$ 346,125
License revenue	-	250,000
Research grants and development income	68,597	135,760
TOTAL REVENUES	1,237,667	731,885
Cost of sales	802,128	464,550
GROSS PROFIT	435,539	267,335
OVERHEAD COSTS:		
Research and development expenses	392,806	334,751
Selling, general and administrative expenses	1,297,646	556,060
	1,690,452	890,811
LOSS FROM OPERATIONS	(1,254,913)	(623,476)
OTHER INCOME (EXPENSES):		
Interest income	597	9,468
Interest (expense)	(9,398)	(5,978)
LOSS BEFORE INCOME TAXES	(1,263,714)	(619,986)
Income taxes	-	-
NET LOSS	(1,263,714)	(619,986)
Dividends payable in stock to preferred stockholders	212,923	182,178
Dividend accreted to preferred stock for associated costs and a beneficial conversion feature	463,434	2,698,701
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (1,940,071)	\$ (3,500,865)

Basic and diluted loss per share	\$	(.22)	\$	(.50)
<hr/>				
Weighted number of shares outstanding, basic and diluted		9,004,466		6,945,849

See notes accompanying the financial statements.

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

	Three months ended	
	March 31, 2006	March 31, 2005
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (1,263,714)	\$ (619,986)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	37,144	16,440
Provision for doubtful accounts	(348)	(2,350)
Common stock, options and warrants issued as compensation	136,423	-
Changes in:		
Accounts receivable	308,532	(101,364)
Restricted cash	-	250,000
Inventories	(230,181)	(84,212)
Prepaid expenses and other current assets	48,454	71,232
Other assets and deposits	-	(83,646)
Accounts payable and accrued expenses	949,434	(365,634)
Net cash used in operating activities	(14,256)	(919,520)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of fixed assets	(183,283)	(85,745)
Net cash used in investing activities	(183,283)	(85,745)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Sale of Series B Preferred Stock and associated warrants, net of cash cost of financing for the periods ended in 2006 and 2005 of \$2,750 and \$321,639, respectively	997,250	4,725,861
Payment of capital lease obligation	(9,201)	(13,852)
Proceeds from working capital loan	-	161,917
Payment of working capital loan	-	(206,917)
Payment of dividends	(140,226)	-
Net cash provided by financing activities	847,823	4,667,009
NET INCREASE IN CASH	650,284	3,661,744
Cash - beginning of the period	232,148	34,837

CASH - end of the period	\$	882,432	\$	3,696,581
Supplemental disclosure of cash flow information:				
Cash paid during the period for interest	\$	9,398	\$	5,978
Supplemental disclosures for non-cash investing and financing activities:				
Stock issued as payment for financing fees	\$	-	\$	15,000
Warrants issued as payment for financing fees		-		364,268
Preferred B issued as payment for financing fees		100,000		249,000
Preferred A and associated warrants exchanged for Preferred B and associated warrants		-		20,000
Cost of royalty rate reduction accrued and included in other assets		250,000		-
Allocated value of warrants issued to additional paid in capital		481,470		2,349,893
Accreted beneficial conversion to preferred stock		463,434		2,698,701
Accreted dividend to preferred stock		676,357		2,880,879
Preferred B issued as payment of dividend		89,899		-
Preferred A converted to common stock		47,884		42,088
Preferred B converted to common stock		202,740		-

See notes accompanying the financial statements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2006
UNAUDITED

NOTE	1	—	Description of Business:
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Chembio Diagnostics, Inc. and its subsidiaries (the Company) develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases and other conditions in humans and animals. 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 Chembio Diagnostic Systems, Inc. (CDS) or the private labels of its distributors or their customers. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV, HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and its rapid test for Chagas Disease.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although the Company's revenues and gross margins increased significantly in recent periods, it has sustained significant operating losses in the first quarter of 2006 and the years 2005 and 2004. At March 31, 2006, the Company had stockholders' equity of \$806,436 and a working capital deficiency of \$41,960. The Company believes its resources are sufficient to fund its needs through mid second quarter of 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. The Company's liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that the Company will be successful in raising sufficient capital.

RECENT DEVELOPMENTS:

On March 30, 2006, the Company sold \$1 million of additional Series B preferred stock to a Series B Preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. Approximately \$140,000 of these proceeds were used to pay cash dividends which were accrued as of December 31, 2005. The Company is continuing to pursue additional financing opportunities in order to provide for its longer term financing needs.

NOTE	2	—	SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:
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<i>(a)</i>	Basis of Presentation:
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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, 2006, and the results of operations and the cash flows for all periods presented. The results of operations for the interim periods are not necessarily indicative of the results to be achieved in any future interim period or for the entire year.

For a summary of significant accounting policies (which have not changed from December 31, 2005) and additional financial information, see the Company's annual report on Form 10-KSB filed March 30, 2006.

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.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2006
UNAUDITED

(b)

Inventories:

Inventory consists of the following at:

	March 31, 2006	December 31, 2005
Raw		
Materials	\$ 532,111	\$ 425,758
Work in		
Process	167,100	86,001
Finished		
Goods	218,953	176,224
	\$ 918,164	\$ 687,983

(c)

Earnings Per Share

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

	<u>For the three months ended</u>	
	<u>March 31, 2006</u>	<u>March 31, 2005</u>
Basic	9,004,466	6,945,849
Diluted	9,004,466	6,945,849

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, 2006 and 2005 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:

	<u>For the three months ended</u>	
	<u>March 31, 2006</u>	<u>March 31, 2005</u>
1999 Plan		
Stock		
Options	1,601,750	952,000
Other		
Stock		
Options	144,625	190,250
Warrants	23,114,990	21,204,316
Preferred		
Stock	17,574,184	16,680,717

(d) Employee Stock Option Plan:

The Company's 1999 Plan, which is shareholder approved, permits the grant of share options and shares to its employees for up to 3,000,000 shares of common stock. All stock options under the 1999 Plan are granted at the fair market value of the common stock at the grant date. Employee stock options vest ratably over a zero to three-year period and generally expire 5 years from the grant date. Annual stock option grants to non-employee directors vest one-third immediately, one-third at the end of one year and the balance at the end of two years.

Effective January 1, 2006, the Company's Plan is accounted for in accordance with the recognition and measurement provisions of Statement of Financial Accounting Standards ("FAS") No. 123 (revised 2004), Share-Based Payment ("FAS 123(R)", which replaces FAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion ("APB") No. 25, Accounting for Stock Issued to Employees, and related interpretations. FAS 123 (R) requires compensation costs related to share-based payment transactions, including employee stock options, to be recognized in the financial statements. In addition, the Company adheres to the guidance set forth within Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 107, which provides the Staff's views regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides interpretations with respect to the valuation of share-based payments for public companies.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
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Prior to January 1, 2006, the Company accounted for similar transactions in accordance with APB No. 25 which employed the intrinsic value method of measuring compensation cost. Accordingly, compensation expense was not recognized for fixed stock options if the exercise price of the option equaled or exceeded the fair value of the underlying stock at the grant date.

While FAS No. 123 encouraged recognition of the fair value of all stock-based awards on the date of grant as expense over the vesting period, companies were permitted to continue to apply the intrinsic value-based method of accounting prescribed by APB No. 25 and disclose certain pro-forma amounts as if the fair value approach of SFAS No. 123 had been applied. In December 2002, FAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of SFAS No. 123, was issued, which, in addition to providing alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation, required more prominent pro-forma disclosures in both the annual and interim financial statements. The Company complied with these disclosure requirements for all applicable periods prior to January 1, 2006.

In adopting FAS 123(R), the Company applied the modified prospective approach to transition. Under the modified prospective approach, the provisions of FAS 123 (R) are to be applied to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date shall be recognized as the requisite service is rendered on or after the required effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated for either recognition or pro-forma disclosures under FAS 123.

As a result of the adoption of FAS 123 (R), the Company's results for the three month period ended March 31, 2006 include share-based compensation expense totaling approximately \$125,000. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold (\$10,775), research and development (\$37,950) and selling, general and administrative expenses (\$76,275). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to history of operating losses.

Stock option compensation expense in the first quarter of 2006 is the estimated fair value of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the award.

The weighted average estimated fair value of stock options granted in the three months ended March 31, 2006 and 2005 was \$0.536 and \$0.657, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. During 2006, the Company took into consideration guidance under SFAS 123R and SEC Staff Accounting Bulletin No. 107 (SAB 107) when reviewing and updating assumptions. The expected volatility is based upon historical volatility of our stock and other contributing factors. The expected term is based upon an estimate as no employee has exercised any options to date. Previously such assumptions were determined based on historical data.

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

	Three Months Ended	
	March 31,	March 31, 2005

	2006	
Expected term (in years)	5	5
Expected volatility	118.03%	114.94%
Expected dividend yield	0%	0%
Risk-free interest rate	4.66%	4.18%

The following table addresses the additional disclosure requirements of 123(R) in the period of adoption. The table illustrates the effect on net income and earnings per share as if the fair value recognition provisions of FAS No. 123 had been applied to all outstanding and unvested awards in the prior year comparable period.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2006
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	For the three months ended March 31, 2005
Net loss attributable to common stockholders, as reported	\$ (3,500,865)
Add:	
Stock-based compensation included in reported net loss	-
Deduct: Total stock based compensation expense determined under the fair value based method for all awards (no tax effect)	(60,719)
Pro forma net loss attributable to common stockholders	\$ (3,561,584)
Net loss per share:	
Basic and diluted loss per share - as reported	\$ (0.50)
Basic and diluted loss per share - pro forma	\$ (0.51)

The Company granted 316,000 options under the Plan during the three months ended March 31, 2006 at exercise prices ranging from \$0.55 per share to \$0.62 per share.

The following table represents our stock options granted, exercised, and forfeited during the first quarter of 2006.

Stock Options

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	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2006	1,285,750	\$1.20		
Granted	316,000	\$0.60		
Exercised	-	-		
Forfeited/expired	-	-		
Outstanding at March 31, 2006	1,601,750	\$1.08	4.39 years	\$52,261
Exercisable at March 31, 2006	1,158,250	\$1.14	4.26 years	\$42,181

No options were exercised the first quarter of 2006 and 2005.

On April 17, 2006 the Compensation Committee of the Company's Board of Directors approved the cancellation of all employee options where the exercise price was greater than \$.75 per share (an aggregate of 795,250 options) and issuance of new options at an exercise price of \$.75 per share with the same vesting schedule and expiration dates (except for 122,500 new options that were issued with a vesting date of January 1, 2007 which is later than the vesting date of the options they replaced). The expense related to this transaction for the second quarter will be \$58,000.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED STATEMENTS
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(e) *Geographic Information:*

SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information" establishes standards for the way that business enterprises report information about operating segments in financial statements and requires that those enterprises report selected information. It also establishes standards for related disclosures about product and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as "rapid medical tests". As per the provisions of SFAS 131, management believes that it operates in a single business segment. Net sales by geographic area are as follows:

	For the three months ended	
	March 31, 2006	March 31, 2005
Africa	\$ 210,464	\$ 41,070
Asia	42,811	27,400
Australia	-	11,623
Europe	38,698	34,458
Middle East	675	84,806
North America	59,961	75,213
South America	816,461	71,555
	\$1,169,070	\$346,125

(f) **Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities:

	March 31, 2006	December 31, 2005
Accounts payable - suppliers	\$ 1,066,999	\$ 550,247
Accrued commissions	187,124	171,587
Accrued royalties / licenses	766,727	381,510
Accrued payroll and other taxes	135,203	63,146
	155,870	145,566

Accrued vacation		
Accrued legal and accounting	62,889	50,024
Accrued expenses - other	285,592	115,845
TOTAL	\$ 2,660,404	\$ 1,477,925

NOTE

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LONG-TERM DEBT:

In connection with the Series B offering interest payable on certain debt was agreed to be paid over 33 months in installments of \$10,000 per month and a final payment of \$2,950 in the 34th month. These payments are subordinate to the redemption rights of the Series B preferred stockholders. No interest accrues on this payable.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED STATEMENTS
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NOTE 4—STOCKHOLDERS' EQUITY:

(a) Common Stock

During the three months ended March 31, 2006 the Company issued 8,333 shares of its Common Stock to a consultant as compensation. The shares were valued at \$0.55 per share and were expensed in the period.

In the three months ended March 31, 2006 Series A Preferred shareholders converted 2.75196 shares into 137,598 shares of Common Stock. Series B Preferred shareholders converted 6.70680 shares into 549,737 shares of Common Stock.

(b) Warrants

The warrants to purchase 1,713,114 shares of Common Stock issued in connection with the March 2006 Series B offering were assigned a value of \$481,470.

During the three months ended March 31, 2006, the Company issued warrants to purchase 73,904 shares of Common Stock at exercise prices from \$0.55 to \$0.70 per share to a distributor as payment for commissions accrued at year end 2005 (value \$24,000) and to consultants as compensation for 2006 (value \$6,824).

(c) Series A 8% Convertible Preferred Stock:

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series A Preferred Stock. The Series A Preferred Stock is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$30,000 per share plus accrued and unpaid dividends, presently \$995.52 per share, an aggregate for all such shares of \$4,833,101. Accrued but unpaid dividends of \$155,230 are included in the preferred stock carrying value as at March 31, 2006.

Dividends: The 8% per annum dividend is payable semi-annually, in cash or, at the Company's option, in Common Stock based on the conversion price. To date all dividends have been paid in Common Stock.

(d) Series B 9% Convertible Preferred Stock:

Redemption: The holders have the right, under certain conditions, to require redemption of all or a portion of such holder's shares of Series B Preferred Stock. The Series B preferred is not currently redeemable and there is no likelihood that it will become redeemable; accordingly, no accretion is being made to bring the value up to its redemption value. The liquidation preference is \$50,000 per share plus accrued and unpaid dividends, presently \$1,023.66 per share, an aggregate for all such shares of \$6,086,550. Accrued but unpaid dividends of \$122,112 are included in the preferred stock carrying value as at December 31, 2005. The accrued but unpaid dividend was paid on January 2, 2006 by the issuance of 4.60249 shares Series B Preferred Stock. Subsequent to this issuance a Series B shareholder asserted their right, which is exclusive to such shareholder, to receive their dividend in cash; the certificate for 2.80452 shares of Series B was surrendered and the equivalent amount of \$140,226 was paid in April

2006.

As per EITF 00-27 “Application of Issue 98-5 to Certain Convertible Instruments” the Company evaluated the series B preferred stock transaction that occurred in January 2005 and found that there was an associated beneficial conversion feature totaling \$2,437,035; the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock in accordance with the conversion provision which allowed for 100% to be converted immediately. The Company also evaluated the series B preferred stock transaction that occurred on March 30, 2006, see Note 1, and found that there was an associated beneficial conversion feature totaling \$463,434; 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.

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2006
UNAUDITED

NOTE 6 ~~E~~VENTS subsequent TO MARCH 31, 2006

(a) *Notice from the U.S. Food and Drug Administration (FDA):*

On April 18, 2006 the Company received an “approvable” letter from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(TM) rapid test Pre-Market Applications (PMAs). The FDA letter states that Chembio’s PMA approval is subject only to final review by the FDA of the package inserts for each of the products, a review which has been ongoing, and other standard conditions related to all PMAs. Chembio therefore anticipates that the PMA will be approved in the very near future. An approved PMA will allow Chembio to market its tests to clinical laboratories and hospitals in the United States.

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 are 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 Diagnostics, Inc. and its subsidiaries (the Company), which develop, manufacture, and market lateral flow rapid diagnostic tests that detect infectious diseases and other conditions in humans and animals. 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 Chembio Diagnostic Systems Inc. (CDS) or the private labels of its distributors or their customers. The Company's main products presently commercially available are its three HIV Rapid Tests (SURE CHECK(R) HIV, HIV 1/2 STAT-PAK(TM) and HIV 1/2 STAT-PAK Dipstick) and our rapid test for Chagas Disease. In 2005, the Company sold substantially all of the business related to its private label pregnancy test and is focusing on the products mentioned above.

The Company has made substantial progress toward FDA approval of its SURE CHECK HIV and HIV 1/2 STAT-PAK products. A pre-approval inspection of its facility was conducted in the third quarter of 2005 and the Company received an "approvable" Pre-Marketing Approval (PMA) application letter from the FDA on April 18, 2006. The Company expects to complete the full process during the second quarter of 2006, which would include receipt from the FDA of a waiver under the Clinical Laboratory Improvement Act ("CLIA"). A CLIA waiver is essential in order to market the product into public health clinics and physicians offices where the level of training is less than clinical laboratories and hospitals. The Company is nearing completion of the CLIA waiver studies so it will be in a position to submit its waiver application immediately upon receipt of the PMA license from the FDA.

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. Although the Company's revenues and gross margins increased significantly in recent periods, it has sustained significant operating

losses in the first quarter of 2006 and the years 2005 and 2004. At March 31, 2006, the Company had stockholders' equity of \$806,436 and a working capital deficiency of \$41,960. The Company believes its resources are sufficient to fund its needs through mid second quarter of 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. Its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that it will be successful in raising sufficient capital.

On March 30, 2006, the Company sold \$1 million of additional Series B preferred stock to a Series B preferred shareholder pursuant to provisions of the January 2005 Series B 9% Preferred Stock financing agreements. Such provisions were exclusive to said shareholder. The Company is continuing to pursue additional financing opportunities in order to provide for its longer term financing needs.

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, 2005), see our annual report on Form 10-KSB for the period ended December 31, 2005 filed March 30, 2006.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2006 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2005

Revenues:

Revenues are comprised of \$1,169,000 in net product sales and \$69,000 in grants and development income for the three months ended March 31, 2006 as compared with \$346,000 in net product sales, \$250,000 license revenue and \$136,000 in grant and development income for the three months ended March 31, 2005. The increase in net product sales is attributable to increased sales of our HIV tests of \$447,000 and increased sales of our Chagas tests of \$459,000 from \$25,000 to \$484,000, partially offset by decreased sales of our pregnancy test kit (a deemphasized product) of \$63,000 and decreases in other product sales aggregating \$20,000. The decrease in license revenue of \$250,000 is due to a technology transfer agreement. The Company does not expect that this particular license revenue will continue in the future. The decrease in grant and development income of \$67,163 was due to grants received in 2005 that weren't continued or awarded in 2006.

Net product sales for the three month period ended March 31, 2006 increased 238% compared to the same period in 2005. HIV net product sales increased 496% in this period compared to the same period in 2005. The Company believes that sales of its HIV products will continue to increase in 2006 as compared to 2005 both as a result of the international marketing strategies that were implemented in 2005 and from the sales to the United States market after anticipated approval from the U.S. Food and Drug Administration (FDA). The Chagas net product sales increase was a result of the Company obtaining its first significant order for this product, in the amount of \$1.2 million of which it shipped \$480,000 in the first quarter of 2006 and expects to ship the balance in the second and third quarters of 2006.

Gross Margin:

Gross margin on net product sales for the three months ended March 31, 2006 was 31.4%, as compared to gross margin deficit of 34.2% for the three months ended March 31, 2005. The increase in gross margin percentage is attributable to the increased sales of HIV products, which were at a higher margin than other product lines, and because sales volume in 2005 was significantly lower, fixed overhead expenses per dollar of sales were disproportionately high.

Research and Development:

Research and development expenses for the three months ended March 31, 2006 were \$393,000 compared with \$335,000 for the three months ended March 31, 2005.

This category includes costs incurred for regulatory approvals, product evaluations and registrations. Expenses for Clinical & Regulatory Affairs, totaled \$78,000 for the three months ended March 31, 2006, a decrease of \$61,000 compared to the three months ended March 31, 2005. This category also reflects reductions in costs for clinical studies of \$30,000 and outside regulatory consultants of \$33,000. The costs related to the clinical trials and consulting in 2005 were related to the evaluation of the Company's HIV tests in preparation of its FDA Pre-Marketing Approval ("PMA") application submitted in February of 2005.

Expenses other than Clinical & Regulatory Affairs increased \$119,000 and were related to increased salaries and wage-related costs of \$42,000 for new hires in the R&D group, the cost related to employee stock options vesting in the period of \$30,000, increased cost of materials of \$57,000, net of a reduction in travel and entertainment costs of \$9,000.

The Company presently plans to increase its spending on research and development because it believes such spending will result in the development of new and innovative products. The Company will continue to focus its development efforts on its tuberculosis related products and new lateral flow technologies, some of which have patents pending.

The Company currently has several R&D projects underway. Some highlights include:

Rapid Test for the detection of antibodies to active pulmonary tuberculosis in non-human primate whole blood samples

The Company has filed an application with the United States Department of Agriculture (USDA) to license its rapid test, Prima TB STAT-PAK(TM). A final set of clinical trials is scheduled for the second quarter of 2006, that, if successful, would lead to a conditional license (the ability to sell the product commercially with USDA approval on an order by order basis) by late in the fourth quarter of 2006. The Company anticipates that additional commercialization will begin in the first quarter of 2007, although there are no assurances that it will be successful.

Rapid Test for the detection of antibodies to active pulmonary tuberculosis in multiple host species

Chembio has completed development and is approaching the final validation stage on a series of rapid lateral-flow tests for the detection of veterinary TB in multiple host species including; cattle, cervids, badgers, camels, elephants, and exotic wildlife species. The name for the technology is VETTB STAT-PAK(TM). Application to the USDA is targeted for the third quarter of 2006 for all species. The Company anticipates commercialization of these products to start in the first quarter of 2007, although there are no assurances that it will be successful.

New Generation Rapid Tests Based Upon Patent Pending Platform

The Company has done substantial laboratory work on prototypes of its new patent-pending lateral flow rapid test platform. This work has confirmed the advantages of this new platform in terms of sensitivity to weak and early sero-conversion samples. The Company believes that this platform may provide the level of sensitivity that will be needed in order to complete development of a human TB rapid test which could not be achieved with sufficient sensitivity based upon the existing platform.

Selling, General and Administrative Expense:

Selling, general and administrative expense increased \$742,000 to \$1,298,000 in the three months ended March 31, 2006 compared with \$556,000 for the same period in 2005. This increase was attributable to increased staff costs in the accounting, administration and sales and marketing departments of \$119,000 and the cost related to employee stock options vesting in the period of \$53,000. Increased sales resulted in an increase in royalties, licenses and commissions of \$214,000. In addition there was an increase of \$96,000 in costs regarding investor relations, \$35,000 which resulted from an increase in the number of members of the Company's Board of Directors, \$23,000 from increased travel and entertainment costs, \$30,000 related to marketing consultants and increased legal expenses of \$127,000 related to patent litigation.

As the Company's sales of its HIV rapid test products increase, it expects selling, general and administrative expense to also increase. This will be in large measure due to increased costs for commissions and royalties on intellectual property licenses. At the end of 2005, the Company renegotiated one of its license agreements to provide for a decrease of 50% in the royalty rate, from 10% to 5% of sales of HIV products, in exchange for \$350,000 in cash payments (of which \$100,000 was paid in 2005 and the balance accrued as of March 31, 2006). Such payment is being amortized over the life of the royalty agreement.

Other Income and Expense:

Interest expense increased by \$3,000 for the three months ended March 31, 2006 compared with the three months ended March 31, 2005 resulting from accrued interest payable on license fees of \$2,250, which were extended as well as interest paid of approximately \$3,000 on cash dividends not paid on the due date offset by reductions in interest expense of leases. Interest income for the three months ended March 31, 2006 decreased \$8,871 due to less availability of funds to invest.

LIQUIDITY AND CAPITAL RESOURCES

The Company had a working capital deficiency of \$42,000 at March 31, 2006 and a working capital surplus of \$650,000 at December 31, 2005. On March 30, 2006, the Company completed a transaction related to the Series B Offering which raised \$1,000,000 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 have been and are being used primarily for general corporate purposes including for sales and marketing, research and development, and intellectual property, and also for working capital, investor relations, and capital expenditures.

The Company believes its resources are sufficient to fund its needs through mid second quarter of 2006 and it is considering alternatives to provide for its capital requirements for the balance of 2006 and beyond in order to continue as a going concern. Its liquidity and cash requirements will depend on several factors. These factors include (1) the level of revenue growth; (2) the extent to which, if any, that revenue growth improves operating cash flows; (3) its investments in research and development, facilities, marketing, regulatory approvals, and other investments it may determine to make, and (4) the investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that it will be successful in raising sufficient capital.

The following table lists the future payments required on the Company's debt and any other contractual obligations as of March 31, 2006:

<u>OBLIGATIONS</u>	<u>Total</u>	<u>Less than 1 Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>Greater than 5 Years</u>
Long Term					
Debt(1)	\$ 213,767	\$ 120,000	\$ 93,767	\$ -	\$ -
Capital Leases					
(2)	\$ 73,584	\$ 39,435	\$ 34,149	\$ -	\$ -
Operating Leases	\$ 100,450	\$ 100,450	\$ -	\$ -	\$ -
Other Long Term					
Obligations(3)	\$ 795,717	\$ 610,942	\$ 59,775	\$ 25,000	\$ 100,000
Total Obligations	\$ 1,183,518	\$ 870,827	\$ 187,691	\$ 25,000	\$ 100,000

- (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 fixed cost licenses and employment contracts.

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

Please see section entitled Overview and in particular the last two paragraphs.

During 2006, the Company expects to start marketing its SURE CHECK HIV and HIV 1/2 STAT-PAK in the U.S. as it has made substantial progress toward its FDA approval of these products as set forth in the second paragraph of Overview above.

Based upon the expected FDA approval and CLIA waivers referred to above, the Company is developing plans for marketing its HIV products in the U.S. and is considering entering into marketing arrangements with major companies who distribute diagnostic products in the U.S.

A recent development of note is the White House 2007 budget request for \$90 million to test an additional three million Americans using rapid HIV tests. Also, the Company has been following with great interest the consideration by an FDA advisory committee of the conditions under which rapid HIV tests could be approved for direct over-the-counter sales to U.S. consumers. On March 10, 2006, proposed guidelines were presented to this committee. While the Company believes that both President Bush's budget request and the possibility for over-the-counter approval bode well for the expansion of the U.S. rapid HIV test market, there are still many obstacles and uncertainties to be overcome before these items become a reality and can result in realizable opportunities for the Company, and there is no assurance that they will be realized.

During 2005, the Company established offices in Nigeria and Tanzania which it believes will be significant in its continuing efforts to become part of the national testing protocols in many countries in Africa. The Company's STAT-PAK is designated as the confirmatory test in all of the national rapid HIV testing protocols in the Republic of Uganda and was just recently designated in four of the eight parallel testing algorithms (two tests used on each patient) adopted by the Nigerian Ministry of Health in its Interim National Testing Algorithm. The Company is making good progress towards having its HIV products designated in other countries where it has focused its efforts. The Company has registered its products and has established distribution partners in certain of these countries and is in negotiations to do so in other countries. The Company believes that its strategy of establishing offices in these challenging markets is a very effective way to obtain sustainable and supportable business. The Company is also actively looking at several new opportunities for establishing distribution and/or local assembly programs for its rapid HIV tests with strong local partners such as it has done in Brazil.

In 2006, Chembio was one of four companies selected by the Clinton Foundation HIV/AIDS Initiative ("CHAI") to make available low-cost rapid HIV tests in order to more quickly and cost effectively achieve treatment objectives. Under the CHAI agreement, the Company has agreed to offer its HIV STAT-PAK Dipstick, Chembio's lowest cost HIV rapid test product, at a reduced price in the expectation that the Company will receive significant order volume not otherwise obtainable; this should result in efficiencies of scale that will more than justify the reduced sales price. If these order volumes are not realized, the Company has the right to terminate the agreement or renegotiate pricing. Chembio is the only U.S.-based manufacturer of the four companies in this agreement. The CHAI Procurement Consortium is currently comprised of more than 50 countries in Africa, Asia, Eastern Europe, Latin America and the Caribbean that have Memoranda of Understanding (MOUs) with CHAI. Consequently, the Company is now actively engaged with CHAI in developing sales opportunities in many of these countries. Although in some of these countries the Company has already made substantive sales efforts, there are many more where this is not the case. There is no commitment or assurance that either the Company's direct efforts to establish additional distributors and/or local assembly, or its activities through CHAI will materialize into meaningful sales.

The Company's technology transfer and supply agreement in Brazil is moving forward. The Company shipped 167,500 HIV rapid tests in the three months ended March 31, 2006, a 100% increase over the quantity sold in the same period in 2005. The Company expects to deliver components for an additional 632,500 tests during the rest of 2006, although there is no assurance that this will occur.

The Company also received, in January of 2006, an order for \$1.2 million to supply its Chagas Disease rapid test. The Company shipped approximately \$480,000 in the three months ended March 31, 2006, with the balance expected to be delivered in the second and third quarters of 2006. This procurement is being made by the Pan American Health Organization, headquartered in Washington D.C., which is affiliated with the World Health Organization. The procurement will be used to implement a nationwide Chagas screening program for all children under the age of 10 in endemic regions of Bolivia. The Company is actively looking at developing additional business opportunities for this product in Bolivia, and other markets in Latin America that are impacted by this disease.

In September 2005, the Company hired a senior diagnostics marketing executive to focus on its Tuberculosis products, both for veterinary and human TB. The Company's Non-human primate Tuberculosis product is currently under review by the United States Department of Agriculture (USDA) and it expects USDA approval toward the end of 2006 provided its tests meet certain performance and other criteria; the Company plans to submit additional veterinary TB products to the USDA this year, including a cattle TB test, subject to having the necessary performance data.

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

ITEM 3. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company conducted an evaluation under the supervision and with the participation of the principal executive officer and principal financial officer, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

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 March 18, 2006, the Company issued an option to acquire 36,000 shares of common stock to two of the Company's non-employee directors: Gary Meller, and Gerald Eppner. The exercise price of each option is \$.55 per share, and each option vests in three equal annual installments beginning on March 18, 2006. Each option expires on March 18, 2011. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

On March 24, 2006, the Company granted options to purchase 50,000 shares of common stock under the Company's 1999 Equity Incentive Plan to Avi Pelossof, a Vice President of the Company, at an exercise price of \$.62 per share until March 24, 2011. One-half of these options are currently exercisable, and the other one-half vest on January 1, 2007. On March 24, 2006, the Board also granted options to purchase 37,500 shares of common stock under the Plan to Richard Larkin, the Chief Financial Officer of the Company, at an exercise price of \$.62 per share until March 24, 2011. One-half of these options are currently exercisable, and the other one-half vest on January 1, 2007. On March 24, 2006, the Company granted options to purchase 6,000 to an independent consultant, Joseph Nnorom, at an exercise price of \$.62 per share until March 24, 2011. Also on March 24, 2006, in accordance with the terms of the Company's 1999 Equity Incentive Plan, the Company granted to additional employees of the Company options to purchase 156,500 shares of the Company's common stock. The exercise price for these options is equal to \$.62. Each option granted will expire and terminate, if not exercised sooner, upon the earlier to occur of (a) 30 days after termination of the employee's employment with the Company or (b) the fifth anniversary of the vesting date. All options with the exception of two that vest on January 1, 2007 immediately vested on March 24, 2006. The Company relied on Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated thereunder as the basis for its exemption from registration of this issuance. Executive officers of the Company are considered to be "accredited investors" when purchasing securities issued by the Company.

On March 30, 2006, the Company issued to Crestview Capital Master, LLC ("Crestview") 20 shares (face amount \$1,000,000) of the Company's series B preferred stock together with warrants to purchase a total of 1,557,377 shares of Common Stock at an exercise price of \$0.61 per share for a period of five years. The Company agreed to issue, and Crestview agreed to purchase for \$1,000,000, the securities described above pursuant to the terms of a Securities Purchase Agreement dated January 26, 2005 (the "Agreement") by and among the Company, Crestview, and various purchasers. This transaction represents the second closing under the Agreement, and was triggered upon the Company's achieving, as of the fourth fiscal quarter of 2005, certain financial milestones. The proceeds from the sale of the securities at the second closing 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. Midtown Partners & Co., LLC acted as the placement agent for this offering. As compensation for services rendered to the Company by Midtown for the second closing, the Company agreed to issued to Midtown two shares (face amount \$100,000) of its Series B Preferred and warrants to purchase a total of 155,738 shares of its Common Stock at an exercise price of \$.061 per share for a period of five years. The Company relied on Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated thereunder as the basis for its exemption from registration of this issuance. It is the Company's understanding that each of Crestview and Midtown is an accredited investor as defined under Rule 501 promulgated under the Securities Act of 1933. The Company did not engage in any public advertising or general solicitation in connection with the issuances of these securities.

On April 15, 2006, the Company issued an option to acquire 36,000 shares of common stock to one of the Company's non-employee directors: Alan Carus. The exercise price of the option is \$.75 per share, and the option vests in three equal annual installments beginning on April 15, 2006. Each option expires on April 15, 2011. The Company relied on Section 4(2) of the Securities Act of 1933 as the basis for its exemption from registration of this issuance.

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 annual report on Form 10-KSB filed with the Commission on March 31, 2005.

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: M a y B y : / s / Lawrence A.

1 2 Siebert

2006

Lawrence A. Siebert
Chief Executive
Officer
(Principal Executive
Officer)

Date: M a y B y : / s / Richard J.

1 2 Larkin

2006

Richard J. Larkin
Chief Financial
Officer
(Principal Financial
and Accounting
Officer)