November 8, 2017

Chembio Diagnostics Reports Third Quarter 2017 Financial Results

Conference Call and Webcast Today at 4:30 p.m. Eastern Time

MEDFORD, N.Y., Nov. 08, 2017 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care ("POC") diagnostic tests for infectious diseases, today reported financial results for the third quarter ended September 30, 2017.

John J. Sperzel, III, Chembio's President and CEO, stated, "During the third quarter of 2017, the Company continued to make progress with each of its key objectives: 1) strengthening the core sexually transmitted disease business, 2) building a broad tropical and fever disease portfolio, and 3) building a global commercial team.

"With respect to the Company's sexually transmitted disease business, Chembio increased total HIV product sales during the third quarter of 2017 by 273% compared to the prior year period, achieving HIV product sales growth in the United States, Latin America, Europe and Africa. In the U.S., the Company continues to prioritize development of its DPP® HIV-Syphilis Assay in response to the global concerns related to HIV and Syphilis co-infection and mother-to-child transmission. We expect to complete the U.S. clinical trial for our DPP® HIV-Syphilis Assay by year-end, in preparation for the FDA submission, which we believe keeps us on track to be the first to market a combination HIV-Syphilis Assay in the U.S. Outside the U.S., Chembio experienced significant growth in its HIV Self-Test business, resulting in 219% year-over-year growth through the first three quarters.

"Turning to our tropical and fever disease business, the Company advanced its DPP® Malaria and DPP® Dengue Assays during the third quarter. It is important to note that these two diseases account for approximately 600 million cases annually. The field evaluation of our DPP® Malaria Assay, which previously received funding from the Bill & Melinda Gates Foundation, was completed during the third quarter, and we plan to begin commercialization of this ultra-sensitive test during 2018. We previously initiated sales of our DPP® Dengue Assay, including CDC's pilot program for our DPP® Dengue/Zika/Chikungunya Assay in four countries: India, Peru, Haiti and Guatemala.

"We also reached important regulatory milestones during the third quarter of 2017. In July, Chembio's DPP® Zika System, including the DPP® Micro Reader, was approved by Brazil's Health Regulatory Agency. In September, Chembio became the first company to receive U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for a rapid Zika test. The Company's U.S. DPP® Zika project has been funded with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Contract No. HHSO100201600022C."

Addressing the Company's financial results, Mr. Sperzel commented, "During the third quarter of 2017, Chembio achieved total revenue of $7.6 million, which represents a 102% increase over the prior-year period and the fourth highest quarter in Company history. Product sales during the third quarter of 2017 were $6.1 million, which represents a 145% increase over the prior-year period. During the first nine months of 2017, Chembio achieved total revenue of $18.0 million, which represents a 32% increase over the prior-year period. Product sales during the first nine months of 2017 were $14.4 million, which represents a 38% increase over the prior-year period. The sales growth achieved in several target regions during the third quarter of 2017, compared to the prior-year period, including a 386% increase in Latin America, a 100% increase in Africa, a 32% increase in the United States, and a 27% increase in Europe, further validates the strength and effectiveness of our global sales organization."

Summary Financial Information comparing the 2017 three-month third quarter to the 2016 third quarter:

- Total revenues of $7.6 million, compared with $3.7 million (an increase of 102.5%).
- Product sales of $6.1 million, compared with $2.5 million (an increase of 145.1%).
- Operating loss of $0.6 million, compared with operating loss of $2.1 million.
- Net loss of $0.6 million, or $0.05 per diluted share, compared with net loss of $2.1 million, or $0.19 per diluted share.

Summary Financial Information comparing the first nine months of 2017 to the first nine months of 2016:

- Total revenues of $18.0 million, compared with $13.6 million (an increase of 32.4%).
- Product sales of $14.5 million, compared with $10.5 million (an increase of 38.3%).
- Operating loss of $4.4 million, compared with operating loss of $5.0 million.
- Net loss of $4.4 million, or $0.36 per diluted share, compared with net loss of $10.8, or $1.06 per diluted share. The net loss in the 2016 period includes a tax provision for the recording of a valuation allowance on the Company's deferred tax asset of $5.8 million.

Additional Financial Information:

Third Quarter:

Total revenues in the 2017 third quarter of $7.6 million increased 102.5% compared with $3.7 million in the prior-year period. Product sales in the 2017 third quarter of $6.1 million increased 145.1% compared with $2.5 million in the prior-year period. R&D milestone, and grant and royalty revenues in the 2017 third quarter of $1.5 million increased 16.9% compared with $1.2 million in the prior-year period.

Gross margin dollars in the 2017 third quarter of $3.5 million increased 80.5% compared with $2.0 million in the prior-year period, due primarily to increased product sales. Product gross margin dollars in the 2017 third quarter of $2.1 million increased 192.2% compared with $0.7 million in the prior-year period, which also was primarily due to increased product revenues.

R&D expenses in the 2017 third quarter of $1.8 million decreased 20.2%, compared with $2.3 million in the prior-year period. Selling, general and administrative expenses in the 2017 third quarter of $2.3 million increased 25.8% compared with $1.8 million in the prior-year period, largely due to investments made to the scale-up of our sales and marketing organization globally, and professional fees.

Operating loss in the 2017 third quarter was $0.6 million, compared with an operating loss of $2.1 million in the prior-year period.

Net loss in the 2017 third quarter was $0.6 million, or $0.05 per diluted share, compared with net loss of $2.1 million, or $0.19 per diluted share, in the prior-year period.

First Nine Months:

Total revenues in the 2017 first nine months of $18.0 million increased 32.4% compared with $13.6 million in the prior-year period. Product sales in the 2017 first nine months of $14.5 million increased 38.3% compared with $10.5 million in the prior-year period. R&D milestone, and grant and royalty revenues in the 2017 first nine months of $3.6 million increased 13.1% compared with $3.2 million in the prior-year period.

Gross margin dollars in the 2017 first nine months of $8.5 million increased 27.5% compared with $6.7 million in the prior-year period, due primarily to the increase in product sales. The amount of product gross margin in the 2017 first nine months of $5.0 million increased 40.4% compared with $3.5 million in the prior-year period, which also was primarily due to increased product revenues.

R&D expenses in the 2017 first nine months of $6.0 million decreased 3.7%, compared with $6.3 million in the prior-year period. Selling, general and administrative expenses in the 2017 first nine months of $6.9 million increased 27.1%, compared with $5.4 million in the prior-year period, largely due to investments made to scale up our sales and marketing organization globally, and professional fees.

Operating loss in the 2017 first nine months was $4.4 million, compared with an operating loss of $5.0 million in the prior-year period.

Net loss in the 2017 first nine months was $4.4 million, or $0.36 per diluted share, compared with net loss of $10.8 million, or $1.06 per diluted share, in the prior-year period. The net loss in the 2016 period includes a tax provision for the recording of a valuation allowance on the Company's deferred tax asset of $5.8 million.

Balance Sheet Highlights:

The Company had cash and cash equivalents of $1.9 million as of September 30, 2017, compared with $10.6 million as of December 31, 2016. The decrease was primarily due to net cash used in operating activities of $7.2 million. Our working capital decreased by $4.9 million from $14.7 million as of December 31, 2016 to $9.8 million, largely due to cash used in operating activities and in investing activities, primarily for the acquisition in RVR Diagnostics Sdn Bhd, for the nine months of 2017. Subsequent to that acquisition, we have changed the name of RVR Diagnostics Sdn Bhd to Chembio Diagnostics Malaysia Sdn Bhd.

Conference Call

To participate on the conference call, please dial (888) 567-1602 from the U.S. or (404) 267-0373 from outside the U.S. To listen live via the Internet, please visit the Investor Relations section of Chembio's website at www.chembio.com.

To listen to a replay of the call, which will be accessible until November 15, 2017 at 11:59 p.m. ET, please dial (877) 481-4010 from the U.S. or (919) 882-2331 from outside the U.S., and enter conference ID #:22282. An archive of the webcast will be available for 90 days on the Company's website at www.chembio.com.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing $8.0 billion point-of-care testing market. Chembio markets each of its DPP® HIV 1/2 Assay, HIV 1/2 STAT-PAK® Assay, and SURE CHECK® HIV 1/2 Assay, with these Chembio brand names, in the U.S. and internationally, and its STAT-VIEW® Assay in Europe, both directly and through third-party distributors.

Chembio has developed a patented point-of-care test platform technology, the Dual Path Platform (DPP®) technology, which has significant advantages over lateral-flow technologies. This technology is providing Chembio with a significant pipeline of business opportunities for the development and manufacture of new products.

Headquartered in Medford, NY, Chembio is licensed by the U.S. Food and Drug Administration (FDA) as well as the U.S.

Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13485. Each of Chembio Diagnostic Systems, Inc. and Chembio Diagnostics Malaysia Sdn Bhd (formerly known as RVR Diagnostics Sdn Bhd) is a wholly-owned subsidiary of Chembio Diagnostics, Inc. For more information, please visit: www.chembio.com.

Forward-Looking Statements

Statements contained herein 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 additional financing and 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.

(Tables to follow)

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Chembio Diagnostics, Inc. & Subsidiaries
Summary of Consolidated Results of Operations
(UNAUDITED)

	For the three months ended		For the nine months ended	
	September 30, 2017	**September 30, 2016**	**September 30, 2017**	**September 30, 2016**
Net product sales	**$ 6,132,725**	$ 2,502,097	**$ 14,453,097**	$ 10,453,188
License and royalty revenue	**150,000**	77,754	**477,631**	133,850
R&D, milestone and grant revenue	**1,304,649**	1,166,610	**3,096,626**	3,026,927
TOTAL REVENUES	**$ 7,587,374**	$ 3,746,461	**$ 18,027,354**	$ 13,613,965
GROSS MARGIN	**$ 3,522,583**	$ 1,952,097	**$ 8,539,506**	$ 6,697,950
Research and development expenses	**$ 1,805,738**	$ 2,263,719	**$ 6,034,735**	$ 6,265,483
Selling, general and administrative expenses	**$ 2,305,358**	$ 1,832,451	**$ 6,903,055**	$ 5,430,668
LOSS FROM OPERATIONS	**$ (588,513)**	$ (2,144,073)	**$ (4,398,284)**	$ (4,998,201)
OTHER INCOME:	**$ 3,852**	$ 5,855	**$ 24,956**	$ 9,729
Income tax provision	**$ -**	$ -	**$ -**	$ 5,800,818
NET LOSS	**$ (584,661)**	$ (2,138,218)	**$ (4,373,328)**	$ (10,789,290)
Basic loss per share	**$ (0.05)**	$ (0.19)	**$ (0.36)**	$ (1.06)
Diluted loss per share	**$ (0.05)**	$ (0.19)	**$ (0.36)**	$ (1.06)
Weighted average number of shares outstanding, basic	**12,311,098**	11,142,090	**12,293,781**	10,150,737
Weighted average number of shares outstanding, diluted	**12,311,098**	11,142,090	**12,293,781**	10,150,737

Chembio Diagnostics, Inc. & Subsidiaries
Summary of Consolidated Balance Sheets
(UNAUDITED)

	September 30, 2017	December 31, 2016
CURRENT ASSETS:		
Cash and cash equivalents	**$ 1,871,982**	$ 10,554,464
Accounts receivable, net of allowance for doubtful accounts of $52,000 at September 30, 2017 and December 31, 2016, respectively	**5,768,920**	3,383,729
Inventories, net	**5,235,164**	3,335,188
Prepaid expenses and other current assets	**842,532**	840,145
TOTAL CURRENT ASSETS	**13,718,598**	18,113,526
FIXED ASSETS, net of accumulated depreciation	**1,964,427**	1,709,321
OTHER ASSETS	**3,561,679**	752,389
TOTAL ASSETS	**$ 19,244,704**	$ 20,575,236
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
TOTAL CURRENT LIABILITIES	**$ 3,870,161**	**$ 3,405,650**
TOTAL LIABILITIES	**4,305,631**	3,405,650
STOCKHOLDERS' EQUITY:		
Common stock - $.01 par value; 100,000,000 shares authorized; 12,318,570 and 12,026,847 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	**123,185**	120,268
Additional paid-in capital	**62,733,065**	60,721,783
Accumulated other comprehensive income	**128,616**	-
Accumulated deficit	**(48,045,793)**	(43,672,465)
TOTAL STOCKHOLDERS' EQUITY	**14,939,073**	17,169,586
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 19,244,704**	$ 20,575,236

Chembio Diagnostics, Inc. & Subsidiaries
Summary of Consolidated Cash Flows
For the nine months ended
(UNAUDITED)

	September 30, 2017	September 30, 2016
Net cash used in operating activities	$ (7,176,935)	$ (5,676,073)
Net cash used in investing activities	(1,639,827)	(79,877)
Net cash provided by financing activities	134,280	12,550,973
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**$ (8,682,482)**	**$ 6,795,023**