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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 8-K

### CURRENT REPORT

#### PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 8, 2017 (November 8, 2017)



#### **CHEMBIO DIAGNOSTICS, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction  
of Incorporation)

**0-30379**

(Commission File Number)

**88-0425691**

(IRS Employer  
Identification Number)

**3661 Horseblock Road**

**Medford, NY 11763**

(Address of principal executive offices)

**631-924-1135**

(Registrant's Telephone Number)

**N/A**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**ITEM 7.01.****REGULATION FD DISCLOSURE.**

On November 8, 2017, the Company issued a press release entitled "Chembio Diagnostics Reports Third Quarter 2017 Financial Results". A copy of the press release is furnished herewith as Exhibit 99.1

On November 8, 2017, the Company posted a PowerPoint Presentation to their website entitled "Investor Presentation November, 2017." A copy of the presentation is furnished herewith as Exhibit 99.2.

In addition, also on November 8, 2017, the Company posted an Investor Fact Sheet to their website. A copy of the fact sheet is furnished herewith as Exhibit 99.3

The information in this Item 7.01 of this Form 8-K is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Form 8-K also shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference.

**ITEM 9.01.****FINANCIAL STATEMENTS AND EXHIBITS**

Exhibit Number	Description
99.1	Press Release entitled "Chembio Diagnostics Reports Third Quarter 2017 Financial Results" dated November 8, 2017
99.2	Presentation entitled "Investor Presentation November 2017" dated November 8, 2017
99.3	Investor Fact Sheet posted to the company website dated November 8, 2017

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

November 8, 2017

Chembio Diagnostics, Inc.

By: By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer

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**EXHIBIT INDEX**

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## **Chembio Diagnostics Reports Third Quarter 2017 Financial Results**

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

MEDFORD, NY, November 8, 2017 -- 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](http://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](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® 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](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)**

## Contacts:

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

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

	<u>For the three months ended</u>		<u>For the nine months ended</u>	
	<u>September 30, 2017</u>	<u>September 30, 2016</u>	<u>September 30, 2017</u>	<u>September 30, 2016</u>
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
<b>TOTAL REVENUES</b>	<b>\$ 7,587,374</b>	<b>\$ 3,746,461</b>	<b>\$ 18,027,354</b>	<b>\$ 13,613,965</b>
<b>GROSS MARGIN</b>	<b>\$ 3,522,583</b>	<b>\$ 1,952,097</b>	<b>\$ 8,539,506</b>	<b>\$ 6,697,950</b>
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
<b>LOSS FROM OPERATIONS</b>	<b>\$ (588,513)</b>	<b>\$ (2,144,073)</b>	<b>\$ (4,398,284)</b>	<b>\$ (4,998,201)</b>
<b>OTHER INCOME:</b>	<b>\$ 3,852</b>	<b>\$ 5,855</b>	<b>\$ 24,956</b>	<b>\$ 9,729</b>
Income tax provision	\$ -	\$ -	\$ -	\$ 5,800,818
<b>NET LOSS</b>	<b>\$ (584,661)</b>	<b>\$ (2,138,218)</b>	<b>\$ (4,373,328)</b>	<b>\$ (10,789,290)</b>
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)**

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
<b>CURRENT ASSETS:</b>		
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
<b>TOTAL CURRENT ASSETS</b>	<b>13,718,598</b>	<b>18,113,526</b>
<b>FIXED ASSETS, net of accumulated depreciation</b>	<b>1,964,427</b>	<b>1,709,321</b>
<b>OTHER ASSETS</b>	<b>3,561,679</b>	<b>752,389</b>
<b>TOTAL ASSETS</b>	<b>\$ 19,244,704</b>	<b>\$ 20,575,236</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>TOTAL CURRENT LIABILITIES</b>	<b>\$ 3,870,161</b>	<b>\$ 3,405,650</b>
<b>TOTAL LIABILITIES</b>	<b>4,305,631</b>	<b>3,405,650</b>
<b>STOCKHOLDERS' EQUITY:</b>		
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)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>14,939,073</b>	<b>17,169,586</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 19,244,704</b>	<b>\$ 20,575,236</b>

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

	<u>September 30, 2017</u>	<u>September 30, 2016</u>
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
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>\$ (8,682,482)</b>	<b>\$ 6,795,023</b>





# Corporate Fact Sheet

November 8, 2017

## STOCK INFORMATION (as of November 7, 2017)

Ticker:	CEMI
Exchange:	Nasdaq
Share Price:	\$ 6.40/share
Market Cap:	\$74.47 Million

## CORPORATE HIGHLIGHTS

### **A global leader in point-of-care (POC) infectious disease diagnostics**

- § Sales in 40+ countries
- § Global commercialization organization servicing the U.S., Europe, Africa, Asia Pacific and Latin America
- § Operations and manufacturing in the U.S. and Southeast Asia

### **Groundbreaking patented DPP® technology platform**

- § Superior sensitivity and specificity vs. traditional lateral flow technology
- § Multiple tests from a tiny (10uL) drop of fingertip blood (multiplexing)

### **Robust pipeline of new DPP® POC assays in development**

- § DPP® HIV-Syphilis Combination Assay (U.S. version)
- § DPP® Fever Assays –Africa (Malaria, Dengue, Zika, Chikungunya, Ebola, Lassa, Marburg)
- § DPP®Fever Assay-Asia (Malaria, Dengue, Zika, Chikungunya, Leptospirosis, *Rickettsia typhi*, *Burkholderia Pseudomallei Orientia tsutsugamushi*.)
- § DPP® Technology Collaborations (Traumatic Brain Injury, Cancer, Bovine TB)

### **Multiple high-value collaborations**

- § U.S. Government, HHS/ASPR/BARDA: Zika, Dengue, Chikungunya
- § Paul G. Allen Ebola Program: Fever Panel- Africa, Zika
- § Bill & Melinda Gates Foundation: Malaria Oral Fluid/Saliva
- § Centers for Disease Control & Prevention (CDC): Malaria, Ebola
- § FIND: Fever Panel- Asia

## COMPANY SNAPSHOT

**Chembio Diagnostics, Inc.** (NASDAQ: CEMI) develops, manufactures, licenses and markets rapid diagnostic assays in the growing \$8.0 billion point-of-care (POC) testing market. In addition to its branded and proprietary HIV and fever disease assays, which it sells in the U.S. and/or internationally, the Company has several ongoing collaborations for the development of diagnostic assays for Malaria, Dengue Fever, Zika, Ebola and other febrile illness, brain injury and a specific form of cancer.

**Dual Path Platform (DPP®)** is Chembio's patented POC technology, which offers significant advantages over lateral-flow technologies including enhanced sensitivity and the ability to conduct multiple tests from a single sample (multiplexing). DPP® continues to provide Chembio with a growing pipeline of business opportunities for the development and manufacture of new products.

## CHEMBIO'S LEAD PRODUCTS

### **DPP® HIV-Syphilis Assay** \*available in selected non-U.S. markets

- o Rapid, multiplex detection of HIV 1, HIV 2 and syphilis using a single sample



## **DPP® HIV 1/2 Assay**

- o Rapid detection of HIV 1 and HIV 2 antibodies in oral fluid and all blood matrices

## **HIV 1/2 STAT-PAK® Assay**

- o Single-use, rapid, visual detection of HIV 1 and HIV 2 antibodies

## **SURE CHECK® HIV 1/2 Assay**

- o Self-contained, single-use collection & testing device

(See graphics)

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## **CHEMBIO'S DPP® DUAL PATH PLATFORM**

- § Patented technology
- § Allows improved sensitivity and specificity compared to lateral flow technology
- § Enables multiple test results via a single blood sample (e.g., HIV-Syphilis Combo Assay)
- § Utilized with DPP® Micro Reader for semi-quantitative results
- § Offers application within infectious disease and potential for a number of other indications

(See graphics)

## **SALES AND MARKETING**

- § Global commercialization organization
- § Internal sales and marketing infrastructure
- § Partnerships with leading distributors
- § Experienced and accomplished leadership
- § Strategic base of operations in Southeast Asia
- § Sales organization servicing the U.S., Europe, Africa, Asia Pacific and Latin America

## **MANUFACTURING AND OPERATIONS**

- § Operations in Medford, New York and Malaysia
- § High volume manufacturing capabilities
- § 65,000 sq. ft. leased facilities
- § Robust quality management system
- § Regulatory access in Southeast Asia
- § Total employees: ~165

## **Sexually Transmitted Diseases**

### **HIV**

- o Approximately 37 million people living with HIV/AIDS worldwide (2015)
- o More than 1.1 million people in the U.S. are living with HIV infection, and approximately 1 in 8 are unaware of their infection

## **SYPHILIS**

- Approximately 12 million people globally become ill with syphilis annually (2015)
- From 2005-2013, syphilis cases in the U.S. nearly doubled, from 8,724 to 16,663

## **Fever Diseases**

### **Malaria**

- Approximately 214 million infections and 438,000 deaths annually (2015)

### **Dengue Fever**

- Approximately 390 million infections annually with 40% of the world population at risk (2013)

### **Ebola**

- Approximately 28,000 infections and 11,000 deaths in 2014 – 2015

### **Zika**

- Since 2015, the geographical range of Zika virus has expanded rapidly, with transmission reported in 60+ countries

## **DPP PIPELINE & COLLABOTATORS**

### **Chembio Current Internal Development:**

- DPP® HIV-Syphilis Assay (U.S. market)
- DPP® Malaria Assay
- DPP® Chikungunya Assay

### **Current Development Collaborations:**

- DPP® Dengue Fever – Undisclosed collaborator
- DPP® Ebola & Febrile Illness – CDC Research Agreement
- DPP® Fever Panel – Africa- The Paul G. Allen Ebola Program
- DPP® Fever Panel – Asia- FIND
- DPP® Malaria OF/Saliva– The Bill & Melina Gates Foundation
- DPP® Zika Assay – The Paul G. Allen Family Foundation & HHS/BARDA
- DPP® Zika/Dengue/Chikungunya Assay – HHS/BARDA (HHS option)
- DPP® Traumatic Brain Injury – Perseus Science Group LLC
- DPP® Cancer (a specific form) – Undisclosed collaborator
- DPP® BovidTB Assay – U.S. Department of Agriculture

### **Tech Transfer and Distribution:**

- DPP® technology for Geenius™ HIV 1/2 Confirmatory Assay – Bio Rad
- DPP® product distribution in Brazil – Oswaldo Cruz Foundation
- DPP® co-branding and distribution in Brazil – Labtest Diagnostica SA

## **SENIOR EXECUTIVE OFFICERS**

John J. Sperzel III, Chief Executive Officer

Javan Esfandiari, M.S., Chief Science & Technology Officer

Richard Larkin, CPA, Chief Financial Officer

Sharon Klugewicz, M.S., President, America's Region

Robert Passas, Ph.D, President, EMEA & APAC Regions

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Company Contact  
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snorcott@chembio.com





## Investor Presentation November 8, 2017

NASDAQ:CEMI

*Rapid Tests for Earlier Treatment™™*

Slide 2

### Forward Looking Statements

Statements contained herein that are not historical facts are forward-looking statements within the meaning of the Securities Act of 1933, as amended. Those statements include statements regarding the intent, belief or current expectations of Chembio and its management. Such statements 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 develop, manufacture, market and finance new products and 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. Other 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.

Slide 3

### Investment Highlights

- § **A global leader in point-of-care (POC) infectious disease**
  - Sales & marketing organization in U.S., Europe, Africa, APAC and LATAM
  - Manufacturing operations in the U.S. (Medford, NY) and Southeast Asia (Malaysia)
- § **Groundbreaking patented DPP® technology platform**
  - Superior sensitivity and specificity vs. traditional lateral flow technology
  - Multiple tests from a tiny (10µL) drop of fingertip blood (multiplexing)
- § **Robust pipeline of new DPP® POC assays in development**
  - DPP® HIV-Syphilis Combination Assay (U.S. version)
  - DPP® Fever Assays (Malaria, Dengue, Zika, Chikungunya, Ebola, Lassa, Marburg)
  - DPP® Technology Collaborations (Traumatic Brain Injury, Cancer, Bovine TB)
- § **Multiple high-value collaborations**
  - U.S. Government:
    - HHS/ASPR/BARDA: Zika (HHS option: Zika/Dengue/Chikungunya);
    - CDC: Malaria, Ebola, Zika, Zika/Dengue/Chikungunya
  - Paul G. Allen Ebola Program: Fever Panel- Africa, Zika
  - Bill & Melinda Gates Foundation: Malaria Oral Fluid/Saliva
  - FIND: Fever Panel - Asia

Slide 4

### Chembio's Dual Path Platform (DPP®) Technology Next-Generation Point-of-Care Technology Platform

- § Patented POC technology platform
- § Improved sensitivity vs. lateral flow technology
- § Multiplex capability - multiple test results from a single patient sample
- § Adapts to multiple sample types (blood, oral fluid)
- § Application across a range of diseases and markets
- § Unique sample collection device: Sampletainer®

See graphics

Slide 5

## **Chembio's Dual Path Platform (DPP®) Technology Leveraging Our Technology Platform to Enter New Markets**

Three areas of Strategic Focus:

- **STD Business**
- Fever Portfolio
- Technology Collaborations

DPP® Technology Platform

Slide 6

## **HIV Continues to be a Global Health Crisis U.S. Syphilis Cases Increase and Risk of HIV-Syphilis Co-Infection**

### **United States (HIV)**

- ~ **1.2 million** living with HIV/AIDS
- ~ **50,000** new HIV infections/year
- ~ **1 in 8** unaware of HIV infection

### **United States (SYP)**

- ~ **63,000\*** new infections (2014)

### **Global (HIV)**

- ~ **36.7 million** living with HIV/AIDS (2015)
- ~ **1.1 million** died of AIDS-related illnesses (2015)

### **Global (SYP)**

- ~ **12 million** new infections/year

*\*"Between 2014 and 2015, the number of reported primary and secondary (P&S) cases in the United States increased by 19%. In the United States, approximately half of men who have sex with men (MSM) with primary and secondary (P&S) syphilis were also living with HIV. In addition, MSM who are HIV-negative and diagnosed with P&S syphilis are more likely to be infected with HIV in the future."*

Source: Centers for Disease Control & Prevention (CDC) website; World Health Organization (WHO) website

Slide 7

## **Chembio Lateral Flow HIV Tests Foundational HIV Product Suite**

### **Product Features & Benefits**

- FDA (PMA) approved, CLIA-waived
- CE marked, WHO pre-qualified
- 2.5 - 5.0 µL blood sample
- 15 - 20 minute test time
- Specificity: 99.9%, Sensitivity: 99.7%

### **Commercialization**

- High quality brands, marketed globally since 2007
- Sold to Public Health Clinics, POLs, Hospitals, Self Test (EU)
- Distribution Partners US: Fisher, McKesson/PSS, H. Schein, Medline, Caribbean: Isla Lab

See graphics

Slide 8

## **Chembio DPP® HIV-SYP and DPP® HIV 1/2 Assays Strengthening our HIV/STD Portfolio**

- § **DPP® HIV-Syphilis Combo Assay**

- Chembio has a history of leadership
  - First to receive USAID, ANVISA, COFEPRIS (Mexico) approval
  - First to market/sell in Latin America
- Global screening opportunity:
  - Pregnant women
  - MSM (up to 70% HIV-Syphilis co-infection)
- Received CE mark (Q1 2017)
- Completed U.S. clinical trial for FDA PMA submission to be completed during Q4'17
- **DPP® HIV 1/2 Assay**
  - FDA-approved (2013), CLIA-waived (2014) (blood and oral fluid)
  - Superior performance vs. competitors (sensitivity)
  - Patented SampleTainer® Sample Collection System

See graphics

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## **Chembio's Dual Path Platform (DPP®) Technology Leveraging Our Technology Platform to Enter New Markets**

Three areas of Strategic Focus:

- STD Business
- **Fever Portfolio**
- Technology Collaborations

DPP® Technology Platform

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## **Fever Disease – Product Development Chembio is Collaborating with World Leading Organizations**

- Bill & Melinda Gates foundation
- CDC - Center for Disease Control
- BARDA
- FIND
- Fiocruz
- The Paul G. Allen Family Foundation

See graphics

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## **DPP® Fever Disease - Product Development Malaria, Dengue, Zika, Chikungunya, Ebola, Lassa, Marburg**

**DPP® Fever Panel-Africa: Collaborator: The Paul G. Allen Family Foundation (PGAFF)**

**DPP® Malaria-Ebola Assay: Collaborator: CDC**

**DPP® Ebola Assay: Collaborator: CDC**

**DPP® Fever Panel- Asia: Collaborator: FIND**

**DPP® Zika Assay: Collaborators: HHS/BARDA & The Paul G. Allen Family Foundation (PGAFF)**

**DPP® Zika/Dengue/Chik Assay: Collaborator: HHS/BARDA**

**DPP® Dengue Assay: Chembio Internal Development**

**DPP® Chikungunya Assay: Chembio Internal Development**

Slide 12

## **Fever Diseases - A Growing Global Concern**

### **Malaria, Dengue, Zika, Chikungunya, Ebola, Lassa, Marburg**

#### **§ Mosquito-Borne Illnesses**

- Mosquito à world's deadliest animal
- Responsible for 725,000 deaths/year
- Global geographic coverage

#### **§ Established Fever Markets:**

- Malaria: > 214 million annual infections
- Dengue: ~390 million annual infections

#### **§ Emerging Fever Markets:**

- Zika
- Chikungunya
- Ebola
- Lassa
- Marburg

#### **§ What Crisis Will We Face Next?**

Source: Centers for Disease Control & Prevention (CDC) website; World Health Organization (WHO) website

See graphics

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## **Chembio is Well-Positioned to Address Zika Virus**

#### **§ Local Zika Transmission**

- 2015 (Brazil) à 2017 (~60 countries)

#### **§ Who Needs to Be Tested**

- Pregnant Women
- Travelers to/from endemic Areas
- Others?

#### **§ Molecular (MDx) Test Limitations**

- Laboratory test, venous sample
- Detects acute infections only - not antibodies
- No immediate results
- High cost

#### **§ Chembio Zika Test Advantage**

- Convenience: POC Test; fingerstick sample
- Detects Antibodies (IgM/IgG)
- Time to Result: 15 minutes
- Low cost compared to MDX tests

Source: Centers for Disease Control & Prevention (CDC) website

See graphics

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## **DPP® Zika/Dengue/Chikungunya - Development**

### **Demonstrates Expertise, Efficiency and Dedication**

#### **§ DPP® Zika IgM/IgG Development/Commercialization Timeline**

- Received PGAFB grant; initiated project DPP® Zika Project – 2/16
- Announced Zika collaboration with Bio-Manguinhos/Fiocruz (Brazil) – 3/16
- Completed initial testing; including 600 pregnant women – 4/16
- Announced regulatory filings with FDA-EUA, ANVISA – 5/16
- Announced regulatory filings with WHO-EUA, Cofepris, CE mark – 7/16
- Received CE mark (Europe, Caribbean)- 7/16
- Announced HHS/BARDA funding contract– 8/16
- Awarded CDC Surveillance Program: DPP® Zika/Dengue/Chikungunya (Peru, India, Guatemala, Haiti)- 9/16



- Received ANVISA approval, DPP® Zika Assay –11/16
- Successful INCQS Evaluation- 2017

See graphics

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## **Chembio's Dual Path Platform (DPP®) Technology Leveraging Our Technology Platform to Enter New Markets**

Three areas of Strategic Focus:

- § STD Business
- § Fever Portfolio
- § **Technology Collaborations**

DPP® Technology Platform

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### **Technology Collaborations:**

#### **Bio-Rad(NYSE:BIO) and DPP® Micro Reader**

##### **§ Bio-Rad Geenius™ System: HIV-1 and HIV-2 Confirmation**

- Multiplex DPP® Assay
- Developed by Chembio
- Licensed by Bio-Rad
- Marketed/sold by Bio-Rad (ex-Brazil)

##### **§ Chembio DPP® Micro Reader: Quantitative Results & Data Management**

- Improves DPP ® Performance
- Provides quantitative results
- Standardizes result interpretation
- Data capture, storage, transmission
- Key features: simple, palm-sized, battery-operated, cost-effective

See graphics

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## **Chembio's Dual Path Platform (DPP®) Technology Leveraging Our Technology Platform to Enter New Markets**

##### **§ DPP® Cancer Assay**

- Undisclosed Partner
- Biomarkers to Detect Specific Form of Cancer
- 10uL Blood Sample, 20 Minute Test
- Quantitative Result
- In development Phase

##### **§ DPP® TBI/Concussion Assay**

- Perseus Science Group, LLC
- Biomarker to Detect TBI/Concussion
- 10uL Blood Sample, 20 Minute Test
- Quantitative Result
- In development Phase

##### **· DPP® BovineTB**

- o U.S. Department of Agriculture (USDA)
- o Biomarker to detect bovine tuberculosis
- o 20 minute test results
- o In development phase

See graphics

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## Chembio's Global Commercial Organization

### Shift from Product Supply Model to Direct Sales Model

- § **Regained control of U.S. HIV products (2014 – 2016)**
  - Terminated prior U.S. exclusive distribution agreements (HIV 1/2 STAT-PAK® and SURE CHECK® HIV 1/2)
- § **Developed internal commercialization structure (2014 – 2016)**
  - Direct sales of DPP® HIV 1/2, HIV 1/2 STAT-PAK®, and SURE CHECK® HIV 1/2 products in the U.S. market
- § **Established geographic coverage model in U.S. (2014 – 2016)**
  - Established agreements with U.S. distributors (e.g., McKesson, H. Schein, Fisher, Medline)
- § **Hired Experienced and Accomplished Leadership (Q4 2016)**
  - Robert Passas, Ph.D. – President, EMEA and APAC Regions
    - Trinity Biotech; The Binding Site; Abbott, Quidel
  - Sharon Klugewicz - President, Americas Region
    - Chembio COO (since 2012); Pall Corporation
- § **Hired international sales executives to build commercial channels in Latin America, Africa and Asia Pacific (Q4 2016 – Q1 2017)**

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## Manufacturing Capabilities

### Expanding Global Manufacturing and Distribution

Medford, NY

Kuala Lumpur, Malaysia

- o **Acquired RVR Diagnostics (January 2017), Changed name to Chembio Diagnostics Malaysia Snd Bhd**
- o **Chembio Diagnostics Malaysia, a subsidiary of Chembio Diagnostics**
  - o International base of operations and existing sales revenue
  - o Cost effective manufacturing operations, ISO 13485 certification
  - o Strategic location in Southeast Asia provides access to new markets
  - o Regulatory access in Southeast Asia market
- Combined Manufacturing Operations**
  - o High volume manufacturing capabilities; current capacity 25MM tests
  - o 65,000 sq. ft. leased facilities (Medford, NY and Malaysia)
  - o Robust quality management system (Medford, NY)
    - o Full compliance with regulatory requirements (i.e., FDA, USDA, WHO, ISO)
    - o Expertise in manufacturing scale up, process validation and cGMP
  - o Total number of employees: ~165

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## Selected Financial Highlights

	Quarter Ended (in 000's)		9 Months Ended (in 000's)	
	Sept. 30, 2017	Sept. 30, 2016	Sept. 30, 2017	Sept. 30, 2016
<b>Net Product Revenues</b>	\$ 6,133	\$ 2,502	\$ 14,453	\$ 10,452
<b>Total Revenues</b>	\$ 7,587	\$ 3,746	\$ 18,027	\$ 13,614
<b>Gross Margin</b>	\$ 3,523	\$ 1,952	\$ 8,539	\$ 6,698
<b>Loss from Operations</b>	\$ (589)	\$ (2,144)	\$ (4,398)	\$ (4,998)
<b>Net Loss</b>	\$ (585)	\$ (2,138)	\$ (4,373)	\$ (10,879)*
<b>Accounts Receivable Net</b>	\$ 5,768	\$ 4,208	\$ 5,768	\$ 4,208
<b>Cash (as of end of period)</b>	\$ 1,872	\$ 12,172	\$ 1,872	\$ 12,172

\* 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.

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## Experienced Executive Leadership Team

**Executive:** John J. Sperzel III, President & CEO

**Joined Chembio:** 2014

**Previous Experience:** 2011-2013, President and CEO of ITC/Accriva; 1987-2011 Axis-Shield, Bayer Diagnostics, Instrumentation Laboratory and Boehringer Mannheim

**Executive:** Richard Larkin, CPA Chief Financial Officer; Executive Vice President  
**Joined Chembio:** 2003  
**Previous Experience:** 2000-2003 CFO of Visual Technology Group; 1987-2000 CFO of Protex International Corp.

**Executive:** Javan Esfandiari, M.S. Chief Science and Technology Officer; Executive Vice President  
**Joined Chembio:** 2000  
**Previous Experience:** 1997-2000, Co-founder of Sinovus Biotech AB (Sweden), acquired by Chembio in 2000; 1993-1997 R&D Director of On-Site Biotech

**Executive:** Sharon Klugewicz, M.S., President, Americas Region  
**Joined Chembio:** 2012  
**Previous Experience:** 2009-2012, Sr. VP Scientific & Laboratory Services of Pall Corporation; 1991-2009 Pall Corporation

**Executive:** Robert Passas, Ph.D., President, EMEA & APAC Regions  
**Joined Chembio:** 2016  
**Previous Experience:** 2015-2016, VP, Worldwide Marketing and International Sales at Trinity Biotech; 1993-2015 The Binding Site, Abbott, Trinity Biotech, Quidel

**Executive:** Thomas Ippolito, VP Regulatory & Clinical Affairs  
**Joined Chembio:** 2005  
**Previous Experience:** 2000-2005, VP Quality & Regulatory of Biospecific Technologies Corp.; 1984-2000 United Biomedical Inc., Analytab Products Inc. and Eastern Long Island Hospital

**Executive:** Paul Lambotte, Ph.D, VP Product Development  
**Joined Chembio:** 2014  
**Previous Experience:** 2009 – 2014, President of PLC Inc.; 2009 – 2012 Chief Science Officer of Axxin Pty Ltd.; 2000-2009, VP of R&D and Business Development of Quidel, Inc.

**Executive:** David Gyorke, VP Manufacturing Operations  
**Joined Chembio:** 2017  
**Previous Experience:** 2011-2016, VP operations of Nanomix, 1983-2011, NeoVista, Farallon Medical, Inc., Cholestech Corporation, Bio-Rad

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