



August 11, 2016

RAPID
TESTS
FOR
EARLIER
TREATMENT

**NASDAQ: CEMI** 

# **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 direct sales in the United States
- Core business in POC HIV testing; 8% revenue growth (2010-2015)

# Groundbreaking patented DPP® technology platform

- Superior sensitivity and specificity vs lateral flow technology
- Multiple tests from a single oral fluid or blood sample (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, Micro Reader)

### Multiple high-value collaborations

- Paul G. Allen Ebola Program: Fever Panel, Zika
- Bill & Melinda Gates Foundation: Malaria Oral Fluid/Saliva
- Centers for Disease Control & Prevention (CDC): Malaria, Ebola, Flu Immunostatus

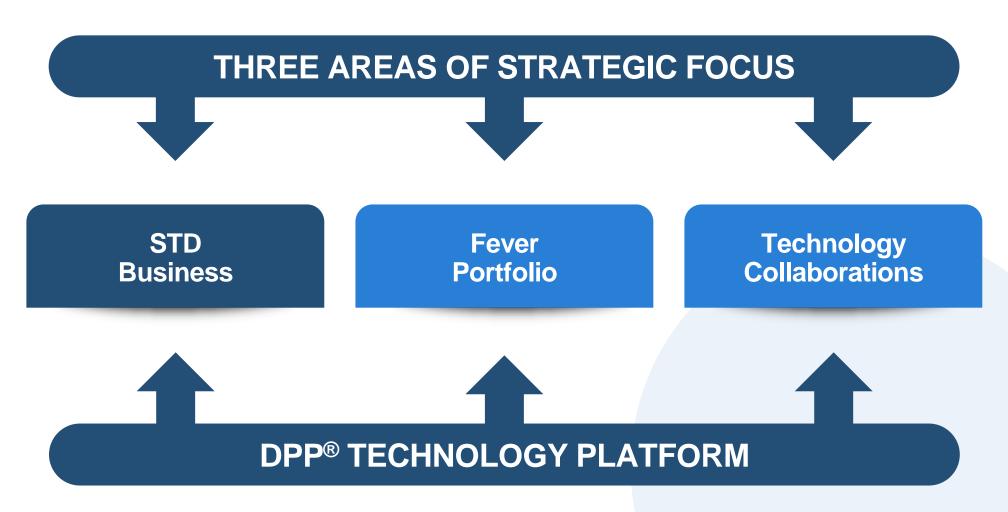
# Experienced leadership team



# 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®





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

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

~1.2 million

living with HIV/AIDS

~50,000

new HIV infections/year

Global (HIV)

36.7 million

living with HIV/AIDS (2015)

1 in 8

unaware of HIV infection

1.1 million

died of AIDS-related illnesses (2015)

**United States (SYP)** 

~63,000

new infections (2014)

Global (SYP)

12 million

new infections/year

"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

"An estimated two million pregnancies are affected annually; approximately 25% of these pregnancies end in stillbirth or spontaneous abortion, and in a further 25% the newborn has a low birth rate or serious infection, both of which are associated with an increased risk of perinatal death" -WHO

# **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  $\mu$ L 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



# Chembio DPP® HIV and DPP® HIV-SYP Combo Tests Strengthening our HIV/STD Portfolio

# DPP® HIV-Syphilis Combo Assay

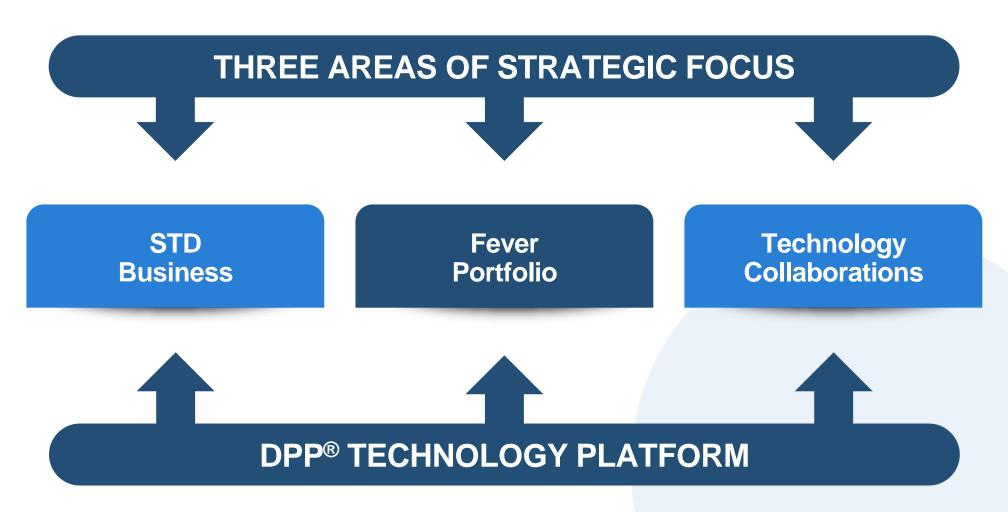
- Chembio has a history of leadership
  - First to receive USAID, ANVISA, Cofepris approval
  - First to market/sell in Latin America
- Global screening opportunity:
  - Pregnant women
  - MSM (up to 70% HIV-Syphilis co-infection)
- Initiated US clinical trials for FDA approval and CLIA Waiver (Q1 2016)

# 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







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

# BILL & MELINDA GATES foundation







# THE PAUL G. ALLEN FAMILY FOUNDATION

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

### Mosquito-Borne Illnesses

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

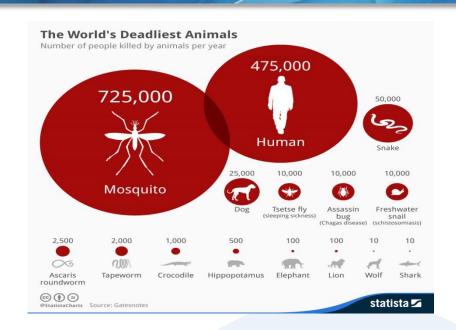
#### Established Fever Markets:

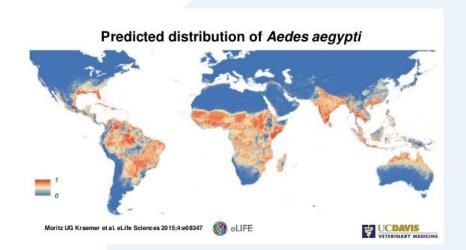
- Malaria: 214 million infections
- Dengue: 300 million infections

### Emerging Fever Markets:

- Zika
- Chikungunya
- Ebola
- Lassa
- Marburg

#### What Crisis Will We Face Next?





# **Zika Virus**Why is Zika a Concern and Why is Chembio Well-Positioned?

#### Local Zika Transmission

2015 (Brazil) → 2016 (50+ countries)

#### Who Needs to Be Tested

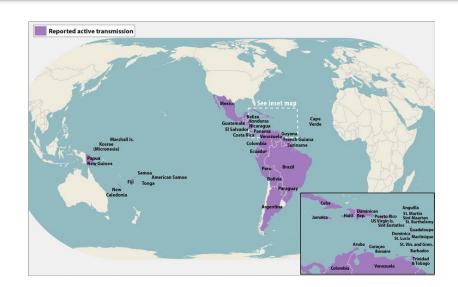
- Pregnant Women
- Travelers to/from Endemic Areas
- Others?

#### Molecular Tests Limitations

- Convenience: Lab Test, Venous Sample
- Cost
- Time to Result
- Detects Acute Infections

### Chembio Zika Test Advantage

- Convenience: POC Test; Fingerstick Sample
- Cost
- Time to Result: 20 minutes
- Detects Antibodies (IgM/IgG)







# DPP® Zika/Dengue/Chikungunya - Development Zika Virus represents the latest global health crisis

# Accelerated DPP® Zika Assay Development

- Received grant from Paul G. Allen Foundation and initiated project 2/16
- Announced Zika collaboration with Bio-Manguinhos/Fiocruz (Brazil) 3/16
- Completed testing of >1,000 samples (including 600 pregnant women) 4/16
- Announced regulatory filings with FDA-EUA (US, PR), ANVISA (Brazil) 5/16
- Announced regulatory filings with WHO-EUA, Cofepris (Mexico), CE mark 7/16

# Development of Zika-related DPP® Assays

- Continued development of DPP® Dengue IgM/IgG Assay
- Initiated development of DPP® Chikungunya IgM/IgG Assay
- Initiated development of DPP® Zika/Chikungunya/Dengue IgM/IgG Combo Assay



# DPP® Fever Disease- Product Development Fever Panel, Ebola, Malaria, Malaria-Ebola

#### **DPP® Fever Panel**

Collaborator: The Paul G. Allen Family Foundation

#### **DPP® Malaria Assay**

Chembio Internal Development

#### **DPP®** Ebola Assay

Collaborator: CDC

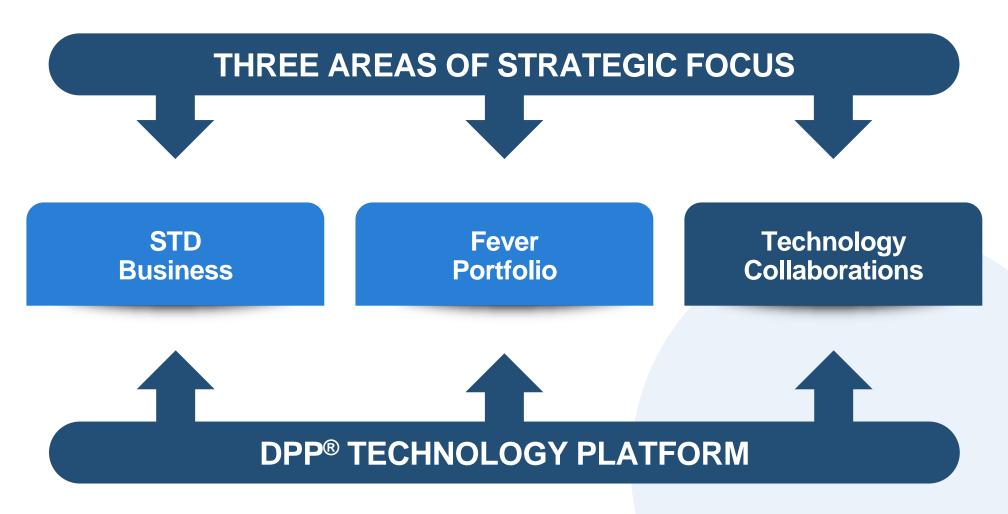
#### DPP® Malaria-Ebola Assay

Collaborator: CDC

#### DPP® Malaria OF/Saliva Assay

Collaborator: Bill & Melinda Gates Foundation





# **Technology Collaborations:**Bio-Rad (NYSE: BIO) and opTricon (Berlin, Germany)

- Bio-Rad Geenius<sup>™</sup> 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: Improves Results & Data Mgmt.
  - Improves DPP® Performance
  - Provides quantitative results
  - Standardizes result interpretation
  - Data capture, storage, transmission
  - Key features: Simple, Palm-Sized, Battery-Operated, Cost-Effective



# 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® FLU Immunostatus

- CDC / Contractor
- Identifies 9 Different Seasonal & Pandemic Flu
- 10uL Blood Sample, 20 Minute Test
- In Development Phase



# **Manufacturing Capabilities**

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



- High volume manufacturing capabilities
  - Current capacity: 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: ~140

#### Malaysia (RVR)



- Completed license and technology transfer
- Completed contract manufacturing readiness
- Received initial regulatory approval for distribution of Chembio's products into Malaysia
- Initiated plan to manufacture certain Chembio-branded products

# **Selected Financial Highlights**

#### Six Months Ended (in 000's)

	June 30, 2016	June 30, 2015
Net Product Revenues	\$7,951	\$11,936
Total Revenues	\$9,868	\$12,947
Gross Margin	\$4,746	\$5,706
Loss from Operations	(\$2,854)	(\$1,773)
Net Loss	(\$8,651)*	(\$1,311)
Cash (as of end of period)	\$1,440**	\$1,564

<sup>\*</sup> 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.



<sup>\*\*</sup>Company public offering of securities, closed August 3,2016, resulted, after expenses, in an additional approximately \$12.5MM in net funds to the company.

# **Experienced 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 of On-Site Biotech	
Thomas Ippolito 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	
Michael Steele 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 of Axxin Pty Ltd.; 2000-2009, VP of R&D and Business Development of Quidel, Inc.	

