



Chembio Diagnostics Reports Fourth Quarter and Full Year 2018 Financial Results

March 7, 2019

Issues 2019 Revenue Guidance

MEDFORD, N.Y., March 07, 2019 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today reported financial results for the fourth quarter and year ended December 31, 2018.

Recent Accomplishments & Highlights

- Achieved total revenue of \$7.6 million for the fourth quarter of 2018 and \$33.4 million for the full year 2018, increases of 27% and 39% respectively, over prior year
- Introduced 5-year targets of \$100 million in revenue by 2023 and 50%5,313,777 gross margins by year end 2023
- Acquired opTricon GmbH, the developer and manufacturer of the DPP® Micro Reader
- Received CE mark for DPP® eosinophilic respiratory disease test developed in collaboration with AstraZeneca
- Received U.S. FDA Emergency Use Authorization for DPP® Ebola test and DPP® Micro Reader
- Obtained \$10.5 million 2019 commitment from Bio-Manguinhos for production of DPP® Assays in Brazil
- Completed public offering of common stock raising \$16.5 million in net proceeds

"Chembio had a milestone year in 2018, marked by continued execution in our core business which drove strong product sales growth, and the advancement of strategic and operational initiatives that will lay the foundation for continued growth," said John Sperzel, Chembio's Chief Executive Officer. "As we look to 2019, the Chembio team is focused on three priorities: expand our commercialization, advance our R&D pipeline, and prepare for growth. We are excited about 2019 and increasingly confident about the company's growth trajectory and long-term potential."

Fourth Quarter 2018 Financial Results

Total revenue for the fourth quarter of 2018 was \$7.6 million, an increase of 26.8% compared to the fourth quarter of 2017. Net product sales for the fourth quarter of 2018 were \$5.6 million, an increase of 15.6% compared to the fourth quarter of 2017. License and royalty and R&D, milestone and grant revenue for the fourth quarter of 2018 was \$2.0 million, an increase of 75.7% compared to the fourth quarter of 2017.

Gross product margin for the fourth quarter of 2018 was \$1.0 million, a decrease of 28.3% compared to the fourth quarter of 2017. Gross product margin percent for the fourth quarter of 2018 was 18.3% compared to 29.5% for the fourth quarter of 2017. The lower gross product margin percent for the 2018 fourth 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 \$0.3 million, or 10.7% for the three months ended December 31, 2018 compared to the three months ended December 31, 2017. Selling, general and administrative expenses increased by \$1.0 million, or 46.9% for the three months ended December 31, 2018 compared to the three months ended December 31, 2017. The increase is primarily associated with increased personnel, compensation and acquisition costs.

Net loss for the fourth quarter of 2018 was \$3.2 million, or \$0.21 per diluted share, compared with a net loss of \$2.0 million, or \$0.16 per diluted share, for the fourth quarter of 2017.

Full Year 2018 Financial Results

Total revenues for 2018 were \$33.4 million, an increase of 39.1% compared to 2017. Net product sales for 2018 were \$26.7 million, an increase of 38.4% compared to 2017. License and royalty and R&D, milestone and grant revenues in 2018 totaled \$6.7 million, an increase of 42.1% compared to 2017.

Gross product margin for 2018 was \$5.3 million, a decrease of 17% compared to 2017, the \$1.1 million decrease was primarily due to increased product sales volume. Gross product margin percent for 2018 was 19.9% compared to 33.1% for 2017. The lower gross product margin percent for 2018 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 of \$8.5 million for the year ended December 31, 2018 were flat compared to the year ended December 31, 2017. Selling, general and administrative expenses increased by \$2.1 million, or 23.8% for the year ended December 31, 2018 compared to the year ended December 31, 2017. The increase was primarily associated with increased personnel, compensation and acquisition costs.

Net loss for 2018 was \$7.9 million, or \$0.55 per diluted share, compared with net loss of \$6.4 million, or \$0.52 per diluted share, in 2017.

Cash and cash equivalents as of December 31, 2018 totaled \$12.5 million.

2019 Financial Outlook

Management expects 2019 full year revenue to be in the range of \$36.0 million to \$40.0 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 844-369-8770 from the U.S. or 862-298-0840 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: 44364 until 4:30pm ET on March 14, 2019.

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 second bullet and the last paragraph under "Recent Accomplishments & Highlights" and in the paragraph under "2019 Financial Outlook" 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)

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

	For the twelve months ended	
	December 31, 2018	December 31, 2017
REVENUES:		
Net product sales	\$ 26,741,020	\$ 19,322,302
License and royalty revenue	948,773	741,534
R&D, milestone and grant revenue	5,719,458	3,951,591
TOTAL REVENUES	33,409,251	24,015,427
COSTS AND EXPENSES:		
Cost of product sales	21,427,243	12,921,157
Research and development expenses	8,526,256	8,555,381
Selling, general and administrative expenses	11,100,775	8,963,363
Acquisition Costs	337,645	58,076
	41,391,919	30,497,977
LOSS FROM OPERATIONS	(7,982,668)	(6,482,550)
OTHER INCOME:		
Interest income, net	49,498	22,845
LOSS BEFORE INCOME TAXES	(7,933,170)	(6,460,065)
Income tax provision	(67,521)	(88,305)
NET LOSS	\$ (7,865,649)	\$ (6,371,760)
Basic and diluted loss per share	\$ (0.55)	\$ (0.52)
Weighted average number of shares outstanding, basic and diluted	14,432,505	12,300,031

Weighted average number of shares outstanding, diluted

14,432,505

12,300,031

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

	December 31, 2018	December 31, 2017
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 12,524,551	\$ 3,790,302
Accounts receivable, net	7,373,971	2,085,340
Inventories, net	7,851,222	4,423,618
Prepaid expenses and other current assets	702,010	554,383
TOTAL CURRENT ASSETS	28,451,754	10,853,643
FIXED ASSETS, net	2,873,920	1,909,232
OTHER ASSETS:		
Intangible assets, net	3,884,831	1,597,377
Goodwill	4,348,127	1,666,610
Deposits and other assets	715,658	589,159
TOTAL ASSETS	\$ 40,274,290	\$ 16,616,021
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 5,888,681	\$ 3,046,303
Deferred revenue	422,905	50,000
Current Portion of Note Payable	207,694	
TOTAL CURRENT LIABILITIES	6,519,280	3,096,303
OTHER LIABILITIES:		
Note payable	171,821	99,480
Deferred tax liability	315,332	341,042
TOTAL LIABILITIES	7,006,433	3,536,825
TOTAL STOCKHOLDERS' EQUITY	33,267,858	13,079,196
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 40,274,290	\$ 16,616,021

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

	For the twelve months ended	
	December 31, 2018	December 31, 2017
Net cash used in operating activities	\$ (11,789,043)	\$ (5,034,515)
Net cash used in investing activities	(6,950,796)	(1,876,954)
Net cash provided by financing activities	27,483,693	134,280
Effect of exchange rate changes on cash	(9,608)	13,027
INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	8,734,246	(6,764,162)

Cash and cash equivalents - beginning of the period	3,790,305	10,554,464
Cash and cash equivalents - end of the period	\$ 12,524,551	\$ 3,790,302



Source: ChemBio Diagnostics, Inc.