

CHEMBIO DIAGNOSTICS, INC.
Form 10-Q
August 11, 2016

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, 2016

OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: _____ to _____

000-30379
(Commission File Number)

Chembio Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Nevada 88-0425691
(State or other jurisdiction of incorporation) (IRS Employer Identification Number)

3661 Horseblock Road
Medford, New York 11763
(Address of principal executive offices including zip code)
(631) 924-1135
(Registrant's telephone number, including area code)

N/A
(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

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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. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a 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 August 8, 2016, the Registrant had 11,986,242 shares outstanding of its \$.01 par value common stock.

Quarterly Report on FORM 10-Q
For The Quarterly Period Ended
June 30, 2016

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PART I

Item 1. FINANCIAL STATEMENTS

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

	June 30, 2016 (Unaudited)	December 31, 2015
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$1,439,869	\$5,376,931
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at June 30, 2016 and December 31, 2015, respectively	4,579,553	2,422,971
Inventories	3,481,819	3,578,025
Prepaid expenses and other current assets	860,340	1,256,879
TOTAL CURRENT ASSETS	10,361,581	12,634,806
FIXED ASSETS, net of accumulated depreciation	2,035,666	2,374,308
OTHER ASSETS:		
Deferred tax asset, net of valuation allowance	-	5,467,143
License agreements, net of current portion	50,000	100,000
Deposits on manufacturing equipment	52,968	30,918
Deposits and other assets	189,064	209,169
TOTAL ASSETS	\$12,689,279	\$20,816,344
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$2,708,362	\$2,801,432
Deferred revenue	818,848	353,406
TOTAL LIABILITIES	3,527,210	3,154,838
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized; 9,686,242 and 9,628,248 shares issued and outstanding for June 30, 2016 and December 31, 2015, respectively	96,862	96,282
Additional paid-in capital	48,041,697	47,890,642
Accumulated deficit	(38,976,490)	(30,325,418)
TOTAL STOCKHOLDERS' EQUITY	9,162,069	17,661,506
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$12,689,279	\$20,816,344

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, 2016	June 30, 2015	June 30, 2016	June 30, 2015
REVENUES:				
Net product sales	\$2,034,072	\$6,321,554	\$7,951,091	\$11,936,239
License and royalty revenue	33,895	7,882	56,096	14,933
R&D, milestone and grant revenue	1,198,438	386,722	1,860,317	996,123
TOTAL REVENUES	3,266,405	6,716,158	9,867,504	12,947,295
Cost of product sales	1,686,100	3,697,026	5,121,651	7,241,545
GROSS MARGIN	1,580,305	3,019,132	4,745,853	5,705,750
OPERATING EXPENSES:				
Research and development expenses	2,367,466	1,757,007	4,001,764	3,341,543
Selling, general and administrative expenses	1,598,813	2,160,096	3,598,217	4,137,670
	3,966,279	3,917,103	7,599,981	7,479,213
LOSS FROM OPERATIONS	(2,385,974)	(897,971)	(2,854,128)	(1,773,463)
OTHER INCOME:				
Interest income	1,310	316	3,874	1,491
	1,310	316	3,874	1,491
LOSS BEFORE INCOME TAXES	(2,384,664)	(897,655)	(2,850,254)	(1,771,972)
Income tax expense (benefit)	5,962,818	(233,570)	5,800,818	(461,070)
NET LOSS	\$(8,347,482)	\$(664,085)	\$(8,651,072)	\$(1,310,902)
Basic loss per share	\$(0.86)	\$(0.07)	\$(0.90)	\$(0.14)
Diluted loss per share	\$(0.86)	\$(0.07)	\$(0.90)	\$(0.14)
Weighted average number of shares outstanding, basic	9,667,543	9,627,951	9,649,612	9,623,773
Weighted average number of shares outstanding, diluted	9,667,543	9,627,951	9,649,612	9,623,773

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, 2016	June 30, 2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$8,176,364	\$12,274,330
Cash paid to suppliers and employees	(12,036,793)	(14,441,822)
Interest received	3,874	1,491
Net cash used in operating activities	(3,856,555)	(2,166,001)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of License	-	(450,000)
Acquisition of and deposits on fixed assets	(85,877)	(434,466)
Net cash used in investing activities	(85,877)	(884,466)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	5,370	-
Net cash provided by financing activities	5,370	-
DECREASE IN CASH AND CASH EQUIVALENTS		
Cash and cash equivalents - beginning of the period	(3,937,062)	(3,050,467)
	5,376,931	4,614,538
Cash and cash equivalents - end of the period	\$1,439,869	\$1,564,071
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	\$(8,651,072)	\$(1,310,902)
Adjustments:		
Depreciation and amortization	580,159	665,672
Deferred taxes	5,800,818	(461,070)
Share based compensation	146,265	195,591
Changes in assets and liabilities:		
Accounts receivable	(2,156,582)	(528,642)
Inventories	96,206	(143,405)
Prepaid expenses and other current assets	(46,226)	(234,083)
Deposits and other assets	1,505	-
Accounts payable and accrued liabilities	(93,070)	(204,839)
Customer deposits and deferred revenue	465,442	(144,323)
Net cash used in operating activities	\$(3,856,555)	\$(2,166,001)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	\$43,590	\$20,017

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. (the "Company" or "Chembio") and its wholly-owned subsidiary, Chembio Diagnostic Systems Inc., develop, manufacture, and market rapid diagnostic tests that detect infectious diseases. The Company's main lateral flow 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. In addition the Company has several products based on its patented Dual Path Platform (DPP®) technology, including a HIV test approved by the FDA in 2013 and CLIA-Waived in 2014. Lateral Flow Rapid HIV tests represented 53% of the Company's product revenues in the first six months of 2016. The Company's products based on its DPP® platform represented approximately 44% of the Company's product revenues in the first six months of 2016. The Company also has other rapid tests and components that together represented approximately 3% of product sales in the first six months of 2016. 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®, STAT-VIEW® or DPP® registered trademarks, or under the private labels of its marketing partners. All of the Company's products that are currently being developed are based on its patented DPP®, which is a unique diagnostic point-of-care platform that has certain advantages over lateral flow technology.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a) Basis of Presentation:

The preceding (a) condensed consolidated balance sheet as of December 31, 2015, which has been derived from audited financial statements, and (b) the unaudited interim condensed consolidated financial statements as of June 30, 2016 and for the three and six-month periods ended June 30, 2016 and 2015, respectively, have been prepared 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, 2015, 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 condensed consolidated financial position as of June 30, 2016, its condensed consolidated results of operations for the three and six-month periods ended June 30, 2016 and 2015, respectively, and its condensed consolidated cash flows for the six-month periods ended June 30, 2016 and 2015, 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.

The Company currently has positive working capital, however, it has used approximately \$3.9 million in cash for the six months ended June 30, 2016, see Note 8. Approximately \$3.4 million of the total \$4.6 million of accounts receivable is comprised from one customer, and the Company has a high degree of confidence that the receivables are fairly stated and collectible from this customer.

b) Revenue Recognition

The Company recognizes revenue for product sales in accordance with ASC 605, which provides that 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 non-milestone payments and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned. Deferred revenues not earned were \$818,848 and \$353,406 as of June 30, 2016 and December 31, 2015, respectively.

The Company follows Financial Accounting Standards Board ("FASB") authoritative guidance ("guidance") prospectively for the recognition of revenue under the milestone method. The Company applies the milestone method of revenue recognition for certain collaborative research projects defining milestones at the inception of the agreement.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

(UNAUDITED)

c) Inventories:

Inventories consist of the following at:

	June 30, 2016	December 31, 2015
Raw materials	\$2,004,357	\$2,248,371
Work in process	609,548	370,340
Finished goods	867,914	959,314
	\$3,481,819	\$3,578,025

d) Earnings Per Share:

Basic earnings per share is computed by dividing net income or loss by the weighted-average number of common shares outstanding for the period. Diluted income per share reflects the potential dilution from the exercise or conversion of other securities into common stock, but only if dilutive. The following securities, presented on a common share equivalent basis for the three- and six-month periods ended June 30, 2016 and 2015, have been included in the earnings per share computations:

	For the three months ended		For the six months ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Basic	9,667,543	9,627,951	9,649,612	9,623,773
Diluted	9,667,543	9,627,951	9,649,612	9,623,773

As there were losses for the three and six months ended June 30, 2016 and 2015, no common share equivalents are included in the diluted per share computations.

There were 667,995 and 651,768 weighted-average number of options outstanding as of June 30, 2016 and 2015, respectively, that were not included in the calculation of diluted per common share equivalent for the three months ended June 30, 2016 and 2015 respectively. There were 708,514 and 667,082 weighted-average number of options outstanding as of June 30, 2016 and 2015, respectively, that were not included in the calculation of diluted per common share equivalent for the six months ended June 30, 2016 and 2015, respectively, because the effect would have been anti-dilutive as of June 30, 2016 and 2015, respectively.

e) Employee Stock Option Plans and Share-Based Compensation:

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), initially with 625,000 shares of Common Stock available to be issued. At the Annual Stockholder meeting on September 22, 2011, the Company's stockholders voted to approve an increase to the shares of Common Stock issuable under the SIP by 125,000 to 750,000. 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 and the number of shares of common stock to be covered by each grant. 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 at the time of the initial stock option grant. As of June 30, 2016, there were 411,929 options exercised and 286,806 options

outstanding under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("2014-SIP"), with 800,000 shares of Common Stock available to be issued. Under the terms of the 2014-SIP, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted and the number of shares of common stock to be covered by each grant. 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 at the time of the initial stock option grant. As of June 30, 2016, there were no options exercised, 129,750 options outstanding and 670,250 options or shares still available to be issued under the 2014-SIP.

There were 106,875 stock options granted during the six months ended June 30, 2016 and none for the six months ended 2015. The weighted average estimated fair value, at their respective dates of grant, of stock options granted in the six months ended June 30, 2016, was \$2.77 per share. 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 based on historical information.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

(UNAUDITED)

The assumptions made in calculating the fair values of options granted during the periods indicated are as follows:

	For the three months ended		For the six months ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Expected term (in years)	4.5	n/a	4.5 to 5.0	n/a
Expected volatility	43.00 %	n/a	43.00% to 48.66%	n/a
Expected dividend yield	0 %	n/a	0 %	n/a
Risk-free interest rate	0.90 %	n/a	0.90 % to 0.97%	n/a

The Company's results for the three-month periods ended June 30, 2016 and 2015 include share-based compensation expense, consisting solely of stock options, totaling \$92,677 and \$86,282, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development (\$27,300 and \$14,800, respectively) and selling, general and administrative expenses (\$65,400 and \$71,400, respectively). The results for the six-month periods ended June 30, 2016 and 2015 include share-based compensation expense, consisting solely of stock options, totaling \$146,265 and \$195,591, respectively. Such amounts have been included in the Condensed Consolidated Statements of Operations within research and development (\$34,700 and \$33,000, respectively) and selling, general and administrative expenses (\$111,500 and \$162,600, respectively). An operating expense, resulting in income tax benefit, has been recognized in the statement of operations for share-based compensation arrangements.

Stock option compensation expense for the three and six months ended June 30, 2016 and 2015 is based on the estimated fair value, at the date of issuance, of options outstanding, which is being amortized on a straight-line basis over the requisite service period for each vesting portion of the award. Accordingly, for stock options that vested immediately, the estimated fair value was expensed immediately.

The following table provides stock option activity for the six months ended June 30, 2016:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Stock Options Outstanding at December 31, 2015	649,478	\$ 3.75	3.21 years	\$ 1,032,362
Granted	106,875	7.05		
Exercised				