

NASDAQ: CEMI



RAPID tests for EARLIER treatment



**Investor Presentation** 

**June 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**

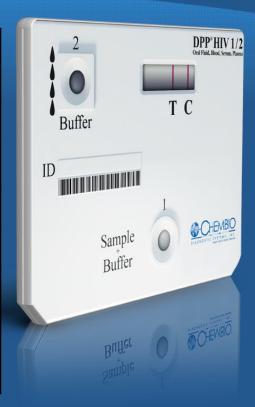


- Develops, Manufactures & Markets Point-of-Care
   Diagnostic Tests (POCTs) Used Globally
- \$25.6MM 2012 Revenues, Profitable
  - >25% CAGR Revenue Growth FY2009-2012
- Patented DPP® A Platform POCT Technology
  - Oral Fluid HIV Test FDA-Approved CLIA waiver pending
- Strong Product Pipeline of Multiplex DPP Products
  - Two New Syphilis Tests for International and US Markets
  - New Government Contracts for Mulitplex Products
  - New Collaboration in Brazil with LabTest



# 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

### 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





DPP® HIV 1/2 Oral Fluid and Blood Assay

@ CHEMBIO

## 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









## 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

Signal Enhancement Features

Molecular
Amplification
Technologies

**CURRENT CAPABILITIES** 

\* announced May 2013

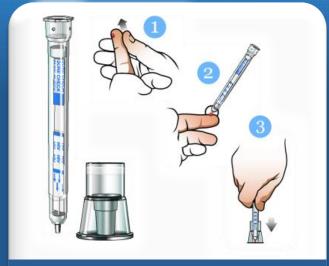
R&D

POTENTIAL NEW
CAPABILITIES
BEING ASSESSED



# Lateral Flow Rapid HIV Tests Marketed World-Wide

- Total \$13.5MM 2012 Revenues
- In U.S. Sold Exclusively through Alere (Clearview<sup>®</sup>)
  - \$7.8MM 2012; \$2.6MM Q1'13 vs. \$2.5MM Q1'12
- International Sales Chembio Branded Through Multiple Channels:
  - E.g., PEPFAR, Global Fund UNICEF, etc.
  - \$5.7MM 2012
  - \$2.3MM Q1'13 92% increase from 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





## Ongoing Collaboration with Brazilian MOH Affiliate Complemented by New Agreement with Labtest

- Five DPP® Products with Brazilian MOH 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® Co-branded
  - 2013 Plan = Initial Products Registrations
  - \*announced May 2013









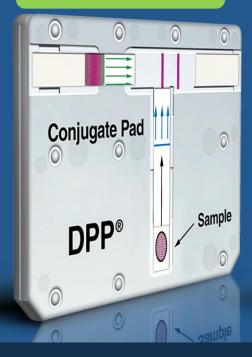




### **DPP® Patented Point of Care Technology**

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

#### Mechanism



#### Result





**Confirmatory/Multiplex Test** 



## Chembio DPP® HIV 1/2 Assay FDA-Approved Dec. '12 CLIA Waiver expected Q4 2013

- 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).

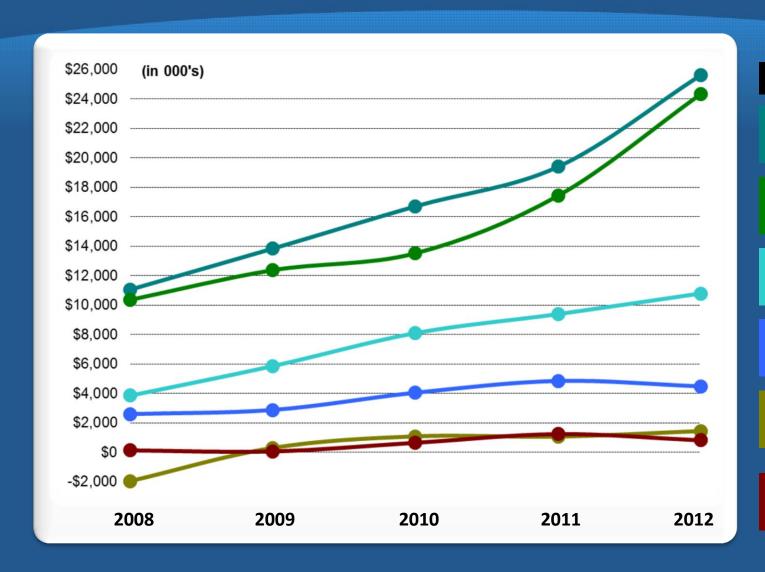
# DPP® Syphilis Screen & Confirm & HIV-Syphilis Multiplex Tests

- 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



#### **FY2010-2012 - Selected Financial Results**

	Year Ended Dec			Year Ended Dec		Year Ended Dec			
in (000's)	31, 2012		31, 2011		31, 2010		31, 2010		
Net Product Revenues	\$	24,327		\$	17,422		\$	13,516	
Non-Product Revenues	\$	1,283		\$	1,966		\$	3,188	
TOTAL REVENUES	\$	25,610		\$	19,388		\$	16,704	
GROSS MARGIN	\$	10,790	42%	\$	9,390	48%	\$	8,101	48%
OPERATING COSTS:									
Research and development exp.	\$	4,486	18%	\$	4,878	25%	\$	2,586	15%
Selling, general and administrative exp.	\$	4,852	19%	\$	3,424	18%	\$	2,941	18%
	\$	9,338		\$	8,302		\$	5,527	
INCOME FROM OPERATIONS	\$	1,452		\$	1,088		\$	2,574	
OTHER INCOME (EXPENSES):	\$	(2)		\$	(12)		\$	(15)	
NET INCOME-Before Taxes	\$	1,450	6%	\$	1,076	6%	\$	2,559	15%
Income tax (benefit) provision	\$	509		\$	(5,133)		\$	46	
NET INCOME	\$	941	4%	\$	6,209	32%	\$	2,513	15%

2012 U.S. Lateral Flow HIV Sales \$ 7.8 MM 2012 Ex-U.S. Lateral Flow HIV Sales \$ 5.7 MM 2012 Brazil DPP Sales \$10.1 MM



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

. (000)	3 Mos Ended		3 Mos Ended		
in (000's)	Ma	rch 31, 2013	March 31, 2012		arch 31, 2012
Net Product Revenues	\$	6,313		\$	6,363
Non-Product Revenues	\$	365		\$	290
TOTAL REVENUES	\$	6,678		\$	6,653
GROSS MARGIN	\$	2,694	40%	\$	3,333 50%
OPERATING COSTS:					
Research and development exp.	\$	1,045	16%	\$	1,379 21%
Selling, general and administrative exp.	\$	1,162	17%	\$	1,234 19%
	\$	2,207		\$	2,613
INCOME FROM OPERATIONS	\$	487		\$	720
OTHER INCOME (EXPENSES):	\$	1		\$	(1)
NET INCOME-Before Taxes	\$	488	7%	\$	719 11%
Income tax (benefit) provision	\$	171		\$	286
NET INCOME	\$	317	5%	\$	433 7%

2013 Increased Lateral Flow Revenues - Reduced 2012 Brazil DPP Revenues



### **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 (NASDA	Q)	CEMI				
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 Holding	gs	1.62				
Avg. Daily Volume (3 mos. to 4/30/13)		32,000				
Average Daily Volume (April 2013)		37,800				
Options – Mgmt. & Board	Amt.	Avg. Ex. Price				
585K	725K	\$2.42				

(\$ in 000s)	Pro Forma Mar'13 for Offering Closed 4/3/13 Unaudited	Mar'13 Unaudited
Cash	\$8,049	\$2,599
Total Current Assets	16,684	11,234
Total Assets	\$22,923	\$17,473
Total Current Liabilities	3,213	3,213
Total Liabilities	3,213	3,213
Stockholders' Equity	19,710	14,260
Total Liabilities & Stockholders' Equity	\$22,923	\$17,473



### Leadership

Executive	Experience	Joined Company
Lawrence Siebert, J.D. Chairman & CEO	1981-1991, Partner, Stanwich Partners, Inc.; 1992-2002 Siebert Associates LLC, Manager; Siebert Capital Corp., President	2002
Richard Larkin, CPA Chief Financial Officer	2000-2003 CFO of Visual Technology Group; 1987-2000 CFO of Protex International Corp.	2003
Sharon Klugewicz, M.S. Chief Operating Officer	20+ Years at Pall Corporation, most recently as Sen. VP - Scientific & Laboratory Services	2012
Javan Esfandiari, M.S. SVP Research & Development	1993-1997, R&D Director On-Site Biotech; 1997-2000, Co-Founder of Sinovus Biotech AB (Sweden), which was acquired by Chembio in 2000	2000



### **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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