

CHEMBIO DIAGNOSTICS, INC.

Form 10-Q

July 29, 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 June 30, 2010

000-30379

(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada 88-0425691
(State or other (IRS Employer
jurisdiction of Identification
incorporation) 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 July 27, 2010, the Registrant had 62,138,151 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-Q For The Period Ended

June 30, 2010

Table of Contents

Chembio Diagnostics, Inc.

| | Page |
|--|-----------|
| Part I. FINANCIAL INFORMATION: | |
| Item 1. Financial Statements: | |
| Condensed Consolidated Balance Sheets as of June 30, 2010 (unaudited) and December 31, 2009. | 2 |
| Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2010 and 2009. | 3 |
| Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2010 and 2009. | 4 |
| Notes to Condensed Consolidated Financial Statements (unaudited) | 5 to 15 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 16 |
| Item 4. Controls and Procedures | 28 |
| Part II. OTHER INFORMATION: | |
| Exhibits | 29 |
| SIGNATURES | 30 |
| EXHIBITS | |

PART I

Item 1. FINANCIAL STATEMENTS

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

| | - ASSETS - | |
|---|------------------------------|---------------------|
| | June 30, 2010 (UNAUDITED) | December 31, 2009 |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 746,848 | \$ 1,068,235 |
| Accounts receivable, net of allowance for doubtful accounts of \$20,000 for 2010 and 2009 | 1,817,284 | 1,776,327 |
| Inventories | 1,849,708 | 1,555,903 |
| Prepaid expenses and other current assets | 300,790 | 266,637 |
| TOTAL CURRENT ASSETS | 4,714,630 | 4,667,102 |
| FIXED ASSETS, net of accumulated depreciation | 853,181 | 580,213 |
| OTHER ASSETS: | | |
| License agreements, net of current portion | 650,000 | 700,000 |
| Deposits on manufacturing equipment | 52,824 | 338,375 |
| Deposits and other assets | 36,226 | 29,560 |
| TOTAL ASSETS | \$ 6,306,861 | \$ 6,315,250 |
| - LIABILITIES AND STOCKHOLDERS' EQUITY - | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued liabilities | \$ 1,310,745 | \$ 1,906,163 |
| Current portion of loans payable | 54,852 | 9,600 |
| Deferred research and development revenue | 115,006 | 360,833 |
| License fee payable | 875,000 | 875,000 |
| Current portion of obligations under capital leases | 23,062 | 21,536 |
| TOTAL CURRENT LIABILITIES | 2,378,665 | 3,173,132 |
| OTHER LIABILITIES: | | |
| Loans payable - net of current portion | 214,113 | 14,931 |
| Obligations under capital leases - net of current portion | 27,347 | 39,273 |
| TOTAL LIABILITIES | 2,620,125 | 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, 62,138,151 and 61,979,901 shares issued and outstanding for 2010 and 2009, respectively | 621,382 | 619,799 |
| Additional paid-in capital | 39,586,170 | 39,453,522 |
| Accumulated deficit | (36,520,816) | (36,985,407) |
| TOTAL STOCKHOLDERS' EQUITY | 3,686,736 | 3,087,914 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 6,306,861 | \$ 6,315,250 |

See accompanying notes to condensed consolidated financial statements

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

| | For the three months ended | | For the six months ended | |
|--|----------------------------|-------------------|--------------------------|----------------------|
| | June 30, 2010 | June 30, 2009 | June 30, 2010 | June 30, 2009 |
| REVENUES: | | | | |
| Net product sales | \$ 2,335,665 | \$ 3,051,385 | \$ 4,550,562 | \$ 5,320,801 |
| License and royalty income | 717,472 | 52,322 | 738,968 | 52,322 |
| R&D contracts and grants | 696,305 | 269,817 | 1,243,328 | 545,999 |
| TOTAL REVENUES | 3,749,442 | 3,373,524 | 6,532,858 | 5,919,122 |
| Cost of product sales | 1,654,476 | 2,011,579 | 3,131,518 | 3,558,488 |
| GROSS MARGIN | 2,094,966 | 1,361,945 | 3,401,340 | 2,360,634 |
| OPERATING EXPENSES: | | | | |
| Research and development expenses | 791,596 | 702,986 | 1,592,354 | 1,350,358 |
| Selling, general and administrative expenses | 680,014 | 542,449 | 1,341,862 | 1,218,262 |
| | 1,471,610 | 1,245,435 | 2,934,216 | 2,568,620 |
| INCOME (LOSS) FROM OPERATIONS | 623,356 | 116,510 | 467,124 | (207,986) |
| OTHER INCOME (EXPENSES): | | | | |
| Other expense | - | (6,696) | - | (6,696) |
| Interest income | 618 | 1,531 | 1,729 | 4,915 |
| Interest expense | (2,057) | (1,406) | (4,262) | (5,527) |
| | (1,439) | (6,571) | (2,533) | (7,308) |
| INCOME (LOSS) BEFORE INCOME TAXES | 621,917 | 109,939 | 464,591 | (215,294) |
| Provision for income taxes | - | - | - | - |
| NET INCOME (LOSS) | \$ 621,917 | \$ 109,939 | \$ 464,591 | \$ (215,294) |
| Basic earnings (loss) per share | \$ 0.01 | \$ 0.00 | \$ 0.01 | \$ (0.00) |

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

| | | | | |
|--|------------|------------|------------|------------|
| Diluted earnings (loss) per share | \$ 0.01 | \$ 0.00 | \$ 0.01 | \$ (0.00) |
| Weighted average number of shares outstanding, basic | 62,070,736 | 61,944,901 | 62,028,450 | 61,944,901 |
| Weighted average number of shares outstanding, diluted | 70,614,048 | 74,814,205 | 71,340,820 | 61,944,901 |

See accompanying notes to condensed consolidated financial statements

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

| | June 30, 2010 | June 30, 2009 |
|---|---------------|---------------|
| INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS: | | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Cash received from customers | \$ 6,491,901 | \$ 6,088,328 |
| Cash paid to suppliers and employees | (6,922,455) | (5,239,948) |
| Interest received | 1,110 | 4,915 |
| Interest paid | (2,204) | (5,527) |
| Net cash (used in) provided by operating activities | (431,648) | 847,768 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Proceeds from sale of fixed assets | - | 13,750 |
| Acquisition of fixed assets | (144,345) | (234,830) |
| Net cash used in investing activities | (144,345) | (221,080) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from option exercises | 20,572 | - |
| Proceeds from loan | 250,000 | 29,228 |
| Payment of loan obligation | (5,566) | - |
| Payment of capital lease obligation | (10,400) | (9,069) |
| Net cash provided by financing activities | 254,606 | 20,159 |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS | | |
| | (321,387) | 646,847 |
| Cash and cash equivalents - beginning of the period | 1,068,235 | 1,212,222 |
| Cash and cash equivalents - end of the period | \$ 746,848 | \$ 1,859,069 |
| RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES: | | |
| Net income (loss) | \$ 464,591 | \$ (215,294) |
| Adjustments: | | |
| Depreciation and amortization | 148,052 | 191,999 |

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

| | | |
|---|---------------|------------|
| Loss on sale of fixed asset | - | 6,696 |
| Share based compensation | 113,659 | 91,850 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (40,957) | 198,434 |
| Inventories | (293,805) | 166,187 |
| Prepaid expenses and other current assets | (34,153) | (23,178) |
| Deposits and other assets | 52,210 | 74,510 |
| Accounts payable and accrued liabilities | (595,418) | (138,184) |
| Deferred research and development revenue | (245,827) | 494,748 |
| Net cash (used in) provided by operating activities | \$ (431,648) | \$ 847,768 |

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
JUNE 30, 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 six months ended June 30, 2010. The Company also has other rapid tests that together represented approximately 9% of sales in the first six 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 Alere North America, Inc. (“Alere”, formerly 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, 2009 and the first six months of 2010, 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 June 30, 2010 and for the three and six-month periods ended June 30, 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, which are 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 June 30, 2010, its consolidated results of operations for the three and six-month periods ended June 30, 2010 and 2009 and its cash flows for the six-month periods ended June 30, 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) Revenue Recognition

The Company recognizes revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition” (“SAB 104”). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of

discounts, rebates and returns.

For certain contracts the Company recognizes revenue from R&D contracts and grants when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

For certain collaborative research projects the Company recognizes revenue by defining milestones at the inception of the agreement and determining when it may be appropriate to apply the milestone method of revenue recognition.

Any projects or grants funded in advance are deferred until earned. As of June 30, 2010, an aggregate of \$115,000 of advanced revenues was unearned.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2010
(UNAUDITED)

(c) Inventories:

Inventories consists of the following at:

| | (Audited) | |
|-----------------|--------------|--------------|
| | December 31, | |
| June 30, 2010 | 2009 | |
| Raw materials | \$ 869,670 | \$ 1,031,567 |
| Work in process | 273,909 | 184,081 |
| Finished goods | 706,129 | 340,255 |
| | \$ 1,849,708 | \$ 1,555,903 |

(d) Earnings (Loss) Per Share:

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

| | For the three months ended | | For the six months ended | |
|---------|----------------------------|---------------|--------------------------|---------------|
| | June 30, 2010 | June 30, 2009 | June 30, 2010 | June 30, 2009 |
| Basic | 62,070,736 | 61,944,901 | 62,028,450 | 61,944,901 |
| Diluted | 70,614,048 | 74,814,205 | 71,340,820 | 61,944,901 |

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted income (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 six-month period ended June 30, 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 that period. The following securities, presented on a common share equivalent basis for the three-month periods ended June 30, 2010 and 2009 and the six-month period ended June 30, 2010, were included in computing diluted earnings per share; for the six month period ending June 30, 2009, these were excluded from the diluted loss per share computation:

| | For the three months ended | | For the six months ended | |
|---------------------|----------------------------|---------------|--------------------------|---------------|
| | June 30, 2010 | June 30, 2009 | June 30, 2010 | June 30, 2009 |
| 1999 and 2008 Plan | | | | |
| Stock Options | 5,704,933 | 4,140,554 | 5,683,602 | 3,264,033 |
| Other Stock Options | 124,625 | 124,625 | 124,625 | 124,625 |
| Warrants | 2,713,754 | 8,604,125 | 3,504,143 | 9,383,684 |
| | 8,543,312 | 12,869,304 | 9,312,370 | 12,772,342 |

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

(e) 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.

The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six-month periods ended June 30, 2010 and 2009 was \$.22 and \$.09 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.

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

| | For the three months ended | | For the six months ended | |
|--------------------------|----------------------------|------------------|--------------------------|------------------|
| | June 30, 2010 | June 30, 2009 | June 30, 2010 | June 30, 2009 |
| Expected term (in years) | n/a | 4 | 5 | 4 |
| Expected volatility | n/a | 123.81% | 116.82% | 123.81% |
| Expected dividend yield | n/a | n/a | n/a | n/a |
| Risk-free interest rate | n/a | 2.98% | 1.43% | 1.81-1.95% |

The Company's results for the six-month periods ended June 30, 2010 and 2009 include share-based compensation expense totaling \$114,000 and \$92,000, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within cost of goods sold (\$13,000 and \$9,000, respectively), research and development (\$60,000 and \$36,000, respectively) and selling, general and administrative expenses (\$41,000 and \$47,000, respectively). No income tax benefit has been recognized in the statement of operations for share-based compensation arrangements due to the history of operating losses.

Stock option compensation expense for the six-month periods ended June 30, 2010 and 2009 represents 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.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(UNAUDITED)

The following table provides stock option activity for the six months ended June 30, 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 | (158,250) | \$ 0.13 | | |
| Forfeited/expired/cancelled | (97,250) | \$ 0.26 | | |
| Outstanding at June 30, 2010 | 5,631,400 | \$ 0.16 | 3.29 years | \$ 734,925 |
| Exercisable at June 30, 2010 | 3,064,725 | \$ 0.13 | 2.75 years | \$ 377,924 |

As of June 30, 2010, there was \$158,000 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 1.33 years. The total fair value of stock options vested during the six-month periods ended June 30, 2010 and 2009, was approximately \$125,000 and \$107,000, respectively.

(f) Geographic Information:

U.S. GAAP establishes standards for the manner in which 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 | | For the six months ended | |
|-------------|----------------------------|---------------|--------------------------|---------------|
| | June 30, 2010 | June 30, 2009 | June 30, 2010 | June 30, 2009 |
| Africa | \$ 820,980 | \$ 999,048 | \$ 1,317,871 | \$ 1,458,785 |
| Asia | 33,457 | 72,458 | 84,511 | 94,599 |
| Europe | 28,178 | 27,087 | 60,632 | 45,772 |
| Middle East | 76,192 | 60,949 | 103,135 | 92,996 |

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

| | | | | |
|---------------|-----------|-----------|-----------|-----------|
| North America | 1,344,134 | 1,252,338 | 2,867,771 | 2,171,365 |
| South America | 32,724 | 639,505 | | |