



November 12, 2015

ChemBio Diagnostics Reports Third Quarter Financial Results

Conference Call and Webcast Today at 10:00 a.m. Eastern Time

MEDFORD, N.Y., Nov. 12, 2015 (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 three and nine months ended September 30, 2015.

John J. Sperzel III, Chief Executive Officer, stated, "ChemBio continues to focus on the following three business areas: Sexually Transmitted Diseases ("STD"), Fever Diseases, and Technology Collaborations. During the third quarter of 2015, the company achieved significant milestones in each of these areas, which created additional value in our products and partnerships. With respect to STD, the launch of our SURE CHECK® HIV 1/2 self-testing kits in Europe was a great success, and we have received orders that will bring our total sales of these kits to approximately \$1.0 million in 2015. Concerning Fever Diseases, the Paul G. Allen Ebola Program selected DPP® as a platform for the first ever POC multiplex fever disease panel, granting ChemBio \$2.1 million for the 12-month development of this groundbreaking test. And, in the area of Technology Collaborations, our successful feasibility work with DPP® as a diagnostic platform for a specific type of cancer allowed us to advance to the development stage with additional committed funding from our DPP® Cancer partner."

Mr. Sperzel continued, "These recent successes drive us to reaffirm our commitment to innovation, the development of new products, and the optimization of existing products. Our successful feasibility work on a DPP® Malaria Assay allowed us to achieve a greater than 10-fold increase in sensitivity as compared to the current market-leading POC malaria test, and we plan to commercialize multiple DPP® Malaria Assays to identify plasmodium falciparum and other plasmodium infections. We also launched the DPP® Micro Reader, which we believe offers important data capture, transmission and storage capabilities. With growing validation from leading healthcare groups and our internal development successes, we believe we are well positioned to expand our product lines, our brands, and our markets worldwide."

Addressing the company's financial results, Mr. Sperzel commented, "During the third quarter of 2015, ChemBio recorded \$6.9 million in revenue — the highest quarterly revenue recorded in 2015. Revenues from our U.S. HIV product sales during the quarter increased by 21% as compared to the third quarter of 2014 and increased by 34% as compared to the second quarter of 2015. It is also important to note that sales of our DPP® Ebola Assay to the Centers for Disease Control and Prevention (CDC) for field testing in West Africa generated revenues of \$150,000 in the third quarter, with orders for our DPP® Malaria-Ebola and DPP® Ebola Assays of \$900,000 for the fourth quarter. We are also pleased to report that in the first half of the fourth quarter, we received payments of \$6.8 million from our customer in Brazil and the account receivable for this customer is current as of November 11, 2015. Initial indications for 2016 product demand from the Ministry of Health lead us to believe that Brazil will continue to be a strong market for ChemBio.

Financial information comparing the 2015 third quarter to the 2014 third quarter:

- | Total revenues of \$6.89 million, compared with \$7.31 million (a decrease of 5.8%).
- | Product sales of \$6.21 million, compared with \$7.25 million (a decrease of 14.3%).
- | Operating loss of \$579,000, compared with operating loss of \$262,000.
- | Net loss of \$437,000, or \$0.05 per diluted share, compared with net loss of \$271,000, or \$0.03 per diluted share.

Financial information comparing the first nine months of 2015 to the first nine months of 2014:

- | Total revenues of \$19.83 million, compared with \$20.55 million (a decrease of 3.5%).
- | Product sales of \$18.15 million, compared with \$19.40 million (a decrease of 6.5%).
- | Operating loss of \$2,352,000, compared with operating loss of \$878,000.
- | Net loss of \$1,748,000, or \$0.18 per diluted share, compared with net loss of \$641,000, or \$0.07 per diluted share.

Additional Financial Information

Third Quarter:

Total revenues for the third quarter of 2015 of \$6.89 million were down 5.8% compared with total revenues of \$7.31 million in the prior-year period. Product sales in the 2015 third quarter of \$6.21 million were down 14.3% compared with product sales of \$7.25 million in the prior-year period. R&D milestone, and grant and royalty revenues for the three months ended September 30, 2015 increased to \$678,000 from \$66,000 in the prior-year period.

Gross margin dollars for the 2015 third quarter increased 9.8% to \$2.91 million compared with \$2.65 million for the prior-year period, due primarily to the increase in non-product revenues. The amount of product gross margin dollars for the third quarter of 2015 decreased 13.6% to \$2.23 million, from \$2.58 million in the prior-year period.

R&D expenses in the third quarter of 2015 were \$1.57 million, compared with \$.97 million in the prior-year period. This increase is due primarily to increased R&D activities for projects and grants. Some projects are on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses to reach that milestone are expensed in the period incurred.

Selling, general and administrative expenses in the third quarter of 2015 decreased to \$1.92 million from \$1.94 million in the prior-year period, largely due to decreased consulting, stock-based compensation and marketing material expenses, partially offset by increases in staffing, wages and related costs, and increased travel expenses (related to our commercialization efforts).

Operating loss for the third quarter of 2015 was \$579,000, compared with an operating loss of \$262,000 for the prior-year period.

Net loss for the third quarter of 2015 was \$437,000, or \$0.05 per diluted share, compared with net loss of \$271,000, or \$0.03 per diluted share, for the prior-year period.

First Nine Months:

Total revenues for the first nine months of 2015 of \$19.83 million were down 3.5% compared with total revenues of \$20.55 million in the prior-year period. Product sales in the 2015 first nine months of \$18.15 million were down 6.5% compared with product sales of \$19.40 million in the prior-year period. R&D milestone, and grant and royalty revenues for the nine months ended September 30, 2015 increased to \$1.69 million from \$1.15 million in the prior-year period.

Gross margin dollars for the 2015 first nine months increased 9.0% to \$8.62 million compared with \$7.91 million for the prior-year period, due primarily to the increase in non-product revenues. The amount of product gross margin for the first nine months of 2015 increased 2.5% to \$6.93 million, from \$6.76 million in the prior-year period.

R&D expenses in the first nine months of 2015 were \$4.91 million, compared with \$3.44 million in the prior-year period. This increase is due primarily to increased R&D activities for projects and grants. Some projects are on a milestone basis for which revenue cannot be recognized until the milestone is achieved, while expenses to reach that milestone are expensed in the period incurred.

Selling, general and administrative expenses in the first nine months of 2015 increased to \$6.06 million from \$5.34 million in the prior-year period, largely due to increased commissions on sales in Brazil, increased staffing, wages and related costs, increased travel expenses (related to our commercialization efforts), and professional fees.

Operating loss for the first nine months of 2015 was \$2,353,000, compared with an operating loss of \$878,000 for the prior-year period.

Net loss for the first nine months of 2015 was \$1,748,000, or \$0.18 per diluted share, compared with net loss of \$641,000, or \$0.07 per diluted share, for the prior-year period.

Balance Sheet Highlights:

The Company had cash and cash equivalents of \$1.10 million as of September 30, 2015, compared with \$4.61 million as of December 31, 2014. The decrease was primarily due to net cash used in operating activities of \$2.58 million, as well as investing activities to fund the purchase of a license and deposits on and purchase of fixed assets of \$.93 million. Our accounts receivable balance as of September 30, 2015 was nearly double our historical levels. As of November 11, 2015 the customer, representing \$7.9 million of the September 30, 2015 receivables has made \$6.8 million in payments since the end of the third quarter of 2015. Our working capital decreased by \$1.77 million during the nine months from \$12.37 million

to \$10.60 million.

Conference Call

To participate on the conference call on November 12, 2015 at 10:00 a.m. Eastern Time, please dial (877) 407-0778 from the U.S. or (201) 689-8565 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until November 19, 2015 at 11:59 p.m. Eastern Time by dialing (877) 660-6853 from the U.S. or (201) 612-7415 from outside the U.S. and entering conference ID #:13623142. Those interested in listening to the conference call live via the internet may do so by visiting the Investor Relations section of Chembio's website at www.chembio.com. The conference call may also be accessed via the internet at <http://www.investorcalendar.com/IC/CEPage.asp?ID=174451>. 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 its DPP[®] HIV 1/2 Assay and HIV 1/2 STAT-PAK[®] Assay in the U.S. and internationally. The Company's SURE CHECK[®] HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview[®] Complete by a single entity. Outside the U.S., Chembio markets its SURE CHECK[®] HIV 1/2 Assay primarily through distributors.

Chembio has developed a patented point-of-care (POC) 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. Chembio Diagnostic Systems, Inc. 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. & Subsidiary
Summary of Consolidated Results of Operations
(UNAUDITED)

	<u>For the three months ended</u>		<u>For the nine months ended</u>	
	<u>September 30,</u>	<u>September 30,</u>	<u>September 30,</u>	<u>September 30,</u>
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Net product sales	\$ 6,209,625	\$ 7,247,881	\$ 18,145,864	\$ 19,400,515
License and royalty revenue	19,084	8,482	34,017	15,613
R&D, milestone and grant revenue	658,665	57,946	1,654,788	1,133,850
TOTAL REVENUES	\$ 6,887,374	\$ 7,314,309	\$ 19,834,669	\$ 20,549,978

GROSS MARGIN	\$	2,910,534	\$	2,650,390	\$	8,616,284	\$	7,905,551
Research and development expenses	\$	1,570,044	\$	972,439	\$	4,911,587	\$	3,438,714
Selling, general and administrative expenses	\$	1,919,551	\$	1,940,424	\$	6,057,221	\$	5,344,914
LOSS FROM OPERATIONS	\$	(579,061)	\$	(262,473)	\$	(2,352,524)	\$	(878,077)
OTHER INCOME (LOSS)	\$	(396)	\$	1,136	\$	1,095	\$	(1,180)
Income tax (benefit) provision	\$	(142,300)	\$	9,284	\$	(603,370)	\$	(237,916)
NET LOSS	\$	(437,157)	\$	(270,621)	\$	(1,748,059)	\$	(641,341)
Basic loss per share	\$	(0.05)	\$	(0.03)	\$	(0.18)	\$	(0.07)
Diluted loss per share	\$	(0.05)	\$	(0.03)	\$	(0.18)	\$	(0.07)
Weighted average number of shares outstanding, basic		9,628,248		9,611,139		9,625,282		9,503,084
Weighted average number of shares outstanding, diluted		9,628,248		9,611,139		9,625,282		9,503,084

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

	September 30, 2015	December 31, 2014
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,102,477	\$ 4,614,538
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at September 30, 2015 and December 31, 2014, respectively	9,514,951	8,338,889
Inventories	3,010,537	3,638,299
Prepaid expenses and other current assets	1,537,070	1,066,473
TOTAL CURRENT ASSETS	15,165,035	17,658,199
FIXED ASSETS, net of accumulated depreciation	2,622,003	2,797,929
OTHER ASSETS	5,021,065	4,554,064
TOTAL ASSETS	\$ 22,808,103	\$ 25,010,192
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 4,414,150	\$ 4,946,030
Deferred revenue	150,000	340,000
TOTAL CURRENT LIABILITIES	4,564,150	5,286,030
TOTAL LIABILITIES	4,564,150	5,286,030

STOCKHOLDERS' EQUITY:

Common stock - \$.01 par value; 100,000,000 shares authorized; 9,628,248 and 9,611,139 shares issued and outstanding for September 30, 2015 and December 31, 2014, respectively

Additional paid-in capital

Accumulated deficit

TOTAL STOCKHOLDERS' EQUITY

96,283	96,112
47,824,105	47,556,426
(29,676,435)	(27,928,376)
<u>18,243,953</u>	<u>19,724,162</u>

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY

<u>\$ 22,808,103</u>	<u>\$ 25,010,192</u>
-----------------------------	----------------------

Chembio Diagnostics, Inc. & Subsidiary

Summary of Consolidated Cash Flow

For the nine months ended

(UNAUDITED)

September 30, 2015 September 30, 2014

Net cash used in operating activities	\$ (2,584,508)	\$ (5,154,604)
Net cash used in investing activities	(927,553)	(1,060,149)
Net cash provided by financing activities	-	237,180
Decrease in cash and cash equivalents	<u>\$ (3,512,061)</u>	<u>\$ (5,977,573)</u>

Contacts:

Chembio Diagnostics
 Susan Norcott
 (631) 924-1135, ext. 125
 snorcott@chembio.com

Vida Strategic Partners (investor relations)
 Stephanie C. Diaz
 (415) 675-7401
 sdiaz@vidasp.com