

CHEMBIO DIAGNOSTICS, INC.  
Form 10-Q  
August 08, 2018

---

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

---

FORM 10 - Q

---

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

For the quarterly period ended June 30, 2018

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  
(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)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer”, “accelerated filer”, “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Yes No

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

Yes No

As of August 2, 2018, the Registrant had 14,173,620 shares outstanding of its \$.01 par value common stock.

---

---

Quarterly Report on FORM 10-Q  
For The Quarterly Period Ended  
June 30, 2018

Table of Contents

Chembio Diagnostics, Inc.

	Page
Part I. FINANCIAL INFORMATION:	
Item 1. Financial Statements:	
<u>Condensed Consolidated Balance Sheets as of June 30, 2018 (unaudited) and December 31, 2017</u>	3
<u>Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2018 and 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three and six months ended June 30, 2018 and 2017</u>	5
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2018 and 2017</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	24
<u>Item 4. Controls and Procedures</u>	24
Part II. OTHER INFORMATION:	
<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 6. Exhibits</u>	26
<u>SIGNATURES</u>	28
EXHIBITS	

---

## PART I

## Item 1. FINANCIAL STATEMENTS

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

	June 30, 2018 (Unaudited)	December 31, 2017
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$9,505,782	\$ 3,790,302
Accounts receivable, net of allowance for doubtful accounts of \$42,000 at June 30, 2018 and December 31, 2017	6,886,319	2,085,340
Inventories, net	6,349,640	4,423,618
Prepaid expenses and other current assets	788,740	554,383
TOTAL CURRENT ASSETS	23,530,481	10,853,643
 FIXED ASSETS, net of accumulated depreciation	 2,371,509	 1,909,232
OTHER ASSETS:		
Intangible assets, net	1,515,112	1,597,377
Goodwill	1,673,144	1,666,610
Deposits and other assets	357,385	589,159
	3,545,641	3,853,146
 TOTAL ASSETS	 \$29,447,631	 \$ 16,616,021
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$6,010,454	\$ 3,046,303
Deferred revenue	660,750	50,000
TOTAL CURRENT LIABILITIES	6,671,204	3,096,303
OTHER LIABILITIES:		
Note payable	426,550	99,480
Deferred tax liability	342,379	341,042
TOTAL LIABILITIES	7,440,133	3,536,825
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized; 14,173,620 and 12,318,570 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	141,736	123,185
Additional paid-in capital	74,033,287	62,821,288
Accumulated deficit	(52,424,943 )	(50,044,225 )
Accumulated other comprehensive income	257,418	178,948
TOTAL STOCKHOLDERS' EQUITY	22,007,498	13,079,196

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$29,447,631	\$ 16,616,021
--	--------------	---------------

See accompanying notes to condensed consolidated financial statements

3

---

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

	For the three months ended		For the six months ended	
	June 30,	June 30, 2017	June 30,	June 30, 2017
	2018		2018	
<b>REVENUES:</b>				
Net product sales	\$6,857,861	\$ 2,892,942	\$13,256,088	\$ 8,320,314
License and royalty revenue	276,526	227,635	478,457	327,689
R&D, milestone and grant revenue	1,585,939	994,237	2,702,913	1,791,977
<b>TOTAL REVENUES</b>	<b>8,720,326</b>	<b>4,114,814</b>	<b>16,437,458</b>	<b>10,439,980</b>
<b>COSTS AND EXPENSES:</b>				
Cost of product sales	5,935,428	2,203,843	10,053,207	5,423,057
Research and development expenses	1,991,412	1,982,426	3,838,514	4,228,998
Selling, general and administrative expenses	2,547,216	2,109,360	4,953,785	4,597,696
	10,474,056	6,295,629	18,845,506	14,249,751
<b>LOSS FROM OPERATIONS</b>	<b>(1,753,730 )</b>	<b>(2,180,815 )</b>	<b>(2,408,048 )</b>	<b>(3,809,771 )</b>
<b>OTHER INCOME:</b>				
Interest income, net	25,355	7,722	27,330	21,104
<b>LOSS BEFORE INCOME TAXES</b>	<b>(1,728,375 )</b>	<b>(2,173,093 )</b>	<b>(2,380,718 )</b>	<b>(3,788,667 )</b>
Income tax provision	-	-	-	-
<b>NET LOSS</b>	<b>\$(1,728,375 )</b>	<b>\$(2,173,093 )</b>	<b>\$(2,380,718 )</b>	<b>\$(3,788,667 )</b>
Basic loss per share	\$(0.12 )	\$(0.18 )	\$(0.17 )	\$(0.31 )
Diluted loss per share	\$(0.12 )	\$(0.18 )	\$(0.17 )	\$(0.31 )
Weighted average number of shares outstanding, basic	14,165,343	12,299,122	13,718,776	12,284,979
Weighted average number of shares outstanding, diluted	14,165,343	12,299,122	13,718,776	12,284,979

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
 (Unaudited)

	For the three months ended		For the six months ended	
	June 30,	June 30, 2017	June 30,	June 30, 2017
	2018		2018	
Net loss	\$(1,728,375 )	\$ (2,173,093 )	\$(2,380,718)	\$ (3,788,667 )
Other comprehensive income (loss):				
Foreign currency translation adjustments	(173,828 )	124,241	78,470	124,241
Comprehensive Loss	\$(1,902,203 )	\$ (2,048,852 )	\$(2,302,248)	\$ (3,664,426 )

See accompanying notes to condensed consolidated financial statements

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

	June 30, 2018	June 30, 2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$ 12,247,228	\$ 8,920,921
Cash paid to suppliers and employees	(17,352,226)	(14,398,812)
Interest received, net	27,330	21,104
Net cash used in operating activities	(5,077,668 )	(5,456,787 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of RVR Diagnostics Sdn Bhd	-	(850,000 )
Acquisition of and deposits on fixed assets	(250,147 )	(555,894 )
Net cash used in investing activities	(250,147 )	(1,405,894 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from option exercises	71,914	-
Proceeds from sale of common stock, net	10,934,352	-
Net cash provided by financing activities	11,006,266	-
Effect of exchange rate changes on cash	37,029	-
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>5,715,480</b>	<b>(6,862,681 )</b>
Cash and cash equivalents - beginning of the period	3,790,302	10,554,464
Cash and cash equivalents - end of the period	<b>\$ 9,505,782</b>	<b>\$ 3,691,783</b>
<b>RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:</b>		
Net Loss	\$ (2,380,718 )	\$ (3,788,667 )
Adjustments:		
Depreciation and amortization	446,625	773,566
Share based compensation	224,283	209,609
Changes in assets and liabilities:		
Accounts receivable	(4,800,979 )	(1,287,898 )
Inventories	(1,926,022 )	(1,658,763 )
Prepaid expenses and other current assets	(215,758 )	(25,043 )
Deposits and other assets	-	8,729
Accounts payable and accrued liabilities	2,964,151	542,841
Deferred revenue	610,750	(231,161 )
Net cash used in operating activities	<b>\$ (5,077,668 )</b>	<b>\$ (5,456,787 )</b>
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$ 257,455	\$ 174,399
Seller-financed equipment purchases	327,070	-
Accrual of contingent earn-out	-	148,000
Issuance of common stock for net assets of business acquired	-	1,682,725



See accompanying notes to condensed consolidated financial statements

6

---

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
June 30, 2018  
(UNAUDITED)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiaries (collectively, the “Company” or “Chembio”) develop, manufacture, and commercialize point-of-care (POC) diagnostic tests that are used to detect or monitor diseases. The Company’s product development efforts are focused on our patented DPP® technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology. POC tests, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POC tests can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

Our product commercialization and product development efforts are focused in three areas: sexually transmitted disease, tropical & fever disease, and technology collaborations. In sexually transmitted disease, we are commercializing tests for HIV and Syphilis. In tropical and fever disease, we are commercializing a test for Zika virus, and developing tests for malaria, dengue virus, chikungunya virus, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of fever panel tests. Through technology collaborations, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for an undisclosed biomarker, the latter in collaboration with global biopharmaceutical company AstraZeneca.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are critical for large scale prevention and treatment programs. Our product development is focused on areas where the availability of rapid, POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally, we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

Our 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, under our STAT PAK®, SURE CHECK®, STAT-VIEW® or DPP® registered trademarks, or under the private labels of our marketing partners.

The Company routinely enters into arrangements with governmental and non-governmental organizations for the funding of certain research and development efforts.

NOTE 2 — ACQUISITION: