

# **Chembio Diagnostics Reports Third Quarter 2014 Financial Results**

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

MEDFORD, NY, November 6, 2014 -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care diagnostic tests for infectious diseases, today reported financial results for the third quarter and nine months ended September 30, 2014.

John J. Sperzel III, Chembio's Chief Executive Officer, stated, "Our third quarter was extremely productive, and we are especially proud of the growth of our patented DPP® product sales which accounted for nearly 75% of our total revenue for the quarter. Total third quarter revenue of \$7.31 million was consistent with total second quarter revenue of \$7.42 million, and included DPP® third quarter product sales of \$5.41 million.

"We are pleased that our DPP® HIV 1/2 Assay was granted a CLIA Waiver last week using oral fluid, finger stick and venous whole blood. This waiver allows us to expand our sales and marketing initiatives to reach physician-office-lab (POL) facilities, clinics and other community healthcare providers. To support this effort, we recently signed agreements with two leading distribution organizations for the sale of our DPP® HIV 1/2 Assay and HIV 1/2 STAT-PAK® Assay in the U.S. With the combination of the DPP® HIV 1/2 CLIA Waiver and these distributor agreements in place, we expect a positive impact to sales going forward.

"And finally, to expand our growing DPP® application, we recently entered into agreements to develop new point-of-care DPP® assays for Ebola, dengue fever, febrile illness, and a specific form of cancer," concluded Mr. Sperzel.

Financial information comparing the 2014 third quarter to the 2013 third quarter (Note: the 2013 quarter included \$3.87 million shipped from a single \$5.3 million STAT-PAK® order, which has not recurred):

- Total revenues of \$7.31 million compared with \$9.62 million (a decrease of 24.0%);
- DPP<sup>®</sup> revenues of \$5.41 million compared with \$1.88 million (an increase of 188%);
- Operating loss of \$262,000, compared with operating income of \$1,074,000;
- Net loss of \$271,000, or \$0.03 per diluted share, compared with net income of \$717,000, or \$0.07 per diluted share.

Financial information comparing the 2014 first nine months to the 2013 first nine months (Note: the 2013 period included \$4.64 million shipped from the single \$5.3 million STAT-

PAK® order, which has not recurred, as described above):

- Total revenues of \$20.55 million compared with \$21.69 million (a decrease of 5.3%);
- DPP<sup>®</sup> revenues of \$11.75 million compared with \$3.72 million (an increase of 216%)
- Operating loss of \$878,000, compared with operating income of \$1,181,000;
- Net loss of \$641,000, or \$0.07 per diluted share, compared with net income of \$793,000, or \$0.08 per diluted share.

#### **Additional Third Quarter Information**

The total revenues for the 2014 third quarter consisted of product sales of \$7.25 million compared with \$9.04 million in the prior-year period, and research and development ("R&D"), milestone, and grant and royalty revenues of \$66,000 compared with \$573,000 for the prior-year period. The decrease in product sales is due primarily to the shipment in 2013 of \$3.87 million from the single non-recurred STAT-PAK® order described above.

Gross margin for the 2014 third quarter was \$2.65 million compared with \$4.06 million for the prior-year period, due primarily to the non-recurrence of the STAT-PAK® order described above and also to product mix. Product gross margin for the 2014 third quarter was \$2.58 million compared with \$3.48 million for the prior-year period, also due primarily to the non-recurrence of the STAT-PAK® order described above and also to product mix.

R&D expenses for the 2014 third quarter were \$.97 million compared with \$1.60 million for the prior-year period.

Selling, general and administrative expenses for the 2014 third quarter were \$1.94 million compared with \$1.38 million for the prior-year period, largely due to higher investment in sales and marketing personnel, increased commissions, and related costs.

Operating loss for the 2014 third quarter was \$262,000 compared with operating income of \$1,074,000 for the prior-year period.

Net loss for the 2014 third quarter was \$271,000, or \$0.03 per diluted share, compared with net income of \$717,000, or \$0.07 per diluted share, for the prior-year period.

#### Additional Nine-Month Information

The total revenues for the 2014 first nine months consisted of product sales of \$19.40 million compared with \$20.42 million for the prior-year period. R&D, milestone, and grant and royalty revenues for the 2014 first nine months were \$1,149,000 compared with \$1,270,000 for the prior-year period. The decrease in product sales is due primarily

to the shipment in 2013 of \$4.64 million from the single non-recurred STAT-PAK® order described above.

Gross margin for the 2014 first nine months was \$7.91 million compared with \$9.03 million for the prior-year period, due primarily to the non-recurrence of the STAT-PAK® order described above and also to product mix. Product gross margin for the 2014 first nine months was \$6.76 million compared with \$7.76 million for the prior-year period, also due primarily to the non-recurrence of the STAT-PAK® order described above and also to product mix.

R&D expenses for the 2014 first nine months were \$3.44 million compared with \$4.15 million for the prior-year period.

Selling, general and administrative expenses for the 2014 first nine months were \$5.34 million compared with \$3.70 million for the prior-year period, largely due to higher investment in sales and marketing personnel, increased commissions, and related costs.

Operating loss for the 2014 first nine months was \$878,000 compared with operating income of \$1,181,000 for the prior-year period.

Net loss for the 2014 first nine months was \$641,000, or \$0.07 per diluted share, compared with net income of \$793,000, or \$0.08 per diluted share, for the prior-year period.

#### **Balance Sheet Highlights**

The Company had cash and cash equivalents of \$3.67 million as of September 30, 2014, compared with \$9.65 million as of December 31, 2013. The decrease was primarily due to net cash used in investing activities to fund deposits on and purchase of fixed assets of \$1.06 million as well as net cash used in operating activities of \$5.15 million, which included an increase in accounts receivable of \$3.72 million, an increase in inventory of \$.79 million and a reduction in accounts payable of \$.49 million. Our working capital decreased by \$1.04 million during the year from \$14.22 million to \$13.18 million.

#### Conference Call

To participate on the conference call, 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 13, 2014 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 #:13594205. The conference call may also be accessed via the Internet at http://www.investorcalendar.com/IC/CEPage.asp?ID=173358. An archive of the webcast will be available for 90 days on the Company's website at www.chembio.com.

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 <a href="www.chembio.com">www.chembio.com</a>. To listen to the live call, please go to the website 15 minutes prior to its start to register, download, and install the necessary audio software. A replay will be available on the website for a limited time.

### **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. Outside the U.S., Chembio markets its SURE CHECK® HIV 1/2 Assay through 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. 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. Forwardlooking 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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# <u>Chembio Diagnostics, Inc. & Subsidiary</u> <u>Summary of Consoldidated Results of Operations</u> (UNAUDITED)

	For the three months ended			For the nine months ended				
	<u> </u>	mber 30, 2014	<u> </u>	ember 30, 2013		ember 30, 2014		ember 30, 2013
Net product sales	\$	7,247,881	\$	9,044,714	\$	19,400,515	\$	20,419,595
License and royalty revenue		8,482		898		15,613		898
R&D, milestone and grant revenue		57,946		572,027		1,133,850		1,268,821
TOTAL REVENUES	\$	7,314,309	\$	9,617,639	\$	20,549,978	\$	21,689,314
GROSS MARGIN	\$	2,650,390	\$	4,056,186	\$	7,905,551	\$	9,031,251
Research and development expenses	\$	972,439	\$	1,602,297	\$	3,438,714	\$	4,148,201
Selling, general and administrative expenses	\$	1,940,424	\$	1,379,845	\$	5,344,914	\$	3,702,181
(LOSS) INCOME FROM OPERATIONS	\$	(262,473)	\$	1,074,044	\$	(878,077)	\$	1,180,869
OTHER (EXPENSE) INCOME	\$	1,136	\$	1,477	\$	(1,180)	\$	10,877
Income tax (benefit) provision	\$	9,284	\$	358,850	\$	(237,916)	\$	398,940
NET (LOSS) INCOME	\$	(270,621)	\$	716,671	\$	(641,341)	\$	792,806
Basic (loss) earnings per share	\$	(0.03)	\$	0.08	\$	(0.07)	\$	0.09
Diluted earnings (loss) per share	\$	(0.03)	\$	0.07	\$	(0.07)	\$	0.08
Weighted average number of shares outstanding, basic		9,611,139		9,324,783		9,503,084		8,886,998
Weighted average number of shares outstanding, diluted		9,611,139		9,824,019		9,503,084		9,433,152

## <u>Chembio Diagnostics, Inc. & Subsidiary</u> <u>Summary of Consolidated Balance Sheets</u>

	Septe	ember 30, 2014	December 31, 2013		
	(U	NAUDITED)			
CURRENT ASSETS:					
Cash and cash equivalents	\$	3,672,702	\$	9,650,275	
Accounts receivable, net of allowance for					
doubtful accounts of \$24,000 at September					
30, 2014 and December 31, 2013, respectively		8,315,651		4,592,121	
Inventories		3,975,250		3,188,726	
Prepaid expenses and other current assets		1,035,435		1,099,379	
TOTAL CURRENT ASSEIS		16,999,038		18,530,501	
FIXED ASSETS, net of accumulated					
depreciation		2,118,756		1,978,232	
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OTHER ASSETS		4,810,825		3,977,859	
TOTAL ASSETS	\$	23,928,619	\$	24,486,592	
CURRENT LIABILITIES:					
Accounts payable and accrued liabilities	\$	3,819,271	\$	4,309,490	
TOTAL LIABILITIES		3,819,271		4,309,490	
STOCKHOLDERS' EQUITY:					
Common stock - \$.01 par value; 100,000,000					
shares authorized; 9,611,139 and 9,324,783 shares					
issued and outstanding for September 30, 2014					
and December 31, 2013, respectively		96,112		93,248	
Additional paid-in capital		47,445,750		46,875,027	
Accumulated deficit		(27,432,514)		(26,791,173)	
TOTAL STOCKHOLDERS' EQUITY		20,109,348		20,177,102	
TOTAL LIABILITIES AND					
STOCKHOLDERS' EQUITY	\$	23,928,619	\$	24,486,592	

# Chembio Diagnostics, Inc. & Subsidiary Summary of Consolidated Cash Flow For the nine months ended (UNAUDITED)

·	Septe	mber 30, 2014	<b>September 30, 2013</b>		
Net cash (used in) provided by operating activities	\$	(5,154,604)	\$	583,808	
Net cash used in investing activities		(1,060,149)		(796,274)	
Net cash provided by financing activities		237,180		5,306,412	
(DECREASE)/INCREASE IN CASH AND CASH					
EQUIVALENTS	\$	(5,977,573)	\$	5,093,946	