



August 11, 2016

## **ChemBio Diagnostics Reports Second Quarter 2016 Financial Results**

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

MEDFORD, N.Y., Aug. 11, 2016 (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 six months ended June 30, 2016.

John J. Sperzel III, the Company's Chief Executive Officer, stated, "ChemBio's sales of sexually transmitted disease tests decreased during the second quarter of 2016, due to the discontinuation of sales to the Company's former U.S. distributor following expiration of their distribution agreement for our SURE CHECK<sup>®</sup> HIV 1/2 product as well as decreased sales of its DPP<sup>®</sup> HIV and DPP<sup>®</sup> Syphilis products in Brazil and HIV products in Africa during the quarter. The decrease in product sales in Brazil was primarily due to the Company's loss of ongoing business as a result of a previously disclosed tender offer in Brazil having been awarded to a competitor at an extremely low price point. Despite the loss of this tender, ChemBio continues to supply other DPP<sup>®</sup> products to Bio-Manguinhos/Fiocruz and the Ministry of Health in Brazil, as well as other organizations in Latin America, and we believe this region will continue to be a strong market for ChemBio. In particular, we believe the anticipated launch of the DPP<sup>®</sup> Zika IgM/IgG Assay and DPP<sup>®</sup> Micro Reader, as well as related fever disease assays currently in development, will be important new products in this region."

Addressing the Company's technology, Mr. Sperzel commented, "The Company believes its patented DPP<sup>®</sup> technology is unique due to its inherent characteristics, such as enhanced sensitivity, the ability to detect multiple diseases with a single patient sample, the ability to use multiple specimen types, such as oral fluid or blood, and the ability to provide quantitative results when combined with the DPP<sup>®</sup> Micro Reader. Considering the progress made in each of ChemBio's three business areas during the quarter, the versatility and utility of this technology has never been more evident.

In our sexually transmitted disease business, the clinical trial for the DPP<sup>®</sup> HIV-Syphilis Assay for the U.S. market is advancing well, and we anticipate completion by the end of the first quarter of 2017. Advances in our fever disease business in the second quarter include initiating development of the world's first oral fluid/saliva POC diagnostic test to detect all species of malaria, which is being funded by the Bill & Melinda Gates Foundation. We also made significant progress toward the development of the DPP<sup>®</sup> Zika IgM/IgG Assay, under initial funding from the Paul G. Allen Family Foundation, which the Company received in February 2016. The progress with this program has been rapid, and results have been highly encouraging. We are hopeful that this product will receive U.S. Government funding as well as approval following submissions to numerous regulatory agencies, providing health organizations around the world with an important tool to combat the further spread of the Zika virus. Just two weeks ago, the first such approval, a CE mark, was obtained for the commercialization of the DPP<sup>®</sup> Zika IgM/IgG System in 17 European countries as well as the Caribbean region. As this system includes a DPP<sup>®</sup> Zika IgM/IgG Assay in combination with the DPP<sup>®</sup> Micro Reader, launch of this system will be the first of the Company's technology collaboration products to be commercialized - another significant milestone for ChemBio and our DPP<sup>®</sup> technology.

And earlier this month, ChemBio successfully raised the funds to support this expanding work and to partially apply toward building the global infrastructure to drive sales of new and existing products. In view of these matters, we are proud of our continued progress in the second quarter of 2016 toward expanding our product portfolio, and our continued work to make much-needed POC diagnostics available to battle the spread of HIV, Syphilis, Zika, Dengue, Malaria and other life-threatening diseases."

### **Selected Summary Financial Information comparing the 2016 second quarter to the 2015 second quarter:**

- | Total revenues of \$3.27 million, compared with \$6.72 million (a decrease of 51.4%).
- | Product sales of \$2.03 million, compared with \$6.32 million (a decrease of 67.8%).

- | Operating loss of \$2,386,000, compared with operating loss of \$898,000.
- | Net loss of \$8,347,000, or \$0.86 per diluted share, compared with net loss of \$664,000, or \$0.07 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 \$5,963,000 (See Valuation Allowance below).

### **Selected Summary Financial Information comparing the first six months of 2016 to the first six months of 2015:**

- | Total revenues of \$9.87 million, compared with \$12.95 million (a decrease of 23.8%).
- | Product sales of \$7.95 million, compared with \$11.94 million (a decrease of 33.4%).
- | Operating loss of \$2,854,000, compared with operating loss of \$1,773,000.
- | Net loss of \$8,651,000, or \$0.90 per diluted share, compared with net loss of \$1,311,000, or \$0.14 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 \$5,801,000 (See Valuation Allowance below).

### **Additional Financial Information**

#### Second Quarter:

Total revenues in the 2016 second quarter of \$3.27 million decreased 51.4% compared with \$6.72 million in the prior-year period. Product sales in the 2016 second quarter of \$2.03 million decreased 67.8% compared with \$6.32 million in the prior-year period. R&D milestone, and grant and royalty revenues in the 2016 second quarter of \$1,232,000 increased 212.3% compared with \$395,000 in the prior-year period.

Gross margin dollars in the 2016 second quarter of \$1.58 million decreased 47.7% compared with \$3.02 million in the prior-year period, due primarily to decreased product revenues. Product gross margin dollars in the 2016 second quarter of \$.35 million decreased 86.7% compared with \$2.62 million in the prior-year period, which also was primarily due to the decreased product revenues.

R&D expenses in the 2016 second quarter of \$2.37 million increased 34.7%, compared with \$1.76 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 2016 second quarter of \$1.60 million decreased 26.0% compared with \$2.16 million in the prior-year period, largely due to decreased commissions, due to decreased sales in Brazil, as well as decreases in wages and related costs, stock-based compensation, travel, entertainment and trade shows, consulting, and professional fees, which were partially offset by increases in marketing materials, and investor relations expenses.

Operating loss in the 2016 second quarter was \$2,386,000, compared with an operating loss of \$898,000 in the prior-year period.

Net loss in the 2016 second quarter was \$8,347,000, or \$0.86 per diluted share, compared with net loss of \$664,000, or \$0.07 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 \$5,963,000.

#### First Six Months:

Total revenues in the 2016 first six months of \$9.87 million decreased 23.8% compared with \$12.95 million in the prior-year period. Product sales in the 2016 first six months of \$7.95 million decreased 33.4% compared with \$11.94 million in the prior-year period. R&D milestone, and grant and royalty revenues in the 2016 first six months of \$1,916,000 increased 89.6% compared with \$1,011,000 in the prior-year period.

Gross margin dollars in the 2016 first six months of \$4.75 million decreased 16.8% compared with \$5.71 million in the prior-year period, due primarily to the decrease in product sales. The amount of product gross margin in the 2016 first six months of \$2.83 million decreased 39.7% compared with \$4.69 million in the prior-year period.

R&D expenses in the 2016 first six months of \$4.00 million increased 19.8%, compared with \$3.34 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 2016 first six months of \$3.60 million decreased 13.0%, compared with

\$4.14 million in the prior-year period, largely due to decreased commissions on sales in Brazil, decreased wages and related costs, stock-based compensation and travel, entertainment and trade shows, which were partially offset by increases in consulting, marketing materials, investor relations expenses and professional fees.

Operating loss in the 2016 first six months was \$2,854,000, compared with an operating loss of \$1,773,000 in the prior-year period.

Net loss in the 2016 first six months was \$8,651,000, or \$0.90 per diluted share, compared with net loss of \$1,311,000, or \$0.14 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 \$5,801,000.

#### Valuation Allowance

The Company elected, based on accounting guidance, to record a full Valuation Allowance ("VA") on its Deferred Tax Asset ("DTA"). Chembio's DTA was primarily based on the Company's Net Operating Loss (NOL) carryforwards. Based primarily on the fact that the Company believes, given information available to it at this time, that it is more likely than not that the deferred tax asset will not be realized in the foreseeable future, the Company concluded that it was appropriate to record a full VA against its DTA. This resulted in a tax provision in the second quarter of 2016 of \$5.96 million and for the six months ended June 30, 2016 of \$5.80 million. This VA does not affect the Company's ability to use its NOLs in the future.

#### Balance Sheet Highlights:

The Company had cash and cash equivalents of \$1.44 million as of June 30, 2016, compared with \$5.38 million as of December 31, 2015. The decrease was primarily due to net cash used in operating activities of \$3.86 million. Our working capital decreased by \$2,646,000 from \$9.48 million as of December 31, 2015 to \$6.83 million.

Subsequent to June 30, 2016, in early August 2016, the Company sold 2,300,000 common shares for a total of \$13.8 million, which after expenses resulted in approximately \$12.5 million in net funds to the Company.

#### **Conference Call**

To participate on the conference call on August 11, 2016 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 August 18, 2016 at 11:59 p.m. Eastern Time by dialing (877) 481-4010 from the U.S. or (919) 882-2331 from outside the U.S. and entering conference ID #: 13642880. 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](http://www.chembio.com). The conference call may also be accessed via the internet at <http://www.investorcalendar.com/IC/CEPage.asp?ID=175233>. An archive of the webcast will be available for 90 days on the Company's website at [www.chembio.com](http://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<sup>®</sup> HIV 1/2 Assay, HIV 1/2 STAT-PAK<sup>®</sup> Assay, and SURE CHECK<sup>®</sup> HIV 1/2 Assay, with these Chembio brand names, in the U.S. and internationally both directly and through third-party distributors. The Company's SURE CHECK<sup>®</sup> HIV 1/2 Assay previously has been exclusively sold in the U.S. as Clearview<sup>®</sup> Complete HIV 1/2 Assay.

Chembio has developed a patented point-of-care (POC) test platform technology, the Dual Path Platform (DPP<sup>®</sup>) 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](http://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 six months ended</u>	
	<u>June 30, 2016</u>	<u>June 30, 2015</u>	<u>June 30, 2016</u>	<u>June 30, 2015</u>
<b>Net product sales</b>	<b>\$ 2,034,072</b>	<b>\$ 6,321,554</b>	<b>\$ 7,951,091</b>	<b>\$ 11,936,239</b>
<b>License and royalty revenue</b>	<b>33,895</b>	<b>7,882</b>	<b>56,096</b>	<b>14,933</b>
<b>R&amp;D, milestone and grant revenue</b>	<b>1,198,438</b>	<b>386,722</b>	<b>1,860,317</b>	<b>996,123</b>
<b>TOTAL REVENUES</b>	<b>\$ 3,266,405</b>	<b>\$ 6,716,158</b>	<b>\$ 9,867,504</b>	<b>\$ 12,947,295</b>
<b>GROSS MARGIN</b>	<b>\$ 1,580,305</b>	<b>\$ 3,019,132</b>	<b>\$ 4,745,853</b>	<b>\$ 5,705,750</b>
<b>Research and development expenses</b>	<b>\$ 2,367,466</b>	<b>\$ 1,757,007</b>	<b>\$ 4,001,764</b>	<b>\$ 3,341,543</b>
<b>Selling, general and administrative expenses</b>	<b>\$ 1,598,813</b>	<b>\$ 2,160,096</b>	<b>\$ 3,598,217</b>	<b>\$ 4,137,670</b>
<b>LOSS FROM OPERATIONS</b>	<b>\$ (2,385,974)</b>	<b>\$ (897,971)</b>	<b>\$ (2,854,128)</b>	<b>\$ (1,773,463)</b>
<b>OTHER INCOME:</b>	<b>\$ 1,310</b>	<b>\$ 316</b>	<b>\$ 3,874</b>	<b>\$ 1,491</b>
<b>Income tax expense (benefit)</b>	<b>\$ 5,962,818</b>	<b>\$ (233,570)</b>	<b>\$ 5,800,818</b>	<b>\$ (461,070)</b>
<b>NET LOSS</b>	<b>\$ (8,347,482)</b>	<b>\$ (664,085)</b>	<b>\$ (8,651,072)</b>	<b>\$ (1,310,902)</b>
<b>Basic loss per share</b>	<b>\$ (0.86)</b>	<b>\$ (0.07)</b>	<b>\$ (0.90)</b>	<b>\$ (0.14)</b>
<b>Diluted loss per share</b>	<b>\$ (0.86)</b>	<b>\$ (0.07)</b>	<b>\$ (0.90)</b>	<b>\$ (0.14)</b>
<b>Weighted average number of shares outstanding, basic</b>	<b>9,667,543</b>	<b>9,627,951</b>	<b>9,649,612</b>	<b>9,623,773</b>
<b>Weighted average number of shares outstanding, diluted</b>	<b>9,667,543</b>	<b>9,627,951</b>	<b>9,649,612</b>	<b>9,623,773</b>

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

	<u>June 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,439,869	\$ 5,376,931
Accounts receivable, net of allowance for doubtful accounts of \$52,000 at June 30, 2016 and December 31, 2015, respectively	4,579,553	2,422,971
Inventories	3,481,819	3,578,025
Prepaid expenses and other current assets	860,340	1,256,879
<b>TOTAL CURRENT ASSETS</b>	<b>10,361,581</b>	<b>12,634,806</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>2,035,666</b>	<b>2,374,308</b>
<b>OTHER ASSETS</b>	<b>292,032</b>	<b>5,807,230</b>
<b>TOTAL ASSETS</b>	<b>\$ 12,689,279</b>	<b>\$ 20,816,344</b>
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 2,708,362	\$ 2,801,432
Deferred revenue	818,848	353,406
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,527,210</b>	<b>3,154,838</b>
<b>TOTAL LIABILITIES</b>	<b>3,527,210</b>	<b>3,154,838</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock - \$.01 par value; 100,000,000 shares authorized; 9,686,242 and 9,628,248 shares issued and outstanding for June 30, 2016 and December 31, 2015, respectively	96,862	96,282
Additional paid-in capital	48,041,697	47,890,642
Accumulated deficit	(38,976,490)	(30,325,418)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>9,162,069</b>	<b>17,661,506</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 12,689,279</b>	<b>\$ 20,816,344</b>

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

	<u>June 30, 2016</u>	<u>June 30, 2015</u>
Net cash used in operating activities	\$ (3,856,555)	\$ (2,166,001)
Net cash used in investing activities	(85,877)	(884,466)
Net cash provided by financing activities	5,370	-
<b>Decrease in cash and cash equivalents</b>	<b>\$ (3,937,062)</b>	<b>\$ (3,050,467)</b>

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