



Chembio Diagnostics Reports Third Quarter 2019 Financial Results

November 7, 2019

MEDFORD, N.Y., Nov. 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 quarter ended September 30, 2019.

Recent Accomplishments & Highlights

- Achieved total revenue of \$9.7 million and product revenue of \$8.5 million for the third quarter of 2019, representing changes of -1% and 2%, respectively, compared to the prior year period;
- Signed a definitive agreement to acquire Orangelife, a Brazilian point-of-care diagnostics company, enabling commercial expansion into the state, private, and pharmacy markets in Brazil;
- Received World Health Organization (WHO) Prequalification approval for SURE CHECK HIV Self-Test, permitting the commercialization of the product across Africa;
- Received WHO Prequalification approval for Malaysian manufacturing facility, allowing the production of Stat-Pak HIV 1/2 tests in Malaysia;
- Entered into a collaboration with Takeda Pharmaceutical, a global pharmaceutical company, to develop a quantitative point-of-care test to detect an undisclosed biomarker; and
- Strengthened balance sheet by closing a \$20 million term loan with Perceptive Advisors.

"During the third quarter, the Chembio team continued to execute on our three corporate priorities: expanding our commercialization, advancing our R&D pipeline, and preparing for additional growth," said John Sperzel, Chembio's Chief Executive Officer. "Total revenue during the third quarter was impacted by lower product sales in Africa; however, we are pleased with the significant product sales increases in the United States, Latin America, and Asia Pacific, and we believe the Orangelife acquisition will provide another growth vehicle for the company."

Third Quarter 2019 Financial Results

Total revenue for the third quarter of 2019 was \$9.7 million, a decrease of 1% compared to the prior year period. Net product sales for the third quarter of 2019 were \$8.5 million, an increase of 2% compared to the prior year period. License and royalty, and R&D and grant revenue for the third quarter of 2019 was \$1.2 million, a decrease of 20% compared to the prior year period.

Gross product margin for the third quarter of 2019 was \$1.9 million compared to \$1.1 million in the prior year period. Gross product margin percent for the third quarter of 2019 was 22% compared to 13% for the prior year period. The increased gross product margin percent for the third quarter of 2019 resulted primarily from reduced labor costs and favorable average selling prices due to geographic mix.

Research and development expenses increased by \$0.3 million, or 17%, for the third quarter of 2019 compared to the prior year period from the acquisition of Chembio Diagnostics Germany GmbH in the fourth quarter of 2018. Selling, general and administrative expenses increased by \$1.4 million, or 47%, for the three months ended September 30, 2019 compared to the prior year period. The increase in selling, general and administrative expenses resulted primarily from the acquisition of Chembio Diagnostics Germany, higher non-cash equity compensation costs, and rent and other costs related to leasing our new facility in Hauppauge, NY.

Net loss for the third quarter of 2019 was \$3.8 million, or \$0.22 per diluted share, compared with a net loss of \$2.3 million, or \$0.16 per diluted share, for the prior year period.

Cash and cash equivalents as of September 30, 2019 totaled \$21.9 million.

Conference Call

Chembio will host a conference call today beginning at 4:30pm ET to discuss financial results and recent business highlights, including the contemplated acquisition of Orangelife. Investors interested in listening to the call may do so by dialing 844-602-0380 from the U.S. or 862-298-0970 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: 53958 until 4:30pm ET on November 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 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: the ability of Chembio to timely close the Orangelife acquisition; the ability of Chembio to maintain existing, and timely obtain additional, regulatory approvals; and the risks of doing business with a foreign country, including geopolitical, international and other challenges as well as potential material adverse effects of tariffs and other changes in U.S. trade policy. 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, 2018, particularly under the heading "Risk Factors."

DPP is our registered trademark. For convenience, this trademark appears in this release without ® symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademark.

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

	For the three months ended		For the nine months ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
REVENUES:				
Net product sales	\$ 8,510,629	\$ 8,304,370	\$ 23,381,906	\$ 22,108,727
License and royalty revenue	238,330	228,553	703,352	707,010
R&D, milestone and grant revenue	971,980	1,292,202	3,528,033	3,995,115
TOTAL REVENUES	9,720,939	9,825,125	27,613,291	26,810,852
COSTS AND EXPENSES:				
Cost of product sales	6,649,114	7,223,081	18,112,676	17,824,557
Research and development expenses	2,223,939	1,897,751	6,542,591	5,736,265
Selling, general and administrative expenses	4,455,588	3,034,130	12,565,601	7,987,914
Acquisition costs	-	-	395,612	-
	13,328,641	12,154,962	37,616,480	31,548,736
LOSS FROM OPERATIONS	(3,607,702)	(2,329,837)	(10,003,189)	(4,737,884)
OTHER INCOME:				
Interest (expense) income, net	(195,970)	15,656	(183,368)	42,985
LOSS BEFORE INCOME TAXES	(3,803,672)	(2,314,181)	(10,186,557)	(4,694,899)
Income tax benefit	20,667	-	400,339	-
NET LOSS	\$(3,783,005)	\$(2,314,181)	\$(9,786,218)	\$(4,694,899)
Basic and Diluted loss per share	\$(0.22)	\$(0.16)	\$(0.58)	\$(0.34)
Weighted average number of shares outstanding, basic	16,923,695	14,173,620	16,912,583	13,872,055
Weighted average number of shares outstanding, diluted	16,923,695	14,173,620	16,912,583	13,872,055

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

(Unaudited)

	September 30, 2019	December 31, 2018
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 21,867,892	\$ 12,524,551
Accounts receivable, net	5,377,985	7,373,971
Inventories, net	8,409,344	7,851,222
Prepaid expenses and other current assets	598,127	702,010
TOTAL CURRENT ASSETS	36,253,348	28,451,754
FIXED ASSETS:		
Property, plant and equipment, net	5,245,794	2,873,920
Finance lease right-of-use asset	222,036	-
TOTAL FIXED ASSETS, net	5,467,830	2,873,920
OTHER ASSETS:		
Operating lease right-of-use asset	6,697,896	-
Intangible assets, net	3,508,594	3,884,831
Goodwill	4,681,511	4,983,127
Deposits and other assets	308,159	717,551
TOTAL ASSETS	\$ 56,917,338	\$ 40,911,183
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 5,445,956	\$ 5,888,681
Deferred revenue	237,500	422,905
Current portion of note payable	207,694	207,694
Current portion of finance lease liability	41,169	-
Current portion of operating lease liability	255,030	-
TOTAL CURRENT LIABILITIES	6,187,349	6,519,280
OTHER LIABILITIES:		
Operating lease liability	6,706,918	-
Finance lease liability	182,702	-
Long-Term debt, less current portion, and debt discount and issuance cost	17,538,481	171,821
Deferred tax liability	505,618	892,308
TOTAL LIABILITIES	31,121,068	7,583,409
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$.01 par value; 100,000,000 shares authorized, 17,565,534 and 17,166,459 shares issued and outstanding as of September 30, 2019 and December 31, 2018	175,655	171,664
Additional paid-in capital	93,376,856	90,953,788
Accumulated deficit	(67,696,092)	(57,909,874)
Accumulated other comprehensive (loss) income	(60,149)	112,196
TOTAL STOCKHOLDERS' EQUITY	25,796,270	33,327,774
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 56,917,338	\$ 40,911,183

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

	For the nine months ended	
	September 30, 2019	September 30, 2018
Net cash used in operating activities	\$ (6,398,207)) \$ (7,530,508)
Net cash used in investing activities	(2,769,147)) (401,897)

Net cash provided by financing activities	18,517,604	10,990,466
Effect of exchange rate changes on cash	(6,909)) 220
INCREASE IN CASH AND CASH EQUIVALENTS	9,343,341	3,058,281
Cash and cash equivalents - beginning of the period	12,524,551	3,790,302
Cash and cash equivalents - end of the period	\$ 21,867,892	\$ 6,848,583



Source: Chembio Diagnostics, Inc.