
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): August 9, 2017 (August 9, 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 August 9, 2017, the Company issued a press release entitled "Chembio Diagnostics Reports Second Quarter 2017 Financial Results". A copy of the press release is furnished herewith as Exhibit 99.1

On August 9, 2017, the Company posted a PowerPoint Presentation to their website entitled "Investor Presentation August, 2017." A copy of the presentation is furnished herewith as Exhibit 99.2.

In addition, also on August 9, 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**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release entitled "Chembio Diagnostics Reports Second Quarter 2017 Financial Results" dated August 9, 2017
99.2	Presentation entitled "Investor Presentation August 2017" dated August 9, 2017
99.3	Investor Fact Sheet posted to the company website dated August 9, 2017

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.

August 9, 2017

Chembio Diagnostics, Inc.

By: /s/ Richard J. Larkin
Richard J. Larkin
Chief Financial Officer

EXHIBIT INDEX

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99.3	Investor Fact Sheet posted to the company website dated August 9, 2017



ChemBio Diagnostics Reports Second Quarter 2017 Financial Results

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

MEDFORD, NY, August 9, 2017 -- 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)

Contacts:

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Vida Strategic Partners (investor relations)
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sdiaz@vidasp.com

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

	<u>For the three months 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	<u>14,135,049</u>	<u>18,113,526</u>
FIXED ASSETS, net of accumulated depreciation	<u>2,093,494</u>	<u>1,709,321</u>
OTHER ASSETS	<u>3,367,733</u>	<u>752,389</u>
TOTAL ASSETS	<u>\$ 19,596,276</u>	<u>\$ 20,575,236</u>
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
TOTAL CURRENT LIABILITIES	<u>\$ 3,862,792</u>	<u>\$ 3,405,650</u>
TOTAL LIABILITIES	<u>4,198,782</u>	<u>3,405,650</u>
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	<u>15,397,494</u>	<u>17,169,586</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 19,596,276</u>	<u>\$ 20,575,236</u>

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	<u>\$ (6,862,681)</u>	<u>\$ (3,937,062)</u>



Corporate Fact Sheet

August 2017

STOCK INFORMATION (as of August 7, 2017)

Ticker:	CEMI
Exchange:	Nasdaq
Share Price:	\$ 6.35/share
Market Cap:	\$78.16 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 assays, which it sells in the U.S. and 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

- Approximately 37 million people living with HIV/AIDS worldwide (2015)
- 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 (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

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

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

Richard Larkin, CPA, Chief Financial Officer

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

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Investor Presentation August 9, 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 (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 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)
 - 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: > 200 million annual infections
 - Dengue: ~300 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

Slide 13

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 PGAFF 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 of up to \$13.2 million – 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

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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 opTricon (Berlin, Germany)

§ 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

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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

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. 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)**

Manufacturing Capabilities

Expanding Global Manufacturing and Distribution

Medford, NY

Kuala Lumpur, Malaysia

- **Acquired RVR Diagnostics (January 2017)**
- **RVR Diagnostics, a subsidiary of Chembio Diagnostics**
 - International base of operations and existing sales revenue
 - Cost effective manufacturing operations, ISO 13485 certification
 - Strategic location in Southeast Asia provides access to new markets
 - Regulatory access in Southeast Asia market

Combined Manufacturing Operations

- High volume manufacturing capabilities; current capacity 25MM tests
- 65,000 sq. ft. leased facilities (Medford, NY and Malaysia)
- Robust quality management system (Medford, NY)
 - Full compliance with regulatory requirements (i.e., FDA, USDA, WHO, ISO)
 - Expertise in manufacturing scale up, process validation and cGMP
- Total number of employees: ~165

Selected Financial Highlights

	Quarter Ended (in 000's)	
	June 30, 2017	June 30, 2016
Net Product Revenues	\$ 2,893	\$ 2,034
Total Revenues	\$ 4,115	\$ 3,266
Gross Margin	\$ 1,911	\$ 1,580
Loss from Operations	\$ (2,181)	\$ (2,386)
Net Loss	\$ (2,173)	\$ (8,347)*
Accounts Receivable Net	\$ 4,672	\$ 3,384
Cash (as of end of period)	\$ 3,692	\$ 1,440

* 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.

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

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: 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
