

**NASDAQ: CEMI** 







RAPID tests for EARLIER treatment



**Investor Presentation** 

May 29-30, 2013

### **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.



### **Investment Summary**



- Develops, Manufactures & Markets Point-of-Care Diagnostic Tests (POCTs)
- \$25.6MM 2012 Revenues, Profitable
  - >25% CAGR Revenue Growth FY2009-2012
  - Established & Growing Global Business of Rapid HIV & Other POCTs
- Patented DPP® A Platform POCT Technology
  - Recent FDA Approval of Oral Fluid HIV Test, CLIA waiver pending
  - Strong Pipeline of Multiplex DPP Products
    - Branded, JVs, Contract Development



# **Chembio's Pipeline - \$850MM Total Addressable Market**

Chembio Pipeline POCT	Total Market Opportunity	Targeted Launch
US HIV	\$ 75 MM	Q4-2013
US Syphilis-HIV	\$ 75 MM	2H -2014
US HCV*	\$100 MM	2015
US OTC-HIV*	\$100 MM	2015-2016
US Veterinary (OEM)*	\$100 MM	2014
International	\$400 MM	2013-2016
Total	\$850 MM	2013-2016



<sup>\*</sup> Subject to market assessments/developments, and/or attainment of R&D and regulatory milestones



### **Chembio's Current & Near Term POCT Market Opportunities**

DPP® HIV 1/2 Oral

Fluid and Blood Assay

#### **HIV Rapid POCTS** -**Established, Growing Market**

- •~50,000 New Infections in US -2012; 2.5 MM Worldwide
- U.S. Routine Testing USPSTF Recommendation
  - ACA Expanding Coverage by 25MM+
- International Designation in PEPFAR & Other Donor-Funded **Countries' Testing Protocols**





#### Syphilis Rapid POCTS – **New Market Opportunity**

- Up to 70% HIV-Syphilis Co-Infection in MSM
- Higher Prevalence of Syphilis (1.9MM) than HIV (1.5MM) in **Pregnant Women** 
  - Leverage Global PMTCT **Programs**
  - All HIV+ Need be Tested for Syphilis & Vice Versa



DPP® HIV-Syphilis Assay





### POCTs - A Growing \$10B Global Market Examples of Product Opportunities for the Long Term

- Labtest Brazil\*
- Veterinary Products (OEM)
- Febrile Illnesses Contract with U.S. Gov. Agency\*
- Influenza Immunity Contract with CDC Contractor\*
- Hepatitis-C and HIV Fourth Generation Tests
  - Associated CDC Recommendations

Lateral Flow Technology Single parameter tests DPP®
Technology
Enabling
Improved
Sensitivity,
Multiplexing

Enhancement Features

Signal

Molecular Amplification Technologies

R&D

POTENTIAL NEW
CAPABILITIES
BEING ASSESSED

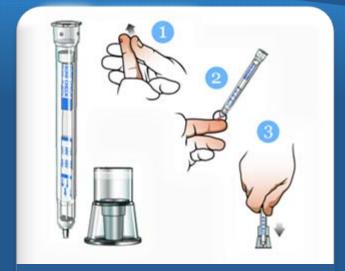
**CURRENT CAPABILITIES** 

\*announced May 2013



## **Current Revenues Are Primarily From Two FDA-Approved Lateral Flow Rapid HIV Tests Sold Globally**

- Total \$13.5MM 2012 Revenues
- In U.S. Sold Exclusively through Alere (Clearview®)
  - \$7.8MM 2012; \$2.6MM Q1'13 vs. \$2.5MM Q1'12
- International Sales Chembio Branded Through Distributors & Directly to Government-NGO-Funded Screening Programs, i.e., PEPFAR, UNICEF
  - \$5.7MM 2012; \$2.3MM Q1'13 vs. \$1.2MM
     Q1 '12
  - Significant Potential 2H'13 for Continued International Revenue Growth



Chembio SURE CHECK® HIV 1/2
Alere Clearview Complete® HIV 1/2



Chembio HIV 1/2 STAT-PAK <sup>®</sup>
Alere Clearview HIV 1/2 STAT-PAK<sup>®</sup>



### **U.S. HIV Self-Testing "OTC" Opportunity**

- Chembio Uniquely Positioned
- Still Assessing Market Size
  - OSUR Spending \$7MM/QTR on HIV OTC Market Launch
- Filing IDE Q2 2013 for Sure Check® HIV





## **Current DPP Product Revenues From Brazil New Long Term Collaboration with Labtest**

- Five DPP® Products with Brazilian MOH Affiliate, Main Supplier
  - \$10.1MM 2012 Revenues
  - ~\$6MM Forecast 2013, Potential of \$9MM in 2014.
- New Collaboration with Labtest Brazil\*
  - Leading Brazilian IVD Company
  - Addressing Private & Public Markets in Brazil
  - Potential Additional Markets, Contract Manufacturing
  - Assembly & Distribution DPP® Cobranded













### **DPP® Patented Point of Care Technology**

- Proprietary Platform Technology that Uniquely Enables
   Multiplexing for Higher Value Tests
- Increases Sensitivity as Compared with Lateral Flow Technology
- Validated with Numerous Partners, Regulated Megulated Numberous Partners, Regulated Numberous







Confirmatory/Multiplex Test



## Chembio DPP® HIV 1/2 Assay FDA-Approved Dec. '12 CLIA Waiver expected Q4 2012

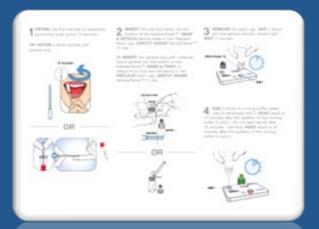
 Superior blood matrix performance over top 4 market share products in early detection study

 Superior Oral Fluid sensitivity v. Market Leader in head-to-head study

User friendly, safe and efficient
 SampleTainer™ Sample Collection System

Separate and reagent free oral fluid collection

device







## DPP® HIV 1/2 Assay v. Leading Competitor Superior U.S. Label Claims

	DPP HIV 1/2	Oraquick ADVANCE
Performance Sensitivity* Specificity*	99.9% WB/P/S; 99.8% FS; 98.9% OF 100% FS; 99.9% OF/WB/P/S	(Note: No S or WB claims) 99.6% FS/P; 99.3% OF 99.9% P, 100% FS, 99.8% OF
<b>External Controls</b>	12 month open vial	30 day open vial
Patient Age	2+ years of age	12+ years of age
Result Read Time	25-40 min OF 10-25 min FS/P/WB/S	20-40 min OF/FS/P

DPP® HIV 1/2 Assay superior performance in recent studies (CDC-Mozambique) in "naïve" (undiagnosed) populations for which the test will be utilized, and more published articles on OraQuick market performance



<sup>\*</sup>Note: Orasure conducted its U.S. trials 1999-2001 before widespread deployment of Highly Active Anti-Retroviral Therapy (HAART).

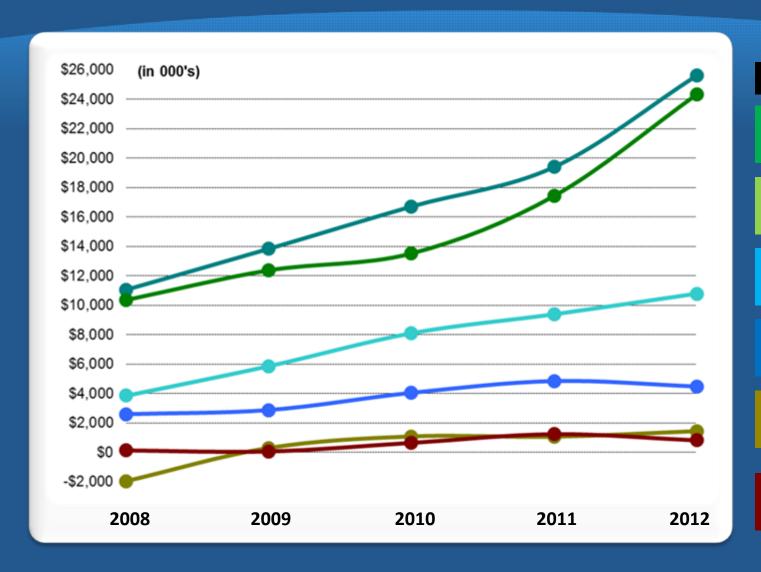
# DPP® Syphilis Screen & Confirm & HIV-Syphilis Multiplex Tests

- Large Global Market Opportunities for Pre-Natal and MSM Screening
  - HIV-Syphilis Comb. Leverages Global PMTCT Funding
  - Syphilis Screen & Confirm
    - 2 Lab Tests (Trep. & Non-Trep.) in 1 POCT
- USAID and WHO Evaluations in Process
  - INDRE (Mexico) Data @100% Sensitivity & Specificity
- Anticipated FDA Submissions in 2013, 2014 Launch
  - Potential International Sales 2013





#### Selected Financial Data FY2008 -2012



2012

Total Revenue \$25,611

Product Revenue \$24,327

Gross Profit \$10,790

R&D Expense\* \$4,486

Pre-Tax Income \$1,451

Clinical Trial Expense \$1,451



### FY2011-2012 & First Quarter 2012-2013 Selected Financial Results

in (000's)	Mos Ended rch 31, 2013		Mos Ended arch 31, 2012		ear Ended cc 31, 2012		ear Ended c 31, 2011	
Net Product Revenues	\$ 6,313		\$ 6,363		\$ 24,327		\$ 17,422	
Non-Product Revenues	\$ 365		\$ 290		\$ 1,283		\$ 1,966	
TOTAL REVENUES	\$ 6,678		\$ 6,653		\$ 25,610		\$ 19,388	
GROSS MARGIN	\$ 2,694	40%	\$ 3,333	50%	\$ 10,790	42%	\$ 9,390	48%
OPERATING COSTS:								
Research and development exp.	\$ 1,045	16%	\$ 1,379	21%	\$ 4,486	18%	\$ 4,878	25%
Selling, general and administrative exp.	\$ 1,162	17%	\$ 1,234	19%	\$ 4,852	19%	\$ 3,424	18%
	\$ 2,207		\$ 2,613		\$ 9,338		\$ 8,302	
INCOME FROM OPERATIONS	\$ 487		\$ 720		\$ 1,452		\$ 1,088	
OTHER INCOME (EXPENSES):	\$ 1		\$ (1)		\$ (2)		\$ (12)	
NET INCOME-Before Taxes	\$ 488	7%	\$ 719	11%	\$ 1,450	6%	\$ 1,076	6%
Income tax (benefit) provision	\$ 171		\$ 286		\$ 509		\$ (5,133)	
NET INCOME	\$ 317	5%	\$ 433	7%	\$ 941	4%	\$ 6,209	32%

- ❖ Anticipated 2013 FIOCRUZ Reduction from \$10.1MM in 2012 to Est. ~\$6MM in 2013 May Be Offset By Significant Gains in Ex-US Lateral Flow HIV Sales
  - Ex-US Lateral Flow HIV Sales \$5.7MM 2012
    - \$2.3MM Q1'13 vs. \$1.2MM Q1 '12



#### **CEMI Selected Share & Balance Sheet Data**

\$6MM Common Stock Public Offering Closed on April 3, 2013 1.2MM Shares @ \$5.00 per share, \$5.450MM Net Proceeds

in millions except per share and daily volume data			
Ticker Symbol (NASDAQ)	СЕМІ		
Price 4/30/13	\$4.53		
52-Week High	\$5.80		
52-Week Low	\$3.61		
Outstanding Shares	9.29		
Market Capitalization	\$42.07		
Fully Diluted Shares	10.01		
Managements Holdings	1.62		
Avg. Daily Volume (3 mos. to 4/30/13)	32,000		
Average Daily Volume (April 2013)	37,800		

Options	Amt.	Avg. Ex. Price
585K held by Mgmt. & Board	725K	\$2.42

(\$ in 000s)	Pro Forma Mar'13 for Offering Closed 4/3/13 non-GAAP	Mar'13 Unaudited	Dec'12	Dec'11
Cash	\$8,049	\$2,599	\$2,952	\$3,011
Total Current Assets	16,684	11,234	11,009	8,992
Total Assets	\$22,923	\$17,473	\$17,335	\$15,486
Total Current Liabilities	3,213	3,213	3,378	2,858
Total Liabilities	3,213	3,213	3,460	2,991
Stockholders' Equity	19,710	14,260	13,875	12,495
Total Liabilities & Stockholders' Equity	\$22,923	\$17,473	\$17,335	\$15,486







### Leadership

Executive		<b>Joined Company</b>
Lawrence Siebert	Chairman & CEO	2002
Richard Larkin	Chief Financial Officer	2003
Sharon Klugewicz	Chief Operating Officer	2012
Javan Esfandiari	SVP Research & Development	2000
Tom Ippolito	VP Regulatory & Clinical Affairs	2005
Michael Steele	VP Sales Marketing & Bus. Dev.	2012
Independent Directors		Joined Board
Gary Meller, MD, MBA		2005
Katherine Davis, MBA		2007
Barbara DeBuono, MD, MPH		2011
Peter Kissinger, Ph.D		2011



### **Organization & Facility**

- FDA- and USDA-Approved
   Development & Manufacturing
   Facility
- All Company Operations in 30,600
   Sq. Ft. Leased Facility in Medford,
   NY
- Pursuing Increased Efficiencies, Automation, Capacity





**TOTAL EMPLOYMENT: Approximately 171** 



### **Anticipated Developments - 2013-2014**

- Oral Fluid HIV Test CLIA Waiver & Launch
  - Direct Distribution in Public Health for Pipeline of Complementary Products
- Expanding International Revenues for Lateral Flow and DPP® Products
- FDA Submission & Approval of Two POCT Multiplex Syphilis Tests Based on DPP® Technology
- New Distribution, Contract Development & OEM Deals
- Acquire/License New Technologies, Product Lines
- Increased Production Capacity



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