



August 9, 2017

Chembio Diagnostics Reports Second Quarter 2017 Financial Results

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

MEDFORD, N.Y., Aug. 09, 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 second quarter ended June 30, 2017.

Sharon Klugewicz, Chembio's acting CEO, stated, "During the second quarter of 2017, the Company continued to execute upon the transition strategy, with a focus in three key areas: 1) strengthening our core sexually transmitted disease business, 2) building a broad tropical and fever disease portfolio, and 3) building a global commercial team.

"To strengthen our core sexually transmitted disease business, the Company continues to prioritize the U.S. development and international commercialization of the DPP[®] HIV-Syphilis Assay. This assay, which is currently available in Europe, Latin America and the Caribbean (except for Puerto Rico), addresses a significant need as co-infection rates and mother-to-child transmission of both HIV and Syphilis continue to present significant health risks in the U.S. and around the world. The U.S. clinical trial for the DPP[®] HIV Syphilis Assay is expected to be completed during the fourth quarter of 2017. During the second quarter of 2017, Chembio secured a \$5.8 million order to supply test components and intermediate product for the production of DPP[®] HIV 1/2 Assays in Brazil and subsequent supply to Brazil's Ministry of Health. We shipped \$0.9 million of this order during the second quarter of 2017 and we anticipate shipping the remaining \$4.9 million during the third and fourth quarters of 2017.

"To build a broad tropical and fever disease portfolio, Chembio committed to commercializing multiple tropical and fever disease products during 2017. We have already initiated sales of our DPP[®] Dengue Assay, our DPP[®] Zika Assay, and we initiated a pilot program with the CDC for our DPP[®] Dengue/Zika/Chikungunya Assay in India, Peru, Haiti and Guatemala. During the second quarter of 2017, the Company added to our accomplishments through a joint collaboration with FIND (www.finddx.org), to develop a POC test that can identify multiple life-threatening acute febrile illnesses common in the Asia Pacific region. Subsequent to the end of the second quarter, Chembio received approval for its DPP[®] Micro Reader from ANVISA, the Brazilian health regulatory agency, through a joint collaboration with Bio-Manguinhos/Fiocruz. With this approval, Chembio's DPP[®] Zika System, which includes the DPP[®] Zika Assay and DPP[®] Micro Reader, is now approved for commercial use in Brazil. The Company continues to pursue additional regulatory approvals for the DPP[®] Zika Assay, including U.S. FDA Emergency Use Authorization and World Health Organization Emergency Use Assessment and Listing. We remain optimistic, given the performance of our DPP[®] Zika Assay.

"To build a global commercial team, the Company continues its transition from a product supply organization, where we marketed and sold our products exclusively through others, to an integrated commercial organization. As previously announced, the Company strengthened its commercial leadership by appointing seasoned executives to lead the Americas region and EMEA and Asia Pacific regions. In addition, we added experienced diagnostics sales executives in Latin America, Africa and Asia Pacific. We believe these key hires position the Company for commercial success, globally."

Addressing the Company's financial results, Ms. Klugewicz commented, "During the second quarter of 2017, we achieved total revenue of \$4.1 million, which represented a 26% increase over the prior year period. Product sales during the second quarter of 2017 were \$2.9 million, which represented a 42.2% increase over the prior year period. During the first six months of 2017, we achieved total revenue of \$10.4 million, which represented a 5.8% increase over the prior year period. Product sales during the first six months of 2017 were \$8.3 million, which represented a 4.6% increase over the prior year period.

"During the second quarter of 2017, we achieved significant product sales growth within all of our target regions compared to the prior year period, including a 187.1% increase in Europe, 41.2% increase in Asia Pacific, 40.4% increase in Latin America, 22.1% increase in Africa, and 8.1% increase in the United States."

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

- | Total revenues of \$4.11 million, compared with \$3.27 million (an increase of 26.0%).
- | Product sales of \$2.89 million, compared with \$2.03 million (an increase of 42.2%).
- | Operating loss of \$2.18 million, compared with operating loss of \$2.39 million.
- | Net loss of \$2.17 million, or \$0.18 per diluted share, compared with net loss of \$8.35 million, or \$0.86 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 \$5.96 million.

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

- | Total revenues of \$10.44 million, compared with \$9.87 million (an increase of 5.8%).
- | Product sales of \$8.32 million, compared with \$7.95 million (an increase of 4.6%).
- | Operating loss of \$3.81 million, compared with operating loss of \$2.85 million.
- | Net loss of \$3.79 million, or \$0.31 per diluted share, compared with net loss of \$8.65, or \$0.90 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 \$5.80 million.

Additional Financial Information

Second Quarter:

Total revenues in the 2017 second quarter of \$4.11 million increased 26.0% compared with \$3.27 million in the prior-year period. Product sales in the 2017 second quarter of \$2.89 million increased 42.2% compared with \$2.03 million in the prior-year period. R&D milestone, grant and royalty revenues in the 2017 second quarter of \$1.22 million decreased 0.8% compared with \$1.23 million in the prior-year period.

Gross margin dollars in the 2017 second quarter of \$1.91 million increased 20.1% compared with \$1.58 million in the prior-year period, due primarily to increased product sales. Product gross margin dollars in the 2017 second quarter of \$0.69 million increased 98.0% compared with \$0.35 million in the prior-year period, which also was primarily due to the increased product revenues.

R&D expenses in the 2017 second quarter of \$1.98 million decreased 16.3%, compared with \$2.37 million in the prior-year period. Selling, general and administrative expenses in the 2017 second quarter of \$2.11 million increased 31.9% compared with \$1.60 million in the prior-year period, largely due to investments made in our global sales and marketing organization, and professional fees.

Operating loss in the 2017 second quarter was \$2.18 million, compared with an operating loss of \$2.39 million in the prior-year period.

Net loss in the 2017 second quarter was \$2.17 million, or \$0.18 per diluted share, compared with net loss of \$8.35 million, or \$0.86 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 \$5.96 million.

First Six Months:

Total revenues in the 2017 first six months of \$10.44 million increased 5.8% compared with \$9.87 million in the prior-year period. Product sales in the 2017 first six months of \$8.32 million increased 4.6% compared with \$7.95 million in the prior-year period. R&D milestone, grant and royalty revenues in the 2017 first six months of \$2.12 million increased 10.6% compared with \$1.92 million in the prior-year period.

Gross margin dollars in the 2017 first six months of \$5.02 million increased 5.7% compared with \$4.75 million in the prior-year period, due primarily to the increase in product sales. The amount of product gross margin in the 2017 first six months of \$2.90 million increased 2.4% compared with \$2.83 million in the prior-year period, which also was primarily due to the increased product revenues.

R&D expenses in the 2017 first six months of \$4.23 million decreased 5.7%, compared with \$4.00 million in the prior-year period. Selling, general and administrative expenses in the 2017 first six months of \$4.60 million increased 27.8%, compared with \$3.60 million in the prior-year period, largely due to investments made in our global sales and marketing organization, and professional fees.

Operating loss in the 2017 first six months was \$3.81 million, compared with an operating loss of \$2.85 million in the prior-

year period.

Net loss in the 2017 first six months was \$3.79 million, or \$0.31 per diluted share, compared with net loss of \$8.65 million, or \$0.90 per diluted share, in the prior-year period. The net loss in the 2017 period includes a tax provision for the recording of a valuation allowance on the Company's deferred tax asset of \$5.80 million.

Balance Sheet Highlights:

The Company had cash and cash equivalents of \$3.69 million as of June 30, 2017, compared with \$10.55 million as of December 31, 2016. The decrease was primarily due to net cash used in operating activities of \$5.46 million. Our working capital decreased by \$4.44 million from \$14.71 million as of December 31, 2016 to \$10.27 million, largely due to cash used in operating activities and in investing activities, including the acquisition of RVR, for the six months of 2017.

Conference Call

To participate on the conference call, please dial (866) 682-6100 from the U.S. or (862) 255-5401 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 August 16, 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 #:19390. 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, 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 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)

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

For the three months

	<u>ended</u>		<u>For the six months ended</u>	
	<u>June 30, 2017</u>	<u>June 30, 2016</u>	<u>June 30, 2017</u>	<u>June 30, 2016</u>
Net product sales	\$ 2,892,942	\$ 2,034,072	\$ 8,320,314	\$ 7,951,091
License and royalty revenue	227,635	33,895	327,689	56,096
R&D, milestone and grant revenue	994,237	1,198,438	1,791,977	1,860,317
TOTAL REVENUES	\$ 4,114,814	\$ 3,266,405	\$ 10,439,980	\$ 9,867,504
GROSS MARGIN	\$ 1,910,971	\$ 1,580,305	\$ 5,016,923	\$ 4,745,853
Research and development expenses	\$ 1,982,426	\$ 2,367,466	\$ 4,228,998	\$ 4,001,764
Selling, general and administrative expenses	\$ 2,109,360	\$ 1,598,813	\$ 4,597,696	\$ 3,598,217
LOSS FROM OPERATIONS	\$ (2,180,815)	\$ (2,385,974)	\$ (3,809,771)	\$ (2,854,128)
OTHER INCOME:	\$ 7,722	\$ 1,310	\$ 21,104	\$ 3,874
Income tax provision	\$ -	\$ 5,962,818	\$ -	\$ 5,800,818
NET LOSS	\$ (2,173,093)	\$ (8,347,482)	\$ (3,788,667)	\$ (8,651,072)
Basic loss per share	\$ (0.18)	\$ (0.86)	\$ (0.31)	\$ (0.90)
Diluted loss per share	\$ (0.18)	\$ (0.86)	\$ (0.31)	\$ (0.90)
Weighted average number of shares outstanding, basic	12,299,122	9,667,543	12,284,979	9,649,612
Weighted average number of shares outstanding, diluted	12,299,122	9,667,543	12,284,979	9,649,612

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

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,691,783	\$ 10,554,464
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at June 30, 2017 and December 31, 2016, respectively	4,671,627	3,383,729
Inventories, net	4,993,951	3,335,188
Prepaid expenses and other current assets	777,688	840,145
TOTAL CURRENT ASSETS	14,135,049	18,113,526
FIXED ASSETS, net of accumulated depreciation	2,093,494	1,709,321
OTHER ASSETS	3,367,733	752,389

TOTAL ASSETS	\$ 19,596,276	\$ 20,575,236
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
TOTAL CURRENT LIABILITIES	\$ 3,862,792	\$ 3,405,650
TOTAL LIABILITIES	4,198,782	3,405,650
STOCKHOLDERS' EQUITY:		
Common stock - \$.01 par value; 100,000,000 shares authorized; 12,299,122 and 12,026,847 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	122,991	120,268
Additional paid-in capital	62,611,394	60,721,783
Accumulated other comprehensive income	124,241	-
Accumulated deficit	(47,461,132)	(43,672,465)
TOTAL STOCKHOLDERS' EQUITY	15,397,494	17,169,586
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 19,596,276	\$ 20,575,236

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

	<u>June 30, 2017</u>	<u>June 30, 2016</u>
Net cash used in operating activities	\$ (5,456,787)	\$ (3,856,555)
Net cash used in investing activities	(1,405,894)	(85,877)
Net cash provided by financing activities	-	5,370
DECREASE IN CASH AND CASH EQUIVALENTS	\$ (6,862,681)	\$ (3,937,062)

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