

CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
May 06, 2010

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

FORM 10 - Q

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

For the quarterly period ended March 31, 2010

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 the Securities Exchange Act of 1934 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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

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

As of May 5, 2010, the Registrant had 61,996,151 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-Q For The Period Ended

March 31, 2010

Table of Contents

Chembio Diagnostics, Inc.

| | Page |
|---|-----------|
| Part I. FINANCIAL INFORMATION: | |
| Item 1. Financial Statements: | |
| Condensed Consolidated Balance Sheets as of March 31, 2010 (unaudited) and December 31, 2009. | 2 |
| Condensed Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2010 and 2009. | 3 |
| Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2010 and 2009. | 4 |
| Notes to Condensed Consolidated Financial Statements (unaudited) | 5 to 12 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 13 |
| Item 4. Controls and Procedures | 21 |
| Part II. OTHER INFORMATION: | |
| Item 6. Exhibits | 22 |
| SIGNATURES | 23 |
| EXHIBITS | |

PART I

Item 1. FINANCIAL STATEMENTS

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
AS OF

| - ASSETS - | March 31, 2010 (UNAUDITED) | December 31, 2009 |
|---|-------------------------------|---------------------|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 797,923 | \$ 1,068,235 |
| Accounts receivable, net of allowance for doubtful accounts of \$20,000 for 2010 and 2009 | 1,178,508 | 1,776,327 |
| Inventories | 1,979,561 | 1,555,903 |
| Prepaid expenses and other current assets | 284,930 | 266,637 |
| TOTAL CURRENT ASSETS | 4,240,922 | 4,667,102 |
| FIXED ASSETS, net of accumulated depreciation | 850,126 | 580,213 |
| OTHER ASSETS: | | |
| License agreements, net of current portion | 675,000 | 700,000 |
| Deposits on manufacturing equipment | 61,700 | 338,375 |
| Deposits and other assets | 36,226 | 29,560 |
| TOTAL ASSETS | \$ 5,863,974 | \$ 6,315,250 |
| - LIABILITIES AND STOCKHOLDERS' EQUITY - | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued liabilities | \$ 1,523,268 | \$ 1,906,163 |
| Current portion of loan payable | 9,670 | 9,600 |
| Deferred research and development revenue | 380,000 | 360,833 |
| License fee payable | 875,000 | 875,000 |
| Current portion of obligations under capital leases | 22,286 | 21,536 |
| TOTAL CURRENT LIABILITIES | 2,810,224 | 3,173,132 |
| OTHER LIABILITIES: | | |
| Loan payable - net of current portion | 12,488 | 14,931 |
| Obligations under capital leases - net of current portion | 33,412 | 39,273 |
| TOTAL LIABILITIES | 2,856,124 | 3,227,336 |

COMMITMENTS AND
CONTINGENCIES

STOCKHOLDERS' EQUITY:

| | | |
|--|------------------|------------------|
| Preferred stock – 10,000,000 shares authorized, none outstanding | - | - |
| Common stock - \$.01 par value; 100,000,000 shares authorized, 61,996,151 and 61,979,901 shares issued and outstanding for 2010 and 2009, respectively | 619,962 | 619,799 |
| Additional paid-in capital | 39,530,621 | 39,453,522 |
| Accumulated deficit | (37,142,733) | (36,985,407) |
| TOTAL STOCKHOLDERS' EQUITY | 3,007,850 | 3,087,914 |

| | | |
|---|---------------------|---------------------|
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 5,863,974 | \$ 6,315,250 |
|---|---------------------|---------------------|

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED
(UNAUDITED)

| | March 31, 2010 | March 31, 2009 |
|--|----------------------|----------------------|
| REVENUES: | | |
| Net product sales | \$ 2,214,897 | \$ 2,269,417 |
| License and royalty income | 21,496 | - |
| R&D contracts and grants | 547,022 | 276,181 |
| TOTAL REVENUES | 2,783,415 | 2,545,598 |
| Cost of product sales | 1,477,041 | 1,546,908 |
| GROSS PROFIT | 1,306,374 | 998,690 |
| OPERATING EXPENSES: | | |
| Research and development expenses | 800,758 | 647,372 |
| Selling, general and administrative expenses | 661,848 | 675,813 |
| | 1,462,606 | 1,323,185 |
| LOSS FROM OPERATIONS | (156,232) | (324,495) |
| OTHER INCOME (EXPENSES): | | |
| Interest income | 1,110 | 3,384 |
| Interest expense | (2,204) | (4,121) |
| | (1,094) | (737) |
| LOSS BEFORE INCOME TAXES | (157,326) | (325,232) |
| Provision for income taxes | - | - |
| NET LOSS | \$ (157,326) | \$ (325,232) |
| Basic loss per share | \$ (0.00) | \$ (0.01) |
| Diluted loss per share | \$ (0.00) | \$ (0.01) |
| Weighted average number of shares outstanding, basic | 61,986,165 | 61,944,901 |
| Weighted average number of shares outstanding, diluted | 61,986,165 | 61,944,901 |

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED
(UNAUDITED)

| | March 31, 2010 | March 31, 2009 |
|---|-------------------|----------------|
| INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS: | | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Cash received from customers | \$ 3,381,234 | \$ 2,732,577 |
| Cash paid to suppliers and employees | (3,572,214) | (2,495,973) |
| Interest received | 1,110 | 3,384 |
| Interest paid | (2,204) | (4,121) |
| Net cash (used in) provided by operating activities | (192,074) | 235,867 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Acquisition of fixed assets | (72,866) | (151,241) |
| Net cash used in investing activities | (72,866) | (151,241) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from option exercises | 2,112 | - |
| Payment of loan obligation | (2,373) | - |
| Payment of capital lease obligation | (5,111) | (4,458) |
| Net cash used in financing activities | (5,372) | (4,458) |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS | (270,312) | 80,168 |
| Cash and cash equivalents - beginning of the period | 1,068,235 | 1,212,222 |
| Cash and cash equivalents - end of the period | \$ 797,923 | \$ 1,292,390 |
| RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES: | | |
| Net loss | \$ (157,326) | \$ (325,232) |
| Adjustments: | | |
| Depreciation and amortization | 79,628 | 99,449 |
| Share based compensation | 75,150 | 17,184 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 597,819 | 186,979 |

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

| | | |
|---|---------------|------------|
| Inventories | (423,658) | 138,613 |
| Prepaid expenses and other current assets | (18,293) | (12,687) |
| Deposits and other assets | 18,334 | 36,045 |
| Accounts payable and accrued liabilities | (382,895) | (272,075) |
| Deferred research and development revenue | 19,167 | 367,591 |
| Net cash (used in) provided by operating activities | \$ (192,074) | \$ 235,867 |
| Supplemental disclosures for non-cash investing and financing activities: | | |
| Deposits on manufacturing equipment transferred to fixed assets | \$ 300,000 | \$ - |

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2010
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the “Company” or “Chembio”) and its subsidiary, Chembio Diagnostic Systems, Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company’s main products are three rapid tests for the detection of HIV antibodies in whole blood, serum and plasma samples, two of which were approved by the FDA in 2006; the third is sold for export only. Rapid HIV tests represented nearly 91% of the Company’s product revenues in the three months ended March 31, 2010. The Company also has other rapid tests that together represented approximately 9% of sales in the first three months of 2010. The Company’s products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments both domestically and internationally. Chembio’s products are sold under the Company’s STAT PAK®, SURE CHECK® or DPP® registered trademarks, or under the private labels of its marketing partners, for example the Clearview® label owned by Inverness Medical Innovations, Inc., which is the Company’s exclusive marketing partner for its rapid HIV lateral flow test products in the United States. These products employ lateral flow technologies that are proprietary and/or licensed to the Company. All of the Company’s products that are currently being developed are based on its patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. In 2008 and 2009, the Company completed development of its first four products that employ the DPP®, and the Company has a number of additional products under development that employ the DPP®.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The consolidated interim financial information as of March 31, 2010 and for the three-month periods ended March 31, 2010 and 2009 have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations, although we believe that the disclosures made are adequate to provide for fair presentation. The interim financial information should be read in conjunction with the Financial Statements and the notes thereto, included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2009, previously filed with the SEC.

In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present a fair statement of the Company’s consolidated financial position as of March 31, 2010, its consolidated results of operations for the three-month periods ended March 31, 2010 and 2009 and its cash flows for the three-month periods ended March 31, 2010 and 2009, as applicable, have been made. The interim results of operations are not necessarily indicative of the operating results for the full fiscal year or any future periods.

(b) Inventories:

Inventory consists of the following at:

| | (Audited) | |
|-----------------|----------------|----------------------|
| | March 31, 2010 | December 31, 2009 |
| Raw materials | \$ 1,034,828 | \$ 1,031,567 |
| Work in process | 255,117 | 184,081 |
| Finished goods | 689,616 | 340,255 |
| | \$ 1,979,561 | \$ 1,555,903 |

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2010
(UNAUDITED)

(c) Loss Per Share:

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

| | For the three months ended | |
|---------|----------------------------|----------------|
| | March 31, 2010 | March 31, 2009 |
| Basic | 61,986,165 | 61,944,901 |
| Diluted | 61,986,165 | 61,944,901 |

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-month periods ended March 31, 2010 and 2009 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 those periods. The following securities, presented on a common share equivalent basis for the three-month periods ended March 31, 2010 and 2009, have been excluded from the per share computations:

| | For the three months ended | |
|---------------|----------------------------|----------------|
| | March 31, 2010 | March 31, 2009 |
| 1999 and 2008 | | |
| Plan Stock | | |
| Options | 5,662,033 | 2,377,772 |
| Other Stock | | |
| Options | 124,625 | 124,625 |
| Warrants | 4,294,531 | 10,163,244 |
| | 10,081,189 | 12,665,641 |

(d) Employee Stock Option Plan:

The Company has a 1999 Stock Option Plan (“SOP”) that originally covered the potential issuance of options to purchase 1,500,000 shares of Common Stock. Under the terms of the SOP, the Compensation Committee of the Company’s Board is authorized to grant incentive options to key employees and to grant non-qualified options to key employees and other key individuals. The options become exercisable at such times and under such conditions as determined by the Compensation Committee. The SOP was amended at the Company’s 2005 stockholders’ meeting. The number of options under the SOP was increased to 3,000,000 shares of Common Stock. It was also amended to allow independent directors to be eligible for grants under the portion of the SOP concerning non-qualified options.

Effective June 3, 2008, the Company’s stockholders voted to approve the 2008 Stock Incentive Plan (“SIP”), with 5,000,000 shares of Common Stock. Under the terms of the SIP, the Compensation Committee of the Company’s Board has the discretion to select the persons to whom awards are to be granted. Awards can be incentive stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such

conditions as determined by the Compensation Committee. Stock option compensation expense represents the estimated fair value, at their respective dates of grant, of options outstanding which are being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the three-month periods ended March 31, 2010 and 2009 was \$.22 and none per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon the historical volatility of our stock. The expected term is determined using the simplified method as permitted by SAB 107, as the Company has limited history of employee exercise of options to date.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2010
(UNAUDITED)

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

| | For the three months ended | |
|--------------------------|-------------------------------|----------------------|
| | March 31, 2010 | March 31, 2009 |
| Expected term (in years) | 5 | n/a |
| Expected volatility | 116.82% | n/a |
| Expected dividend yield | n/a | n/a |
| Risk-free interest rate | 1.43% | n/a |

As a result of the adoption of ASC 718, the Company's results for the three-month periods ended March 31, 2010 and 2009 include share-based compensation expense totaling \$75,000 and \$17,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$8,000 and none, respectively), research and development (\$43,000 and \$7,000, respectively) and S,G&A expenses (\$24,000 and \$10,000, respectively). No income tax benefit has been recognized in the income statement for share-based compensation arrangements due to the history of operating losses.

Stock option compensation expense for the three-month periods ended March 31, 2010 and 2009 represent the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The following table provides stock option activity for the three months ended March 31, 2010:

| Stock Options | Number of Shares | Weighted Average Exercise Price per Share | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|--|---------------------|---|---|---------------------------------|
| Outstanding at January 1, 2009 | 2,416,650 | \$ 0.36 | 3.23 years | \$ - |
| Impact of re-price (for accounting purposes treated as a cancellation and re-issue): | | | | |
| effect as if cancelled | (1,252,750) | \$ 0.48 | | |
| effect as if re-issued | 1,252,750 | \$ 0.13 | | |
| Granted | 3,459,000 | \$ 0.13 | | |
| Exercised | (35,000) | \$ 0.13 | | |
| Forfeited/expired /cancelled | (253,750) | \$ 0.17 | | |
| Outstanding at December 31, 2009 | 5,586,900 | \$ 0.15 | 3.59 years | \$ 756,990 |
| Granted | 300,000 | \$ 0.27 | | |
| Exercised | (16,250) | \$ 0.13 | | |
| Forfeited/expired/cancelled | (36,000) | \$ 0.48 | | |

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

| | | | | |
|-------------------------------|-----------|---------|------------|------------|
| Outstanding at March 31, 2010 | 5,834,650 | \$ 0.16 | 3.46 years | \$ 442,274 |
| Exercisable at March 31, 2010 | 2,109,650 | \$ 0.14 | 2.22 years | \$ 125,024 |

As of March 31, 2010, there was \$199,000 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted average period of approximately 1.58 years. The total fair value of stock options vested during the three-month periods ended March 31, 2010 and 2009, was approximately \$22,000 and \$47,000, respectively.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2010
(UNAUDITED)

(e) Geographic Information:

U.S. GAAP 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 products and services, geographic areas, and major customers.

The Company produces only one group of similar products known collectively as “rapid medical tests”. Management believes that it operates in a single business segment. Net product sales by geographic area are as follows:

| | For the three months ended | |
|---------------|----------------------------|----------------|
| | March 31, 2010 | March 31, 2009 |
| Africa | \$ 496,891 | \$ 459,737 |
| Asia | 51,054 | 22,141 |
| Europe | 32,454 | 18,685 |
| Middle East | 26,943 | 32,047 |
| North America | 1,523,637 | 919,027 |
| South America | 83,918 | 817,780 |
| | \$ 2,214,897 | \$ 2,269,417 |

(f) Accounts payable and accrued liabilities

Accounts payable and accrued liabilities consist of:

| | March 31, 2010 | (Audited) |
|----------------------------------|---------------------|---------------------|
| | | December 31, 2009 |
| Accounts payable – suppliers | \$ 719,944 | \$ 662,739 |
| Accrued royalties / license fees | 444,669 | 612,709 |
| Accrued payroll | 67,810 | 114,234 |
| Accrued vacation | 124,605 | 99,057 |
| Accrued bonuses | - | 238,600 |
| Accrued expenses – other | 166,240 | 178,824 |
| TOTAL | \$ 1,523,268 | \$ 1,906,163 |

(g) Recent Accounting Pronouncements affecting the Company

Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities

In October 2009, the Financial Accounting Standards Board (“FASB”) issued guidance amending a previously issued accounting update. This guidance replaces the quantitative-based risks and rewards calculation for determining which reporting entity, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which reporting entity has the power to direct the activities of a variable interest entity that most significantly impact the entity’s economic performance. The amendments in this update also require additional disclosures about a reporting entity’s involvement in variable interest entities, which will enhance the information provided to users of financial statements. This Update is effective at the start of a reporting entity’s first fiscal year beginning after November 15, 2009. The adoption of this guidance has had no impact on the Company’s financial statements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2010
(UNAUDITED)

Fair Value Measurements

In January 2010, the FASB issued guidance which requires, in both interim and annual financial statements, for assets and liabilities that are measured at fair value on a recurring basis disclosures regarding the valuation techniques and inputs used to develop those measurements. It also requires separate disclosures of significant amounts transferred in and out of Level 1 and Level 2 fair value measurements and a description of the reasons for the transfers. The adoption of this guidance had no impact on the Company's financial statements.

Accounting for Distributions to Shareholders with Components of Stock and Cash

In January 2010, the FASB issued guidance which clarified that the stock portion of a distribution to shareholders that allows them to elect to receive cash or stock with a potential limitation on the total amount of cash that all shareholders can elect to receive in the aggregate is considered a share issuance that is reflected in earnings per share prospectively and is not a stock dividend. This update is effective for interim and annual periods ending on or after December 15, 2009, and should be applied on a retrospective basis. The adoption of this guidance had no impact on the Company's financial statements.

Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades

In April 2010, the FASB issued guidance which clarified that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity shares trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in this guidance are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. The Company is evaluating the impact that this guidance will have on its financial statements, if any.

NOTE 3 — DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

In January 2009, the Company received a refundable license fee of \$340,000 from Bio-Rad Laboratories, Inc., pursuant to a license agreement, related to a specific application of our DPP® technology. This license fee will become fully earned and non-refundable based upon certain future conditions being met and is currently deferred revenue. In addition the Company recognizes income from research projects and grants when earned. Grants are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of March 31, 2010, an aggregate of \$380,000 of advanced revenues was unearned.

NOTE 4 — VEHICLE FINANCING AND LICENSE FEE PAYABLE:

In June 2009, the Company purchased a vehicle for use by the CEO and obtained financing in the amount of \$29,228. The financing is for a period of 3 years, is secured by the vehicle and is guaranteed by the CEO. The

financing agreement provides for monthly principal and interest payments of \$849 and carries an interest rate of 2.9% per annum. The balance due on this loan as of March 31, 2010 was \$22,157.

In February 2008, the Company entered into a sublicense agreement (the "Agreement"), with Bio-Rad Laboratories, Inc. and Bio-Rad Pasteur (collectively, "Bio-Rad"). Bio-Rad is the exclusive licensee of the HIV-2 patent portfolio held by Institute Pasteur of Paris, France. Pursuant to the terms of the Agreement, Bio-Rad sublicensed to the Company patents related to the manufacture, use or sale of screening assays that detect HIV-2. In exchange for global non-exclusive rights to these patents, the Agreement initially provided that the Company will pay Bio-Rad a \$1,000,000 sublicense fee, \$500,000 payable during 2008, of which \$125,000 was paid and \$375,000 was payable by December 31, 2008, with the remaining \$500,000 being payable by December 31, 2009. On January 29, 2009, the Company and Bio-Rad agreed to amend the Agreement so as to defer the remaining \$875,000 of payments due under the Agreement to one payment due in December 2010. The Company will also pay Bio-Rad a royalty on net sales in the United States and Canada, if any, of Licensed Products sold under the Company's brands as defined in the Agreement. The Agreement will continue until the expiration of the last-to-expire of the sublicensed patents, unless otherwise terminated at an earlier date by the Company or Bio-Rad.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
 NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
 MARCH 31, 2010
 (UNAUDITED)

NOTE 5 — RIGHTS AGREEMENT:

In March 2010, the Company entered into a Rights Agreement dated March 8, 2010 (the "Rights Agreement") between the Company and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, the Company declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of Common Stock, \$0.01 par value (the "Common Stock"), of the Company. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2010, and the Rights shall be distributed to the Company's shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

Rights Initially Not Exercisable. The Rights are not exercisable until a Distribution Date. Until a Right is exercised, the holder thereof, as such, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

Separation and Distribution of Rights. The Rights will be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 15% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 15% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

For a more complete description of the material terms of the Rights Agreement and the rights to be issued pursuant thereto, please refer to Item 3.03 of the Company's Form 8-K Current Report filed with the S.E.C. on March 11, 2010.

NOTE 6 — COMMITMENTS AND CONTINGENCIES:

(a) Economic Dependency:

The following table discloses product sales the Company had to customers in excess of 10% of net product sales for the periods indicated:

| | For the three months ended | | Accounts Receivable | |
|-------|----------------------------|----------------|---------------------|----------------|
| | March 31, 2010 | March 31, 2009 | As of | |
| | % of | % of | | |
| Sales | Sales | Sales | Sales | March 31, 2010 |

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

| | | | | | | | | |
|------------|----|-----------|----|----|---------|----|----|---------|
| Customer 1 | \$ | 1,161,927 | 52 | \$ | 844,208 | 37 | \$ | 609,605 |
| Customer 2 | | * | * | | 793,200 | 35 | | - |
| Customer 3 | | * | * | | 370,278 | 16 | | - |

In the table above the asterisk (*) indicates that sales to the customer did not exceed 10% for the period indicated.

10

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2010
(UNAUDITED)

The following table discloses purchases the Company made from a vendor in excess of 10% of total purchases for the periods indicated:

| | For the three months ended | | Accounts Payable | | |
|----------|----------------------------|----------------|------------------|------------|------|
| | March 31, 2010 | March 31, 2009 | As of | | |
| | Purchases | % of Purc. | Purchases | % of Purc. | |
| Vendor 1 | \$ 107,663 | 14 | \$ 125,062 | 25 | \$ - |

The Company currently buys materials which are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which could adversely affect operating results.

(b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration, United States Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping are subject to review. After marketing approval has been granted, Chembio must continue to comply with governmental regulations. Failure to comply with these regulations can result in significant penalties.

(c) Agreement with Inverness:

On June 25, 2009, the Company and Inverness Medical Innovations, Inc. (Inverness) entered into a letter agreement whereby certain obligations aggregating approximately \$1,010,000 as of December 31, 2008 were agreed to be paid from future revenues. The obligations include the Company's share under its agreements with Inverness for the amount of HIV-2 royalties that Inverness paid when Inverness entered into an HIV-2 license agreement with Bio-Rad Laboratories, Inc. of approximately \$485,000 and royalties owed by Chembio on lateral flow licenses to Inverness of approximately \$525,000 as of December 31, 2008. Under the agreement Inverness will retain an additional 10% of Clearview® HIV 1/2 STAT-PAK® net sales and 5% of Clearview® Complete HIV 1/2 net sales until these obligations are extinguished. The approximate aggregate balance due is \$73,000 as of March 31, 2010.

(d) Employment Agreement:

The Company has employment contracts with two key employees. The contracts call for salaries presently aggregating \$510,000 per year. One contract expires in May 2012 and one contract expires in March 2013. In connection with the contract that expires March 2013, the Company issued 300,000 options to purchase common stock with one-third vesting immediately and one-third vesting on each of the second and third anniversaries of the grant.

(e) Equipment Purchase Commitment:

In June and November of 2009, the Company entered into agreements with a tooling manufacturer to design and build a tool for cassettes that house its tests. The estimated cost of \$113,800 is being paid in installments. As of March 31, 2010, an aggregate of \$61,700 has been paid for this tooling and is included in other assets on the Company's balance sheet.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2010
(UNAUDITED)

(f) Research and Development Projects and Grants:

The following is a list of major active R&D projects.

a. NIH Grant:

In June 2009, the Company received a \$3 million, three-year grant from the United States National Institutes of Health to complete development of a test for Leptospirosis. Grants are invoiced after expenses are incurred. In addition the Company has several development contracts with third parties related to its DPP® technology. These development projects are funded in advance and are presented as deferred revenue until earned.

b. Brazil:

On January 29, 2008, the Company signed three new technology transfer, supply and license agreements with the Bio-Manguinhos unit of the Oswaldo Cruz Foundation of Brazil ("FIOCRUZ") for products it has developed or has nearly completed development of.

On October 2, 2008, the Company signed a fourth technology transfer supply and license agreement with FIOCRUZ for its DPP® HIV 1/2 rapid test (for use with oral fluid or whole blood samples).

c. Bio-Rad:

On April 16, 2008, the Company announced a new development agreement with Bio-Rad Laboratories, N.A. ("Bio-Rad"). The agreement with Bio-Rad is for the development of a new multiplex product that would be developed on DPP® and which would be marketed exclusively by Bio-Rad under an exclusive limited DPP® license from Chembio to Bio-Rad limited to the field of application of this product. Our agreement with Bio-Rad contemplated that we were to enter into a license agreement subject to the satisfaction of certain development and other conditions. On January 19, 2009, Chembio granted, effective December 31, 2008, a limited exclusive license within a defined field of application for Chembio's DPP® technology to Bio-Rad. The license was granted following development milestones as set forth in the agreement mentioned above. As part of this agreement, in 2009, Chembio received \$340,000 from Bio-Rad as a license fee.

d. Battelle/CDC DPP® Influenza Immunity Test:

In December 2009, Chembio entered into a milestone-based development agreement for up to approximately \$900,000 in connection with the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplates a period of approximately nine months in which the development activity is to be completed. Chembio entered this agreement with Battelle Memorial Institute which has a master contract with the United States Centers for Disease Control and Prevention ("CDC") to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of CDC.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The terms "Chembio", "Company," "we", "us", and "our" refer to Chembio Diagnostics, Inc. and its subsidiary and consolidated entity, unless the context suggests otherwise.

Overview

This discussion and analysis should be read in conjunction with the accompanying Condensed Consolidated Financial Statements and related notes. The 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 generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP 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 ongoing basis we review our estimates and assumptions. Our estimates were based on our historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our critical accounting policies, the policies we believe are most important to the presentation of our financial statements and require the most difficult, subjective and complex judgments, are outlined below in "Critical Accounting Policies," and have not changed significantly from December 31, 2009.

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," "could", "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.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

The following Management Discussion And Analysis relates to the business of the Company, including its subsidiary, which develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. All of the Company's future products that are currently being developed are based on our patented Dual Path Platform (DPP®), which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology. The Company has completed development of five products that employ the DPP® technology, two of which will be marketed under Chembio's label (DPP® HIV 1/2 Screening Assay and DPP® Syphilis Screen & Confirm) and three that have been

developed specifically related to private label agreements with The Oswaldo Cruz Foundation (“FIOCRUZ”) for the Brazilian public health market, as explained below. The DPP® HIV Screening Assay, will be manufactured as an OEM product for the Brazilian market pursuant to one of our agreements with FIOCRUZ.

During the first quarter of 2010, the Company had a total of \$801,000 of research & development expenses, which expenses were comprised of \$167,000 of clinical & regulatory expenses and \$634,000 of research & development expenses which expenses also include personnel to assist in the transfer of newly developed products into the Company’s manufacturing operation and to otherwise provide technical support to the Company’s manufacturing operation. During the first quarter of 2010, the Company realized income in respect of research and development agreements and grants in the amount of \$547,000,

Therefore, while the Company increased its research and development expenses in the first quarter of 2010 versus the first quarter of 2009, it has more than offset these increased research and development expenses with income from research and development agreements and grants. While these agreements relate to products which in some cases are being developed on behalf of other companies or entities, in most cases the development agreements reserve the right for manufacturing to the Company. In addition, the Company is able to utilize these funded development programs to increase its proprietary capabilities.

The Company has a number of additional products under development that employ the DPP® technology. These product development activities are further described below.

Oswaldo Cruz Foundation OEM DPP® Agreements - During 2008 we signed four agreements with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to products based on our DPP® technology for Leptospirosis, Canine Leishmaniasis, screening for HIV 1/2 with oral fluid samples, and a 5-band multiplex point-of-care confirmation test for HIV 1&2. We now have completed development of all of these products; the Leptospirosis product is the latest product development to be completed. The other products have all been submitted for regulatory approval evaluations in Brazil and we expect the Leptospirosis product will be filed during the third quarter; although there can be no assurance, we believe that all of these products will be approved by Brazilian regulatory authorities (ANVISA for HIV and Leptospirosis tests and MAPA for canine test) during 2010, which would trigger initial orders as well as approximately \$1 million in technology transfer fee payments to the Company. During 2009, we received purchase orders aggregating approximately \$2.4 million from FIOCRUZ for the three products for which development had been completed and that are pending regulatory approval. These orders are subject to regulatory approval, of which there can be no assurance. If regulatory approval is obtained, we anticipate additional orders in 2011. We are currently considering entering additional agreements with FIOCRUZ based on a similar model in 2010. Recently, we have had some delays in the regulatory approval process for one of the products due to some issues relating to the specifications required for the product, which we believe will be resolved in order to obtain the anticipated approval.

Bio-Rad Laboratories OEM DPP® Agreement- On April 6, 2008, we entered a development agreement with Bio-Rad Laboratories N.A., a division of Bio-Rad Laboratories Inc (NYSE:BIO), a leading in-vitro diagnostic and life science company. The agreement with Bio-Rad is for the development of a six band multiplex product on our DPP®. We expect to complete development of this product during this second quarter of 2010 and proceed to manufacture products that will be used for regulatory submissions by Bio Rad.

Battelle/CDC DPP® Influenza Immunity Test – In December 2009 Chembio entered into a milestone-based development agreement for up to approximately \$900,000 in connection with the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplates a period of approximately nine months in which the development activity is to be completed. Chembio entered this agreement with Battelle Memorial Institute which has a master contract with the United States Centers for Disease Control and Prevention ("CDC") to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of the CDC. This program is proceeding on schedule.

DPP® Hepatitis C and DPP® Hepatitis C/HIV Oral Fluid Antibody Tests - Prototypes of these products have been developed and are being evaluated in a study that has been organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the CDC. The evaluation is scheduled to be completed during 2010 and the results should be useful in helping to ascertain the performance characteristics of these products in comparison to other products that will also be in this evaluation. Chembio's DPP® HIV 1/2 test is also being evaluated in this study.

DPP® Influenza –We have developed a prototype multiplex test for FLU A/B Antigen Detection. [This is not to be confused with the immune status antibody detection test we are developing for the U.S. CDC]. This prototype, if successfully developed into a commercial product, would be competitive to the current point-of-care FLU A/B products marketed by Quidel, Meridian, Binax (Inverness) and others. During the first quarter, we contracted with an independent lab to compare our prototype against certain competitive products. This step has helped to confirm that we can develop a test that performs better than the current market leaders, and there is therefore a significant opportunity to participate in this market. This product will be our first commercial antigen detection test on DPP®, and we believe that this has independent value to demonstrate the capabilities of our technology to access large markets beyond serological antibody detection markets. Our current plan is for development to be completed and initiation of our FDA 510(k) submission activities during 2010.

DPP® Leptospirosis – In June 2009, as we previously reported, we were awarded a three-year \$3 million Small Business Innovative Research (SBIR) Phase II grant from the United States National Institutes of Health (NIH) to fully develop, validate, and commercialize a rapid diagnostic test for Leptospirosis for general use worldwide, and our work is progressing on schedule. The test will be developed with DPP® and will utilize proprietary reagents developed by Cornell University and the Oswaldo Cruz Foundation at the Brazilian Ministry of Health. Development of the test will be in collaboration with the Division of Infectious Diseases, Weill Medical College, Cornell University in New York and the Oswaldo Cruz Foundation, the largest biomedical research institution in Latin America.

Other Research & Development Activities - Chembio continues to work with commercial, governmental and private organizations in order to obtain R&D contracts & grant funding for development projects. These programs have subsidized the Company's development expenses while expanding the applications for and know-how related to DPP® and creating important collaborative relationships.

In April 2009, we entered into a Services Agreement with the Infectious Disease Research Institute to develop DPP® products for Leishmaniasis and Leprosy for which we have received \$125,000 and which, subject to attainment of development milestones, is expected to provide us with approximately \$125,000 within the next six months. Under this agreement, we would receive an additional \$150,000 during the second year, subject to the attainment of development milestones.

We have other grant applications pending for which we submitted applications during the first quarter of 2010. There can be no assurance that any of these projects will continue, meet regulatory or other technical requirements and specifications, and/or that if continued, will result in completed products, or that such products, if successfully completed, will be successfully commercialized.

Platform Enhancements - In addition to the specific products we plan to commercialize we also are pursuing enhancements to our DPP® technology platform during 2010 and 2011. These enhancements include enabling a simplified test procedure, lowering the overall manufacturing costs, enabling development of combination antibody and antigen assays, and integrating molecular sample amplification systems with our detection system. We are active in each of these areas subject to available resources, and also are pursuing patent protection where applicable.

Patents - During the first quarter of 2010, the Company's Dual Path Immuno-Assay device which was granted a United States patent in 2007, received patent protection in the United Kingdom. During the first quarter of 2010 the Company received broader protection of its DPP technology in the U.S. through the issuance of a U.S. method patent for its DPP technology. The DPP technology has also been afforded patent protection in certain other foreign jurisdictions over the last year (Malaysia, Singapore and Eur-Asia), and patent protection is being actively prosecuted in all major markets globally.

Regulatory Activities

CE Mark for FDA approved HIV tests – We provided all testing and related documentation that was requested by our Notified Body during the second quarter, however additional data was requested in correspondence we received in January 2010. Based on the most recent dialog we have had with our Notified Body, we now believe we will be able to meet the CE Marking requirements for our two FDA approved rapid HIV tests. Further information is now being gathered to establish the cost and the timetable for completing this, but we were very encouraged by the most recent communication. Regulatory Approvals in Brazil through the Oswaldo Cruz Foundation (FIOCRUZ) – We now anticipate that FIOCRUZ will receive required approvals from its regulatory agencies during the second quarter of 2010 for the DPP® Leishmaniasis test, and the three products during 2010, however, there can be no assurance of this.

DPP® HIV 1/2 Screening Assay for Oral Fluid - We have commenced the clinical trials. We anticipate completing the clinical trials and submitting the PMA application during 2010, and receiving approval of the PMA.

DPP® Syphilis Screen & Confirm - We are preparing to commence clinical trials in connection with our planned 510(k) submission for this product during the third quarter of 2010. There is no point-of-care test for syphilis cleared for marketing in the United States, and we believe that our product, with its multiplexed capacity to identify both treponemal and non-treponemal markers, provides a reliable indication of an active, untreated case of syphilis at the point-of-care. We expect to receive data from an international evaluation soon and to receive CE Mark for this product during the third quarter of 2011.

The table below provides a preliminary summary estimated timetable for the regulatory approval and commercialization of the DPP® HIV Screening Assay and the DPP® Syphilis Screen & Confirm Assay in major markets. There can be no assurance that these dates will be accurate.

| Market | DPP® HIV 1/2 Screening Assay | DPP® Syphilis Screen & Confirm |
|------------------|---------------------------------|-----------------------------------|
| Developing World | 2010 | 2010 |
| CE Mark | 2nd Half 2011 | 2nd Half 2010 |
| US FDA | 2nd Half 2011 | 1st Half 2011 |

Recent Events

In January 2010, warrants to purchase an aggregate of 4,960,370 shares of common stock expired, at an average exercise price of \$.474. These warrants were related to the initial 2005 Series B Preferred Stock Offering (see Form 8-K filed on January 31, 2005 with the SEC for further details on this offering).

We entered into a lease effective February 1, 2010 for additional warehouse space.

In February 2010, the Company took possession of the automated assembly equipment (mentioned below under Equipment Purchase Commitment). This equipment is expected to provide for faster throughput and thereby increasing capacity of our manufacturing facility, in addition to reducing labor costs. The machine will need to go through a validation process and is expected to be in service during the second quarter of 2010.

The Company entered into an employment agreement dated March 4, 2010, to be effective March 5, 2010 (the "Employment Agreement"), with Mr. Esfandiari to continue as the Company's Senior Vice President of Research and Development for an additional term of three years. Please see Item 11 of our Form 10-K, filed with the SEC on March 5, 2010, for further details.

Critical Accounting Policies and Estimates

We believe that there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and the more significant areas involving management's judgments and estimates. These significant accounting policies relate to revenue recognition, research and development costs, valuation of inventory, valuation of long-lived assets, accounting for complex financial instruments and income taxes. For a summary of our significant accounting policies, which have not changed from December 31, 2009, see our annual report on Form 10-K for the twelve months ended December 31, 2009, which was filed with the SEC on March 5, 2010.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2010 AS COMPARED WITH THE THREE MONTHS ENDED MARCH 31, 2009

Revenues:

| Selected Product Categories: | For the three months ended | | | |
|------------------------------|----------------------------|----------------|------------|-----------|
| | March 31, 2010 | March 31, 2009 | \$ Change | % Change |
| HIV | \$ 2,007,333 | \$ 1,596,795 | \$ 410,538 | 25.71 % |
| DPP | - | 415,800 | (415,800) | -100.00 % |
| Other | 207,564 | 256,822 | (49,258) | -19.18 % |
| Net Product Sales | 2,214,897 | 2,269,417 | (54,520) | -2.40 % |
| License and royalty income | 21,496 | - | 21,496 | 100.00 % |
| R&D contracts and grants | 547,022 | 276,181 | 270,841 | 98.07 % |
| Total Revenues | \$ 2,783,415 | \$ 2,545,598 | \$ 237,817 | 9.34 % |

Revenues for our HIV tests and related components during the three months ended March 31, 2010 increased by approximately \$410,000 over the same period in 2009. This was primarily attributable to increased sales in North America, primarily from sales to Inverness of our HIV products which increased by \$318,000 to \$1,162,000 as well as sales to Mexico of \$275,000, partially offset by a decrease in sales to Brazil of \$258,000. The increase in R&D contracts and grants was due to revenue generated from grants and development contracts that are related to potential new products utilizing our patented DPP® technology. This included funds from our recent grants from NIH for Leptospirosis, which was effective as of June 1, 2009 and from Battelle for an influenza immunity test. License and royalty income represents our royalties from Brazil under our 2004 technology transfer and license agreement.

Gross Margin:

| Gross Margin related to Net Product Sales: | For the three months ended | | | |
|---|----------------------------|----------------|------------|----------|
| | March 31, 2010 | March 31, 2009 | \$ Change | % Change |
| Gross Margin per Statement of Operations | \$ 1,306,374 | \$ 998,690 | \$ 307,684 | 30.81 % |
| Less: R&D contracts and grants, license and royalties | 568,518 | 276,181 | 292,337 | 105.85 % |
| Gross Margin from Net Product Sales | \$ 737,856 | \$ 722,509 | \$ 15,347 | 2.12 % |
| Gross Margin % | 33.31 % | 31.84 % | | |

The increase in our gross margin resulted primarily from increased average unit prices on product sales as a result of the increased sales to Inverness, which are at higher average unit prices, and decreased sales to Africa, which are at

lower average unit prices.

Research and Development:

Research and development expenses include costs incurred for regulatory approvals, product evaluations and registrations.

| Selected expense lines: | For the three months ended | | | |
|---|----------------------------|-------------------|-------------------|----------------|
| | March 31, 2010 | March 31, 2009 | \$ Change | % Change |
| Clinical and Regulatory Affairs: | | | | |
| Wages and related costs | \$ 81,471 | \$ 65,549 | \$ 15,922 | 24.29 % |
| Consulting | 14,805 | 15,181 | (376) | -2.48 % |
| Share-based compensation | 4,667 | - | 4,667 | 100.00 % |
| Clinical trials | 56,750 | 1,780 | 54,970 | 3088.20 % |
| Other | 9,274 | 7,260 | 2,014 | 27.74 % |
| Total Regulatory | 166,967 | 89,770 | 77,197 | 85.99 % |
| R&D Other than Regulatory: | | | | |
| Wages and related costs | 424,593 | 354,714 | 69,879 | 19.70 % |
| Consulting | 9,982 | 17,432 | (7,450) | -42.74 % |
| Share-based compensation | 38,260 | 7,182 | 31,078 | 432.72 % |
| Materials and supplies | 107,260 | 110,782 | (3,522) | -3.18 % |
| Other | 53,696 | 67,492 | (13,796) | -20.44 % |
| Total other than Regulatory | 633,791 | 557,602 | 76,189 | 13.66 % |
| Total Research and Development | \$ 800,758 | \$ 647,372 | \$ 153,386 | 23.69 % |

Expenses for Clinical & Regulatory Affairs for the three months ended March 31, 2010 increased by \$77,000 as compared to the same period in 2009. This was primarily due to expenses we incurred in 2010 for clinical trials conducted for our DPP HIV Screen Assay. In addition, increases in wages and related costs also contributed to the increase.

R&D expenses other than Clinical & Regulatory Affairs increased by \$76,000 in the three months ended March 31, 2010 as compared with the same period in 2009 and were primarily related to an increase in personnel required to perform the work related to the funded research and development contracts and grants all related to our patented DPP® technology and an increase in the cost of share-based compensation related to the value of employee stock options issued and amortized. These increases were partially offset by a decrease in consulting and other costs.

Research and development expenses net of revenues from R&D contracts and grants (see sub-heading Revenues above) was \$254,000 for the three months ended March 31, 2010 (\$801,000 less \$547,000) compared to \$371,000 (\$647,000 less \$276,000) for the same period in 2009.

Selling, General and Administrative Expenses:

Selected expense
lines:

| | For the three months ended | | | |
|--|----------------------------|----------------|--------------|-----------|
| | March 31, 2010 | March 31, 2009 | \$ Change | % Change |
| Wages and related costs | \$ 240,455 | \$ 237,082 | \$ 3,373 | 1.42 % |
| Consulting | 55,876 | 61,742 | (5,866) | -9.50 % |
| Commissions | 17,549 | 83,963 | (66,414) | -79.10 % |
| Share-based compensation | 24,322 | 10,001 | 14,321 | 143.20 % |
| Marketing materials | 1,346 | 6,432 | (5,086) | -79.07 % |
| Investor relations | 37,403 | 3,039 | 34,364 | 1130.77 % |
| Legal, accounting and Sox 404 compliance | 175,628 | 160,360 | 15,268 | 9.52 % |
| Travel, entertainment and trade shows | 15,486 | 16,947 | (1,461) | -8.62 % |
| Other | 93,783 | 96,247 | (2,464) | -2.56 % |
| Total S, G &A | \$ 661,848 | \$ 675,813 | \$ (13,965) | -2.07 % |

Selling, general and administrative expenses for the three months ended March 31, 2010 decreased by 2% as compared with the same period in 2009. This was primarily due to a decrease in commissions as a result of lower sales in Brazil, partially offset by an increase in investor relation related expenses, an increase in the cost of share-based compensation related to the value of employee stock options issued and amortized and increased legal expenses. Some of the increase in investor relations and legal expenses include approximately \$37,000 that was related to the distribution of shares held by Crestview Capital to over 100 of its limited partners.

Other Income and (Expense):

| | For the three months ended | | | |
|----------------------------------|----------------------------|----------------|-------------|----------|
| | March 31, 2010 | March 31, 2009 | \$ Change | % Change |
| Interest income | \$ 1,110 | \$ 3,384 | \$ (2,274) | -67.20 % |
| Interest expense | (2,204) | (4,121) | 1,917 | -46.52 % |
| Total Other Income and (Expense) | \$ (1,094) | \$ (737) | \$ (357) | 48.44 % |

Other income and (expense) for the three months ended March 31, 2010 decreased approximately \$400 as compared with the same period in 2009, primarily as a result of a reduction in interest expense net of a decrease in interest income due to a decrease in interest rates in interest-bearing accounts.

LIQUIDITY AND CAPITAL RESOURCES

| | For the three months ended | | | |
|--|----------------------------|----------------|---------------|-----------|
| | March 31, 2010 | March 31, 2009 | \$ Change | % Change |
| Net cash provided by (used in) operating activities | \$ (192,074) | \$ 235,867 | \$ (427,941) | -181.43 % |
| Net cash used in investing activities | (72,866) | (151,241) | 78,375 | -51.82 % |
| Net cash used in financing activities | (5,372) | (4,458) | (914) | 20.50 % |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | \$ (270,312) | \$ 80,168 | \$ (350,480) | -437.18 % |

The Company had a decrease in cash for the three months ended March 31, 2010 as compared to an increase in cash for the same period in 2009. The decrease during the 2010 period is primarily attributable to cash used in operations. The increase in the 2009 period is primarily attributable to the cash provided by operations, including cash received of \$340,000 as deferred revenue. The decreased cash from operations in 2010 was primarily attributable to the increase in inventories of \$424,000 and a decrease in accounts payable of \$383,000. Partially offsetting this decrease was a decrease in accounts receivable of \$598,000. The Company's non-cash expenses totaled \$232,000, which is greater than the net loss for the period, and consisted of \$80,000 from depreciation expense, \$75,000 in share based compensation expense and \$77,000 in the amortization of licenses.

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

During the first quarter of 2010, U.S. market revenues constituted 52% of the Company's total revenues, as compared to 40% during the first quarter of 2009, continuing our favorable trend toward focusing on more profitable U.S. market opportunities in the rapid HIV test market. Although we knew that sales that we had during the first quarter of 2009 to FIOCRUZ relating to our 2004 technology transfer and supply agreement with FIOCRUZ would not be repeated during the first quarter of 2010, our 2010 plan contemplated that during the first quarter we would begin realizing initial fee and product sales revenues from our 2008 DPP® agreements with FIOCRUZ. However these revenues did not materialize as contemplated, though we believe they will materialize soon. Nevertheless, because Chembio's FDA approved rapid HIV tests continued to successfully penetrate the U.S. market, the non-recurrence of product sales to FIOCRUZ was mitigated through increased sales into the US market through our U.S. distributor, Inverness.

Our operating results during the first quarter of 2010 included more than \$232,000 of non-cash expenses, which exceeded the amount of our net loss of \$157,000. As a result, the decrease in cash of approximately \$270,000 was attributable to increased finished goods inventories that were produced, but not sold, during the first quarter. These inventories related to products we anticipate will be sold during the second quarter of 2010, although there can be no assurance of this.

Our business plan in general is to manage our expenditures related to our development, regulatory approval, and commercialization of our new DPP® products based on our current operating cash flow from our base business, and as supplemented by fees and contract development income we receive from our OEM, contract development agreements and grants.

We believe that our cash flow from these sources will enable us to move our development programs forward, as it did during the first quarter, however, there can be no assurance of this. Moreover, as we have seen for the last six months, there can be unanticipated delays in the timing of certain commercialization timetables (as has been the case with our programs in Brazil), which can be offset by better than anticipated results (as has been the case with our U.S. rapid HIV test sales and our resumption of sales to Nigeria last year).

Our ability to fully fund the commercialization of our new HIV, Syphilis and Influenza products, which will cost approximately \$3 million, will depend on our generating positive cash flow from our business or if deemed to be in the Company's interest, other financing sources. We have considered the issuance of common stock as one alternative way toward supplementing and/or insuring our ability to fully fund our business plan. The company is considering other financing alternatives, although there can be no assurance that any of these possibilities will occur or result in an outcome that is more or less favorable to the Company and/or its stockholders.

Our plan is to strive to achieve strong results in the remainder of 2010 by (1) continuing to pursue strong growth in our sales in the U.S. rapid HIV test market through Inverness; (2) realizing a significant increase in our grants and research development income as a result of new contracts we entered into last year which will more fully be reflected in our results this year; and (3) pursuing the receipt of fees and product revenues from our contracts with FIOCRUZ.

Equipment Purchase Commitment:

In June and November of 2009, the Company entered into agreements with a tooling manufacturer to design and build a tool for cassettes that house its tests. The estimated cost of \$113,800 is being paid in installments. As of March 31, 2010, an aggregate of \$61,700 has been paid for this tooling and is included in other assets on the Company's balance sheet.

ITEM 4. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures.** Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company's management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) **Changes in Internal Control over Financial Reporting.** There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the Company's first 2010 fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS.

| Number | Description |
|--------|---|
| 3.1 | Articles of Incorporation, as amended. (2) |
| 3.2 | Amended and Restated Bylaws. (1) |
| 4.1 | Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (6) |
| 4.2 | Amended Form of Common Stock Warrant issued pursuant to the January 26, 2005 Securities Purchase Agreement. (8) |
| 4.3 | Registration Rights Agreement, dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (8) |
| 4.4 | Form of Warrant, dated June 29, 2006, issued pursuant to Company and purchasers of the Company's Secured Debentures. (6) |
| 4.5 | Registration Rights Agreement, dated June 29, 2006. (3) |
| 4.6 | Registration Rights Agreement, dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (3) |
| 4.7 | Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated September 29, 2006 (5). |
| 4.8 | Amended Form of Common Stock Warrant issued pursuant to the Securities Purchase Agreements dated October 5, 2006. (5) |
| 4.9 | Amended Form of Common Stock Warrant issued to Placement Agents pursuant to the October 5, 2005 Securities Purchase Agreement. (8) |
| 4.10* | Form of Employee Option Agreement. (8) |
| 4.11 | 1999 Equity Incentive Plan. (9) |
| 4.12 | 2008 Stock Incentive Plan. (10) |
| 4.21 | Rights Agreement, dated March 8, 2010 (11) |
| 4.22 | Form of Warrant (to be filed by amendment) |
| 10.1* | Employment Agreement dated June 15, 2006 with Lawrence A. Siebert. (4) |
| 10.2* | Employment Agreement dated March 5, 2010 with Javan Esfandiari. (12) |
| 10.3 | Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of January 26, 2005, by and among the Registrant and the purchasers listed therein. (6) |
| 10.4 | Amendment No. 1 to Securities Purchase Agreement, dated as of January 28, 2005 by and among the Registrant and the purchasers listed therein. (7) |
| 10.5 | Security Purchase Agreement, dated June 29, 2006, among the Company and purchasers of the Company's Secured Debentures. (3) |
| 10.6 | Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5) |
| 10.7 | Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of September 29, 2006, by and among the Registrant and the Purchasers listed therein. (5) |
| 10.8 | Letter of Amendment to Securities Purchase Agreements dated as of September 29, 2006 by and among the Registrant and the Purchasers listed therein. (5) |
| 10.9 | HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Inverness and StatSure. (5) |
| 10.1 | HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5) |
| 10.11 | Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Inverness. (5) |
| 10.12 | Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (5) |
| 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 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.
 - 2 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 31, 2005.
 - 3 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on July 3, 2006.
 - 4 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 21, 2006.
 - 5 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.
 - 6 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 31, 2005.
 - 7 Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-123600) filed with the Commission on March 28, 2005.
 - 8 Incorporated by reference to the Registrant's annual report on Form 10-KSB filed with the Commission on March 12, 2008.
 - 9 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on May 11, 2005.
 - 10 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 14, 2008.
 - 11 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on March 11, 2010.
 - 12 Incorporated by reference to the Registrant's registration statement on Form S-1/A (File No. 333-138266) filed with the Commission on March 11, 2010.

(*) An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this registration statement.

SIGNATURES

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

Chembio Diagnostics, Inc.

Date: May 6, By: /s/ Lawrence A. Siebert
2010

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

Date: May 6, By: /s / Richard J. Larkin
2010

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