

# RAPID TESTS <sup>FOR</sup> EARLIER TREATMENT<sup>™</sup>

NASDAQ: CEMI

March 8, 2016

# **Forward-Looking Statement**

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.



# **Investment Highlights**

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

- Sales in 40+ countries, including United States

### Revenue growth

- 8% CAGR over last five years (2010-2015)

# Groundbreaking DPP<sup>®</sup> technology platform

- Superior sensitivity and specificity vs lateral flow technology
- Multiple tests from a single oral fluid or blood sample

### Robust pipeline of new DPP<sup>®</sup> POC assays in development

- DPP<sup>®</sup> HIV-Syphilis Combination Assay (U.S. version)
- DPP<sup>®</sup> Fever Assays (Malaria, Dengue, Zika, Chikungunya, Ebola, Lassa, Marburg)
- DPP<sup>®</sup> Technology Collaborations (Traumatic Brain Injury, Cancer, Micro Reader)

### Multiple high-value collaborations

- Paul G. Allen Ebola Program: Fever Panel
- Paul G. Allen Family Foundation: Zika
- Centers for Disease Control & Prevention (CDC): Malaria, Ebola, Flu Immunostatus

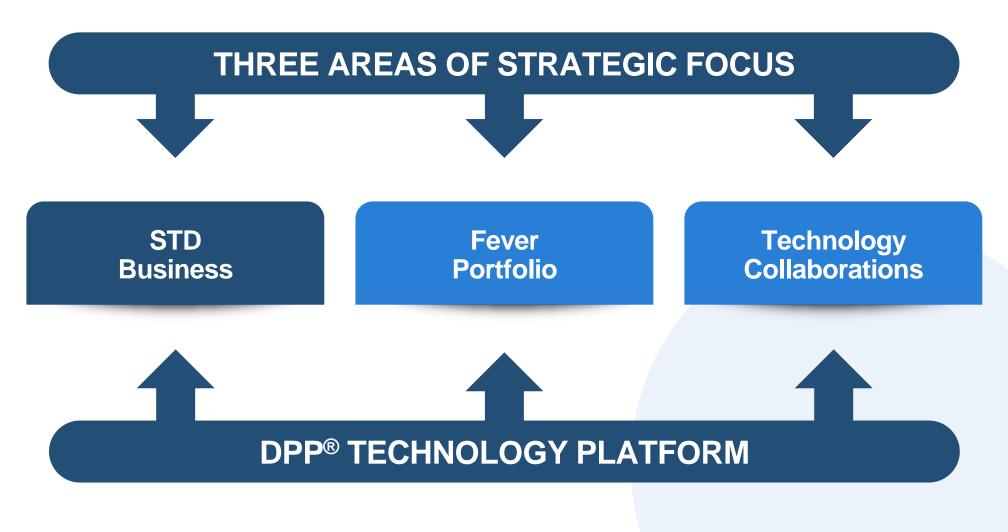


### **Chembio's Dual Path Platform (DPP®) Technology** Next-Generation Point-of-Care Technology Platform

- Patented POC technology platform
- Improved sensitivity vs. lateral flow technology
- 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<sup>®</sup>

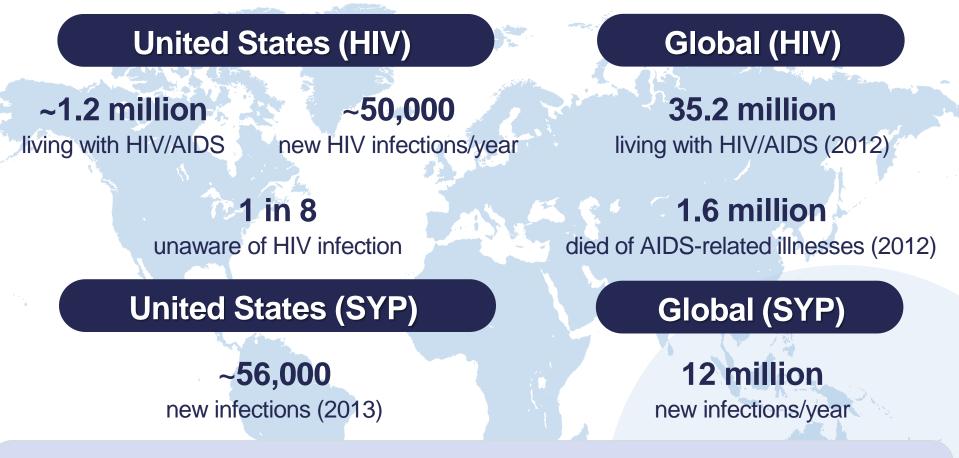


### **Chembio's Dual Path Platform (DPP®) Technology** Leveraging Our Technology Platform to Enter New Markets





# HIV Continues to be a Global Health Crisis Syphilis and HIV-Syphilis Co-Infection are Increasing



"Over the past decade, the number of people living with HIV has increased, while the annual number of new HIV infections has remained relatively stable." -CDC

"About 30% of pregnant women with syphilis will give birth to a dead baby (stillbirth), and another 30% to a live baby with congenital syphilis, a condition with a mortality of up to 50%" -WHO



# **Product Portfolio: Sexually Transmitted Diseases**

#### DPP<sup>®</sup> HIV-Syphilis Combination



#### HIV 1/2 STAT-PAK®



#### DPP<sup>®</sup> HIV 1/2 Blood or Oral Fluid



#### SURE CHECK<sup>®</sup> HIV 1/2





# **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%



#### Chembio HIV 1/2 STAT-PAK®



# 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



# **Chembio DPP® HIV and DPP® HIV-SYP Combo Tests** Addressing a Significant and Growing Need

## DPP<sup>®</sup> HIV-Syphilis Combo Assay

- First to market with POC HIV-Syphilis combo assay
- First to receive USAID and ANVISA (Brazil) approved
- Successfully launched in Mexico
- Global screening opportunity:
  - Pregnant women
  - MSM (up to 70% HIV-Syphilis co-infection)

# DPP<sup>®</sup> HIV 1/2 Assay

- FDA-approved and CLIA-waived (blood and oral fluid)
- Superior performance (sensitivity) vs. competitors
- Patented SampleTainer® Sample Collection System
- U.S. Launch Q4 2014



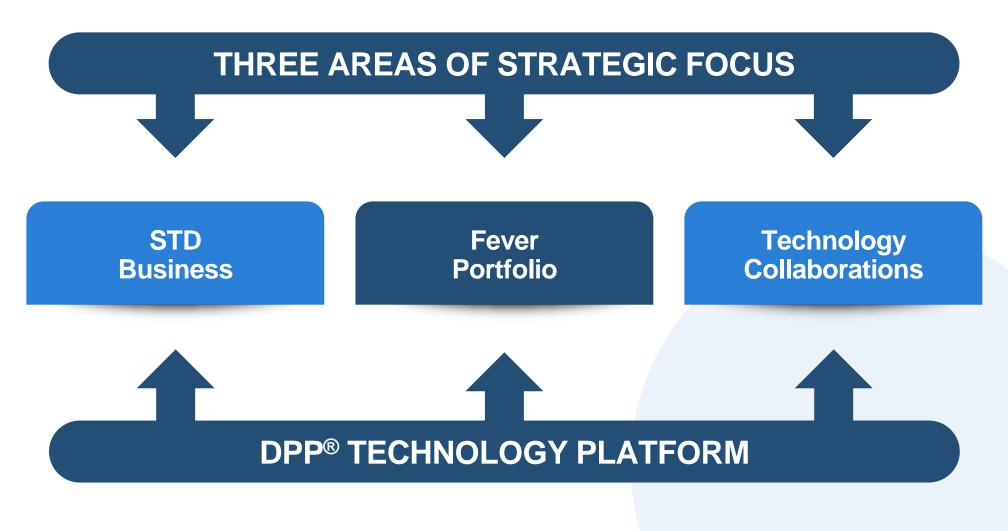


# **DPP® STD - Product Development** Strengthening our STD Portfolio: HIV & Syphilis

## DPP<sup>®</sup> HIV-Syphilis Assay (U.S. market)

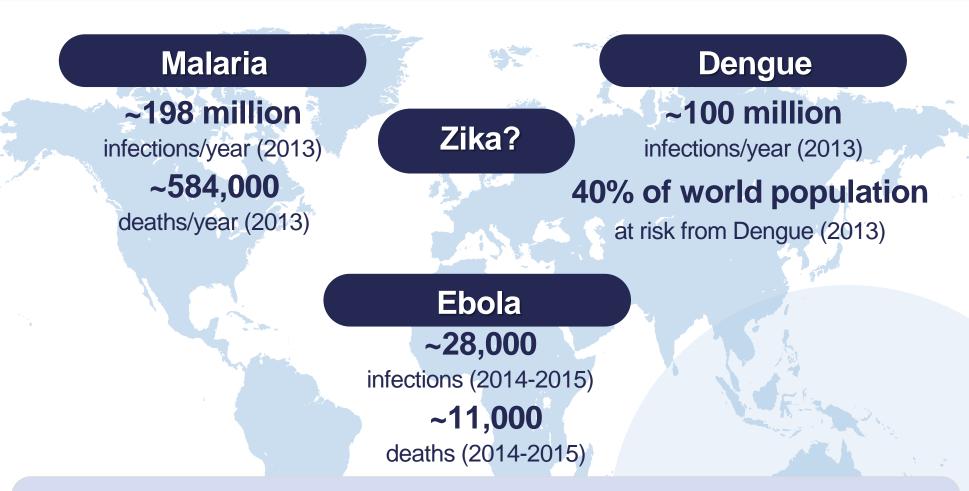
- Next Generation DPP<sup>®</sup> HIV-Syphilis Combo Assay for detection of HIV and Syphilis antibodies
- Expect clinical trials to begin Q1 2016
  - Number of patients: 1200
  - Duration: 6-9 months
  - Cost: \$1.0 \$1.5MM

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





## Fever Diseases - A Growing Global Concern Malaria, Dengue , Zika, Chikungunya, Ebola, Lassa, Marburg

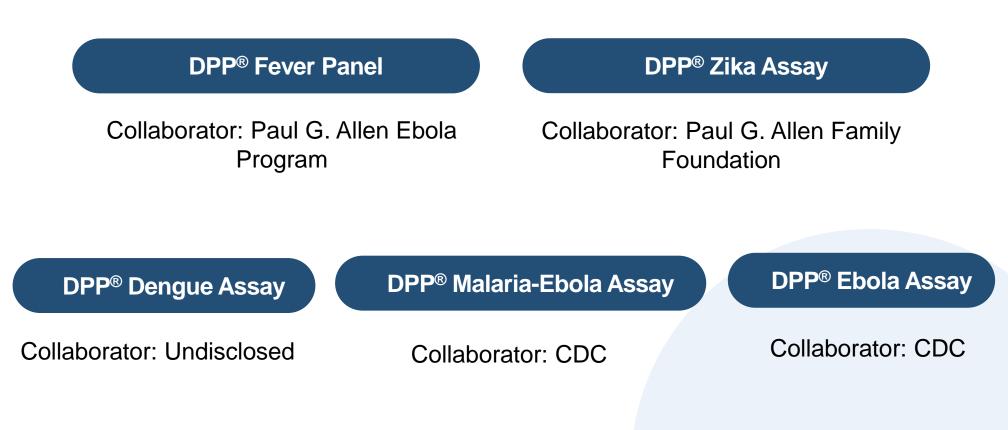


"Early diagnosis and treatment of malaria reduces disease and prevents deaths. It also contributes to reducing malaria transmission. WHO recommends that all cases of suspected malaria be confirmed using parasite-based diagnostic testing (either microscopy or rapid diagnostic test) before administering treatment" -WHO



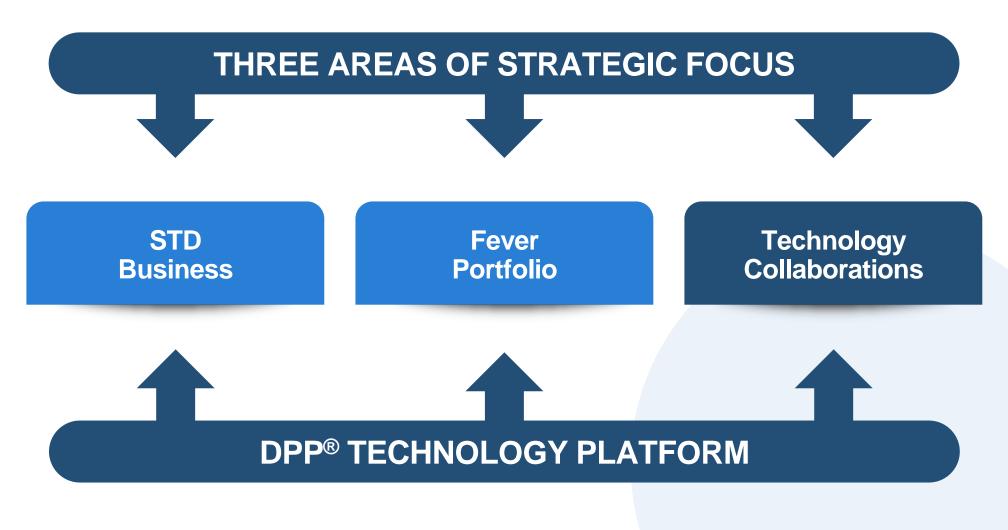
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# **DPP® Fever - Product Development** Partnering with World Leading Organizations





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





## Established DPP<sup>®</sup> Technology Collaborations Building Both STD and Non-STD Businesses

### opTricon (Germany)

 DPP® Micro Reader designed specifically to complement Chembio's patented DPP® technology

# Bio-Rad Laboratories, Inc. (NYSE: BIO)

– DPP<sup>®</sup> used for Bio-Rad's Geenius<sup>™</sup> HIV 1/2 Confirmatory Assay

#### Oswaldo Cruz Foundation (Brazil)

- Five DPP® Products Currently Being Sold to Ministry of Health in Brazil

## RVR (Malaysia)

- License, Technical Transfer, Contract Manufacturing, Distribution (planned)



# **DPP® Technology - Collaborations** Focused on Specific Product Development Opportunities

#### DPP<sup>®</sup> Flu Immunostatus

Collaborator: Centers for Disease Control & Prevention (contractor)

#### **DPP<sup>®</sup> Traumatic Brain Injury**

Collaborator: Perseus Science Group, LLC

#### DPP<sup>®</sup> Cancer (Specific Form)

Collaborator: Undisclosed

#### **DPP<sup>®</sup> Hepatitis C**

**Collaborator: Seeking Partner** 



# **Manufacturing Capabilities**

#### **United States (Chembio)**



- High volume manufacturing capabilities
  - 20MM+ tests annually
- 60,000 sq. ft. leased facilities
  - Medford, NY and Holbrook, NY
- Robust quality management system
  - Full compliance with regulatory requirements (FDA, USDA, WHO, ISO)
  - Expertise in manufacturing scale up, process validation and cGMP
- Number of employees: ~155

#### Malaysia (RVR)



- Completed license and technology transfer
- Completed contract manufacturing readiness
- Initiated distribution of Chembio's products into Malaysia
- Plan to manufacture certain Chembio-branded products



# **Selected Financial Highlights**

Years Ended (in 000's)

	December 31, 2015	December 31, 2014
Net Product Revenues	\$21,887	\$25 <i>,</i> 950
Total Revenues	\$24,255	\$27 <i>,</i> 645
Gross Margin	\$10,487	\$10,814
Loss from Operations	(\$3,554)	(\$1,550)
Net Loss	(\$2,397)	(\$1,137)
Cash (as of end of period)	\$5,377	\$4,615

Note: took a full valuation allowance on our deferred tax asset resulting in the larger Net Loss over Loss from Operations.



# **Executive Leadership Team**

EXECUTIVE	JOINED CHEMBIO	PREVIOUS EXPERIENCE
John Sperzel III President & CEO	2014	2011-2013, President and CEO of ITC.; 1987-2011 Axis Shield, Bayer Diagnostics, Instrumentation Laboratory and Boehringer Mannheim
Richard Larkin, CPA Chief Financial Officer	2003	2000-2003, CFO of Visual Technology Group; 1987-2000 CFO of Protex International Corp.
Sharon Klugewicz, M.S. Chief Operating Officer	2012	2009-2012, Sr. VP Scientific & Laboratory Services of Pall Corporation; 1991-2009 Pall Corporation
Javan Esfandiari, M.S. Chief Science & Technology Officer	2000	1997-2000, Co-Founder of Sinovus Biotech AB (Sweden), acquired by Chembio in 2000; 1993-1997 R&D Director On-Site Biotech
<b>Thomas Ippolito</b> VP Regulatory & Clinical Affairs	2005	2000-2005, VP Quality & Regulatory of Biospecific Technologies Corp.; 1984-2000 United Biomedical Inc., Analytab Products Inc. and Eastern Long Island Hospital
<b>Michael Steele</b> VP Sales, Marketing & Bus. Dev.	2012	2008-2011, VP Business Development of SeraCare Life Sciences; 1992-2008 Corautus Genetics, Life Therapeutics and Serologicals, Inc.
Paul Lambotte VP Product Development	2014	2009-2014, President of PLC Inc.; 2009-2012, Chief Science Officer Axxin Pty Ltd.; 2000-2009, VP of R&D and Business Development Quidel, Inc.



# 2015/2016 Milestones – Achieved

- Signed agreement to develop DPP<sup>®</sup> Brain Injury Assay
  - Perseus Science; January 2015
- Received ANVISA approval for DPP<sup>®</sup> HIV-Syphilis Assay
  - Brazil; February 2015
- Initiated field testing of DPP<sup>®</sup> Ebola Assay in West Africa
  - CDC; June 2015
- Awarded Grant to Develop Multiplex Test for Fever Diseases
  - Paul G. Allen Ebola Program; October 2015
- Signed agreement to launch the DPP® Micro Reader
  - opTricon; October 2015
- Acquired full rights to SURE CHECK<sup>®</sup> HIV 1/2 Assay
  - SDS; signed January 2015 to be effective June 1, 2016
- Awarded Grant to Develop DPP<sup>®</sup> Zika Assay
  - Paul G. Allen Family Foundation; February 2016



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