

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 8, 2018**



CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
*(State or Other Jurisdiction of
Incorporation or Organization)*

0-30379
(Commission File Number)

88-0425691
*(I.R.S. Employer
Identification No.)*

3661 Horseblock Road, Medford, New York 11763
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **(631) 924-1135**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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. ☐

Item 2.02 Results of Operations and Financial Condition

On November 8, 2018, we issued a press release announcing financial results for the quarter ended September 30, 2018. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained herein, including the exhibit furnished hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit	Description
99.1	Press release of Chembio Diagnostics, Inc. dated November 8, 2018

SIGNATURE

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

CHEMBIO DIAGNOSTICS, INC.

Dated: November 8, 2018

By: /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President



ChemBio Diagnostics Reports Third Quarter 2018 Financial Results

MEDFORD, NY, November 8, 2018 -- ChemBio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today reported financial results for the third quarter ended September 30, 2018.

Recent Accomplishments & Highlights

- Achieved total revenue of \$9.4 million, including net product sales of \$7.9 million, for the third quarter 2018, representing increases of 24% and 28%, respectively, compared to the prior year period.
- Announced and closed the acquisition of opTricon GmbH, a privately-held developer and manufacturer of hand-held analyzers for rapid diagnostic tests.
- Filed CE mark application for a point-of-care DPP® test to detect an undisclosed biomarker through the AstraZeneca funded collaboration and development program.
- Received \$10.5 million purchase commitment for 2019 from Bio-Manguinhos for the production of DPP® HIV and DPP® Leishmania assays in Brazil and their subsequent supply to Brazil's Ministry of Health.
- Completed an underwritten public offering bringing an estimated \$16.6 million of net proceeds to the company.

"The ChemBio team delivered strong performance in the third quarter of 2018, highlighted by double-digit revenue growth in our core business," said John Sperzel, ChemBio's Chief Executive Officer. "We also advanced a number of product development, regulatory and operational initiatives which we believe will provide significant growth opportunities. We are especially pleased to have completed the first regulatory submission of our DPP® test to identify an undisclosed biomarker, developed through our collaboration with AstraZeneca."

Third Quarter 2018 Financial Results

Total revenue for the third quarter of 2018 was \$9.4 million, an increase of 24% compared to the third quarter of 2017. Net product sales for the third quarter of 2018 were \$7.9 million, an increase of 28% compared to the third quarter of 2017. License and royalty and R&D, milestone and grant revenue for the third quarter of 2018 was \$1.5 million, an increase of 5% compared to the third quarter of 2017.

Gross product margin for the third quarter of 2018 was \$1.1 million, a decrease of 48% compared to the third quarter of 2017. Gross product margin percent for the third quarter of 2018 was 14% compared to 34% for the third quarter of 2017. The lower gross product margin percent for the 2018 third quarter resulted primarily from sales growth in markets with lower average selling prices and costs associated with the current manual product assembly process.

Research and development expenses increased \$0.1 million, or 5% for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. Selling, general and administrative expenses increased by \$0.7 million, or 32% for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. The increase is primarily associated with merger & acquisition expenses and increased headcount and related costs.

Net loss for the third quarter of 2018 was \$2.3 million, or \$0.16 per diluted share, compared with a net loss of \$0.6 million, or \$0.05 per diluted share, for the third quarter of 2017.

Cash and cash equivalents as of September 30, 2018 totaled \$6.8 million.

Conference Call

Chembio will host a conference call today beginning at 4:30pm ET to discuss financial results and recent business highlights. Investors interested in listening to the call may do so by dialing (877) 407-0778 from the U.S. or (201) 689-8565 from outside the U.S. To listen to a live webcast, please visit the Investor Relations section of Chembio's website at www.chembio.com. Following the call, a replay will be available on the Investor Relations section of the company's website for 90 days. A telephone replay will be available by dialing (877) 481-4010 from the U.S. or (919) 882-2331 from outside the U.S. using the conference ID: 38097 until 4:30pm ET on November 15, 2018.

About Chembio Diagnostics

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. The company's patented DPP® technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in 15-20 minutes. Coupled with Chembio's extensive scientific expertise, its novel DPP® technology offers broad market applications beyond infectious disease, a number of which are under active development with collaboration partners. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers. Learn more at www.chembio.com.

Forward-Looking Statements

Statements contained in the last paragraph under "Recent Accomplishments & Highlights" that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of the Company and its management. Such statements, which are estimates only, reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to Chembio's ability to obtain regulatory approvals in a timely manner, as well as the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and its Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2018, June 30, 2018 and September 30, 2018, particularly under the heading "Risk Factors."

(Tables to follow)

Investor Relations Contact

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

	For the three months ended		For the nine months ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
REVENUES:				
Net product sales	\$ 7,856,038	\$ 6,132,725	\$ 21,112,126	\$ 14,453,097
License and royalty revenue	228,553	150,000	707,010	477,631
R&D, milestone and grant revenue	1,292,202	1,304,649	3,995,115	3,096,626
TOTAL REVENUES	9,376,793	7,587,374	25,814,251	18,027,354
COSTS AND EXPENSES:				
Cost of product sales	6,774,749	4,064,791	16,827,956	9,487,848
Research and development expenses	1,897,751	1,805,738	5,736,265	6,034,735
Selling, general and administrative expenses	3,034,130	2,305,358	7,987,914	6,903,055
	11,706,630	8,175,887	30,552,135	22,425,638
LOSS FROM OPERATIONS	(2,329,837)	(588,513)	(4,737,884)	(4,398,284)
OTHER INCOME:				
Interest income, net	15,656	3,852	42,985	24,956
LOSS BEFORE INCOME TAXES	(2,314,181)	(584,661)	(4,694,899)	(4,373,328)
Income tax provision	-	-	-	-
NET LOSS	\$ (2,314,181)	\$ (584,661)	\$ (4,694,899)	\$ (4,373,328)
Basic and diluted loss per share	\$ (0.16)	\$ (0.05)	\$ (0.34)	\$ (0.36)
Weighted average number of shares outstanding, basic and diluted	14,173,620	12,311,098	13,872,055	12,293,781

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

	<u>September 30, 2018</u> (Unaudited)	<u>December 31, 2017</u>
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 6,848,583	\$ 3,790,302
Accounts receivable, net	7,794,014	2,085,340
Inventories, net	5,978,426	4,423,618
Prepaid expenses and other current assets	1,579,750	554,383
TOTAL CURRENT ASSETS	<u>22,200,773</u>	<u>10,853,643</u>
FIXED ASSETS, net	2,372,896	1,909,232
OTHER ASSETS:		
Intangible assets, net	1,431,921	1,597,377
Goodwill	1,628,864	1,666,610
Deposits and other assets	331,423	589,159
TOTAL ASSETS	<u>\$ 27,965,877</u>	<u>\$ 16,616,021</u>
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 6,798,600	\$ 3,046,303
Deferred revenue	760,750	50,000
Current portion of note payable	202,096	-
TOTAL CURRENT LIABILITIES	<u>7,761,446</u>	<u>3,096,303</u>
OTHER LIABILITIES:		
Note payable	207,694	99,480
Deferred tax liability	333,318	341,042
TOTAL LIABILITIES	<u>8,302,458</u>	<u>3,536,825</u>
TOTAL STOCKHOLDERS' EQUITY	<u>19,663,419</u>	<u>13,079,196</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 27,965,877</u>	<u>\$ 16,616,021</u>

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

	For the nine months ended	
	<u>September 30, 2018</u>	<u>September 30, 2017</u>
Net cash used in operating activities	\$ (7,530,508)	\$ (7,176,935)
Net cash used in investing activities	(401,897)	(1,639,827)
Net cash provided by financing activities	10,990,466	134,280
Effect of exchange rate changes on cash	220	-
INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	3,058,281	(8,682,482)
Cash and cash equivalents - beginning of the period	3,790,302	10,554,464
Cash and cash equivalents - end of the period	<u>\$ 6,848,583</u>	<u>\$ 1,871,982</u>