

NASDAQ: CEMI



*Rapid Tests for Earlier Treatment™*



# 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.

# Our Vision & Mission

**We enable longer and healthier living through detection and monitoring of serious diseases.**

Our mission is to be a leader in the development and commercialization of diagnostic solutions. We are dedicated to delivering high-quality products that provide ease of use, and rapid and accurate results at the point-of-care (POC). As a global company, we are committed to innovation and the highest quality standards.



# Investment Highlights

- Global Provider of High Quality POC Infectious Disease Tests
  - Sales in 43 countries
- Revenue Growth Averaged 15% Over Last Five Years
  - From \$13.83MM for FY 2009; to \$27.65MM for FY 2014
- Patented DPP® (Dual Path Platform) Technology
  - Lead Product: DPP® Blood/Oral Fluid HIV 1/2 Assay (FDA-Approved, CLIA-Waived)
  - DPP® Revenue Growth of 137% in 2014 as compared to 2013
- Future Pipeline of DPP® POC Assays
  - HIV-Syphilis Combination Assay (US version)
  - HIV Ab/Ag Assay
  - Hepatitis C (HCV) Assay
- New Collaborations and Development Projects
  - POC DPP® Assays for Malaria, Dengue Fever, Ebola, Febrile Illness, Flu Immunostatus, Brain Injury and a Specific Type of Cancer

# Global POC Diagnostics Company

## U.S.

- Revenue (FY '14): \$7.2MM or 28%
- Established U.S. Sales & Marketing team (June '14)
- DPP® HIV 1/2 FDA-Approved, CLIA-Waived
- Funded Research: CDC, DOD, NIH (2013)

## EUROPE

- Achieved CE mark for SURE-CHECK® HIV (July '13)
- Achieved CE mark for HIV STAT-PAK® (March '14)
- Pending CE mark for DPP® HIV and DPP® HIV/Syphilis Assays

## ASIA

- Established License, Technical Transfer, Contract Manufacturing, Distribution Agreement (Feb. '14)

## LATIN AMERICA

- Revenue (FY '14): \$16.4MM or 63%
- Strong OEM Collaborations (e.g., FIOCRUZ, Labtest)
- Branded products sold to NGOs, private distributors

## MERA (Middle East, Russia, Africa)

- Revenue (FY '14): \$2.1MM or 8%
- Sales channel: NGO-direct & through distributors
- Procurements primarily funded by PEPFAR, Global Fund, and WHO

# POC In-Vitro Diagnostics (IVD) Total Global Market

## Professional POC Market (\$ million)

	2011 Sales <sup>1</sup>	2016 Sales <sup>2</sup>	CAGR <sup>2</sup>
Glucose	1,530	1,640	1%
Infectious Disease	810	950	3%
Critical Care	725	875	4%
Cardiac Markers	500	650	5%
Hematology	430	500	3%
Coagulation/PT, ACT	400	450	2%
Fecal Occult Blood	295	450	9%
Cholesterol/Lipids	275	355	5%
Drugs of Abuse	265	270	0%
HbA1c	150	300	15%
Other	150	190	n/a
Pregnancy	130	135	1%

1 Historical

2 Projected

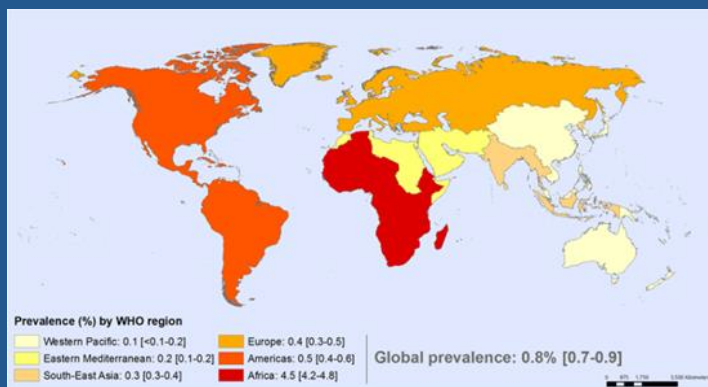


# Current Market Opportunities

## HIV Market

- 35 million people were living with HIV/AIDS worldwide in 2013
- 1.6 million people died of AIDS-related illnesses in 2012
- In total, ~75 million people have been infected with the HIV virus and ~36 million have died of HIV

HIV Prevalence (15-49 years), by WHO Region



## Syphilis Market

- Approx. 12 million people globally become ill with syphilis annually
- From 2005-2013, syphilis cases in the U.S. nearly doubled, from 8,724 to 16,663
- Syphilis in pregnancy leads to ~305,000 fetal & neonatal deaths annually

New Cases of STIs, by WHO Region



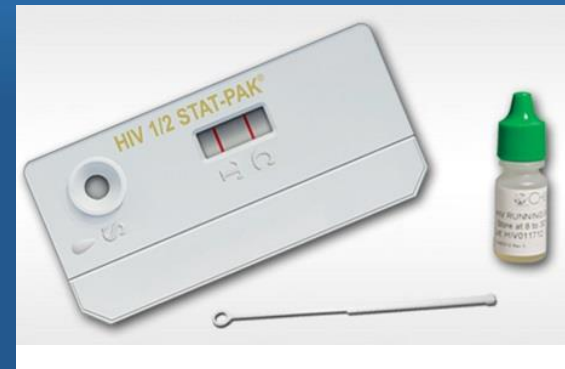
# HIV In The U.S. - The Importance Of Testing

- More than 1.1 million people in the United States are living with HIV infection, and almost 1 in 6 of them (15.8%) are unaware of their infection
- There are ~50,000 new infections per year in the U.S.
- For every HIV infection that is prevented, an estimated \$355,000 is saved in the cost of providing lifetime HIV treatment



# Chembio “Lateral Flow” POC Tests

- Two Lateral Flow POC HIV Tests
  - Chembio HIV 1/2 STAT-PAK<sup>®</sup>
  - Chembio SURE CHECK<sup>®</sup> HIV 1/2 <sup>1</sup>
- Key Product Features
  - FDA (PMA)-Approved, CLIA-Waived
  - Sensitivity: 99%
  - CE Marked, WHO Approved
- Lateral flow patent expired in February 2015
  - Chembio’s royalty payments for lateral flow technology ended Feb 2015



Chembio HIV 1/2 STAT-PAK<sup>®</sup>

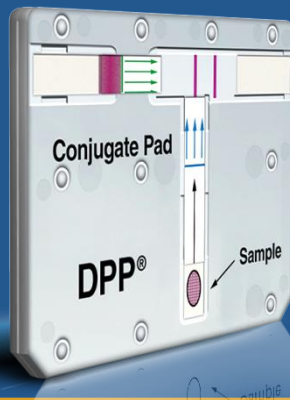


Chembio SURE CHECK<sup>®</sup> HIV 1/2\*

# Chembio's "Dual Path Platform" (DPP®) Technology

- 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)
- Offers application within infectious disease and potential for a number of other indications

## Mechanism



## Results

### Screening Tests



### Confirmatory/Multiplex Tests



# DPP® Assays - Commercial Products

## DPP® HIV 1/2 Assay

- U.S. FDA (PMA) approved, CLIA-Waived for use with blood and oral fluid samples
- U.S. Launch – Q4 2014
- Entering the ~\$35MM oral fluid assay market
- Superior performance (sensitivity) vs. competitors
- Patented SampleTainer® Sample Collection System

## DPP HIV-Syphilis Combo Assay

- First to market with POC HIV-Syphilis combo assay
- First HIV-Syphilis assay to be USAID approved
- First to receive ANVISA approval (Brazil)
- Successfully launched in Mexico
- Global screening opportunity:
  - Pregnant Women (Incidence 1.9MM)<sup>1</sup>
  - MSM (up to 70% HIV-Syphilis co-infection)<sup>2</sup>

# DPP® Internal Development Pipeline

- DPP® HIV-Syphilis Assay (U.S. market)
  - Next Generation DPP® HIV-Syphilis “Combo” Assay for detection of HIV and Syphilis Antibodies
- DPP® HCV Assay
  - Next Generation DPP® HCV Assay for the detection of Hepatitis C Antibody
- DPP® HIV Ab/Ag Assay
  - Next Generation DPP® HIV for the detection of HIV Antibody and Antigen
- DPP® HIV 1/2 Oral Fluid Assay Enhancements
  - Next Generation DPP® HIV 1/2 Assay for the enhanced detection of HIV Antibodies in oral fluid

# DPP® Research Collaborations

- DPP® Malaria (Multiplex Assay)
  - Bill & Melinda Gates Foundation
- DPP® Dengue Fever (Multiplex Assay)
  - Undisclosed Collaborator
- DPP® Ebola and Febrile Illness (Multiplex Assay)
  - Integrated BioTherapeutics, Inc.
- DPP® Flu Immunostatus (Multiplex Assay)
  - Centers for Disease Control & Prevention (CDC) Contractor
- DPP® Traumatic Brain Injury (Multiplex Assay)
  - Perseus Science Group, LLC
- DPP® Cancer (Specific Form) Assay
  - Undisclosed Collaborator

# DPP® Technology Collaborations

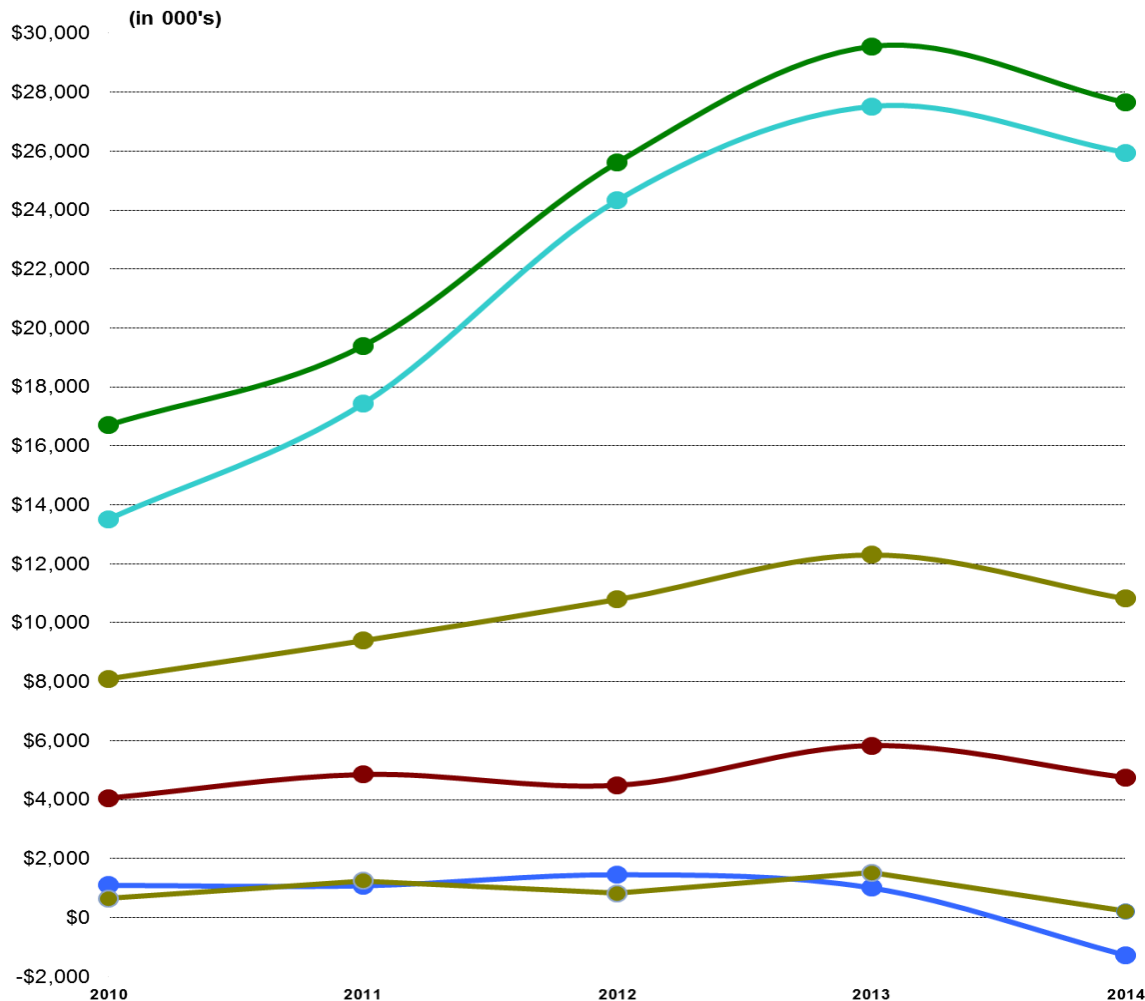
- Bio-Rad Laboratories, Inc. (NYSE: BIO)
  - DPP® Technology Used for Bio-Rad Geenius™ HIV 1/2 Confirmatory Assay
- Oswaldo Cruz Foundation (Brazil)
  - Five DPP® Products Currently Being Sold to NGO's and Private Distributors
- Centers for Disease Control & Prevention (CDC)
  - Research Collaboration Agreement: DPP® Ebola and DPP® Febrile Illness
- LabTest (Brazil)
  - Assembly, Distribution – DPP® Co-branded (2015 Product Registration)
- RVR (Malaysia)
  - License, Technical Transfer, Contract Manufacturing, Distribution
- Other
  - Additional Opportunities in Discussion/Development



# Chembio Manufacturing Capabilities

- Leased facilities (~60,000 sq. ft.) in Medford and Holbrook, NY
- High Volume Manufacturing Capabilities (>15MM tests annually)
- Robust Quality Management System
  - POC tests serve diverse, regulated market
  - Audited routinely by FDA CDRH/CBER, WHO, USDA, ISO (LNE), and our collaborators
  - Expertise in manufacturing scale up, process validation and cGMP
- Approximately 162 total employees

# Selected Financial Data (FY 2010 – 2014)



**2014**

**Total Revenue**  
**\$27,645**

**Product Revenue**  
**\$25,950**

**Gross Profit**  
**\$10,814**

**R&D Expense\***  
**\$4,748**

**Clinical Trial Expense**  
**\$206**

**Income Before Taxes**  
**(\$1,285)**

# Selected Financial Highlights

Three Months Ended (In 000's)	March 31, 2015	March 31, 2014
NET PRODUCT REVENUES	\$5,615	\$4,904
TOTAL REVENUES	\$6,231	\$5,813
GROSS MARGIN	\$2,687	\$2,273
LOSS FROM OPERATIONS	(\$875)	(\$383)
NET LOSS	(\$647)	(\$225)
CASH (as of end of period)	\$2,816	\$9,087

Note: Accounts receivable as of 3/31/14 was \$3,370 compared to 3/31/15 of \$8,260

# 2014 Milestones - Achieved

- **Product Development/Regulatory**
  - Achieved CE Mark for HIV 1/2 STAT-PAK®: Mar 2014
  - Received CLIA Waiver for DPP® HIV 1/2 CLIA: Oct 2014
  - Entered development agreements for Dengue Fever and specific Cancer assay: Oct 2014
  - Signed Agreement with CDC Contractor to Develop POC Influenza Immunity: Nov 2014
- **Corporate/Operations**
  - Finalized Agreement with RVR (Malaysia) to Build Position in Asia: February 2014
  - Established U.S. Distribution/Warehouse Facility in Holbrook, NY: May 2014
  - Obtained Exclusive POC License for Certain IBT Ebola Reagents: Oct 2014
  - Increased Manufacturing Footprint and Capacity in Medford, NY: Dec 2014
- **Commercial / Sales & Marketing**
  - Terminated STAT-PAK® Distribution Agreement with U.S. Distributor: Jun 2014
  - Established U.S. Sales & Marketing team (DPP® HIV 1/2, HIV 1/2 STAT-PAK®): Jun 2014
  - Signed DPP® and STAT-PAK® agreements with 3 leading U.S. distributors: Sep-Oct 2014

# 2015 Milestones – Achieved & Anticipated

- **Product Development/Regulatory**
  - Entered into Agreement with Perseus to Develop DPP® Brain Injury Assay: January 2015
  - Grant from Bill & Melinda Gates Foundation to Develop DPP® Malaria: January 2015
  - Achieved ANVISA Approval for DPP® HIV-Syphilis Assay in Brazil: February 2015
  - Provide DPP Malaria-Ebola Assay to CDC for Field Testing in West Africa
  - Initiate Clinical Trial for DPP HIV-Syphilis Assay (U.S.)
- **Corporate/Operations**
  - Hired Paul Lambotte Ph.D. (VP, Product Development): December 2014
- **Commercial / Sales & Marketing**
  - Acquired Full Rights to SURE CHECK® HIV 1/2 Assay, Effective June 1, 2016: January 2015
  - Expand Chembio U.S. Commercialization Team
  - Enter into Additional Distribution Agreements in the U.S. Market
  - Launch DPP® HIV-Syphilis Assay in Brazil

# Executive Leadership Team

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



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