

**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.



#### **Investment Summary**



 Develops, Manufactures & Markets Point-of-Care Diagnostic Tests (POCTs) Using Company's Patented DPP® - A Platform POCT Technology

>25% CAGR Revenue Growth FY2009-2012

- Products Sold Globally
- Partnered with Leading License & Distribution Partners in U.S. & South America
- Recent FDA Approval of Oral Fluid HIV Test
- Strong Pipeline of POCTs
- Experienced Management Team





# POCTs - A Growing Global Market Converting Lab Tests to POCT and Creating New Markets

**In-Vitro Diagnostics Market** 

\$45 Billion

**Global Point-of-Care Test Market** 

\$10 Billion

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

**CURRENT CAPABILITIES** 

Signal Enhancement Features

Molecular

Amplification

Technologies

R&D

POTENTIAL NEW CAPABILITIES BEING ASSESSED



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

Chembio Pipeline POCT	Total Market Opportunity	Targeted Launch
US HIV (Oral Fluid, 4 <sup>th</sup> Generation)	\$ 75 MM	Q4-2013 (Oral Fluid), 2015 (4 <sup>th</sup> Generation)
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





# **Chembio Diagnostics – Current Revenues & Markets**

# 2012 - \$25.6MM Revenue Business, \$1.45MM Operating Income; Profitable Q1 2013

- •~50% of Revenue: Lateral Flow HIV Tests
  - 25% Share of \$75MM US Market
  - Participate in \$250 MM Ex-US Rapid HIV Professional Test Market
  - New HIV Self-Testing Market Opportunity
- •~40% of Revenue: Patented POCT Platform
  - Oral Fluid HIV Test FDA Approved 12/2012 & Five DPP® Products Approved and Successfully Launched in Brazil – 2011 -2012
  - Significant Developments for Single and Multiplex DPP® POCTs
- ~10% of Revenue: Other Products, Grants



#### **Anticipated Developments - 2013-2015**

- 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
- Development & FDA Approval of Multiplex Antigen/Antibody DPP® Tests for HIV and HCV
- FDA Approval of At-Home HIV Test
- Contract Development & OEM Partnerships e.g.,
   Veterinary, Tropical Diseases



#### **Chembio's Current POCT Market Opportunities**

#### **HIV Rapid POCTS**

- ~50,000 New Infections in US
- 2012; 2.5 MM Worldwide
- Routine Testing USPSTF Recommendation
- CEMI Only Company with 3FDA-Approved Tests
- CEMI Tests Designated in Selected International Protocols

### Syphilis Rapid POCTS – New Market Opportunity

- Up to 70% HIV-Syphilis Co-Infection in MSM
- All HIV+ Need be Tested for Syphilis& Vice Versa
- CEMI Has Two Unique POCTs –Anticipate 2014 Launch

### **Hepatitis-C Rapid POCT – New Market Opportunity**

- •70MM U.S. Baby Boomer Screening Opportunity; New Therapeutics
- Product in Development



# DPP® - Chembio's Patented POCT Platform Technology

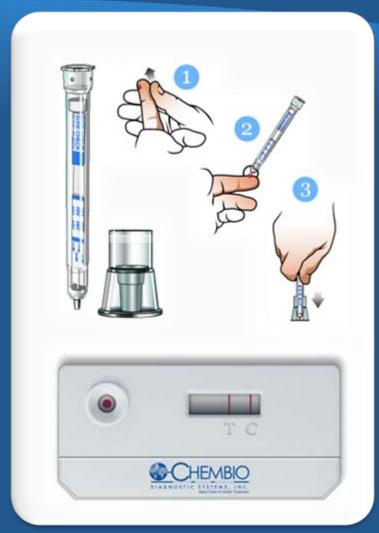
- Proprietary Platform Technology that Uniquely Enables Multiplexing for Higher Value Tests
- Increases Sensitivity as Compared with Lateral Flow Technology
- Validated with Numerous Partners, Regulatory Agencies
  - Bio-Rad Laboratories, Inc. CE Marked HIV Confirmatory Test, April 2013
- Patents Issued in US and Multiple Countries, Continuing





# Two FDA-Approved Lateral Flow Rapid HIV Tests Sold Globally

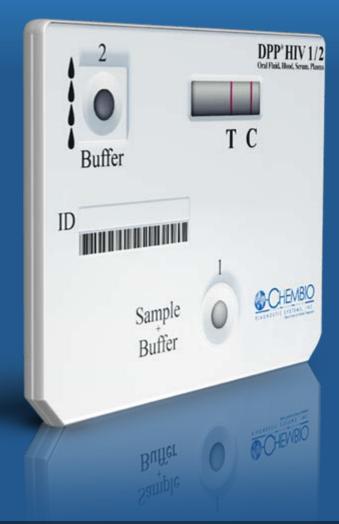
- Utilize In-Licensed Lateral Flow Technology
- Large International Screening Programs (PEPFAR)
- Significant Potential New International Opportunities Pending
- In US Sold Exclusively through Alere (Clearview Brand)
  - 2012 Sales to Alere \$7.8MM
  - Q1 2013 Sales to Alere \$2.6MM





# DPP® HIV®1/2 Test for Use with Oral Fluid or Blood Samples

- First FDA-Approved Product on DPP® (Dec. 2012)
  - Center for Biologics Evaluation and Research (CBER) PMA Approved, CLIA Waiver Pending
- Improved Sensitivity vs. Market Leader\*
- Earlier Detection of Seroconverting Patients
- Proprietary SampleTainer™
   Sample Collection System

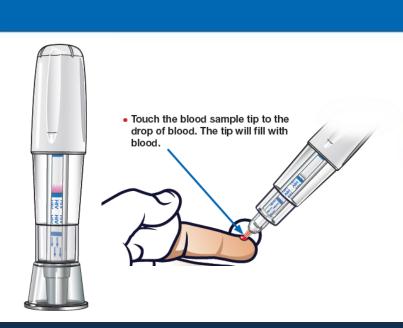




#### **U.S. HIV Self-Testing "OTC" Opportunity**

- Chembio Uniquely Positioned
- Assessing Market Size and Best Approach
- Filing IDE Early 2013 for Sure Check HIV
  - Pre-IDE Self-Testing Studies Show 100% Accuracy (n=300)





#### **Collaboration with FIOCRUZ in Brazil**

- First Commercial Success with DPP®
- Contracts with Supplier to Brazilian Federal Ministry of Health
- \$7MM of Potential Additional Purchases (~\$16MM Revenues 2011-Q1'13) for Five DPP® Products - may be exceeded
- Expect Tech Transfer & Conversion to License 2013-14
- Potential New Products & Partnerships in Brazil





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

- Large Global Market Opportunity for Pre-Natal and MSM Screening
- Anticipated FDA
   Submissions in
   2013, with 2014 Clearances
- Additional Products for Public Health Channel
- Leveraging DPP<sup>®</sup>
   Multiplexing Features





# Pipeline: Rapid Hepatitis C Point-of-Care Diagnostic

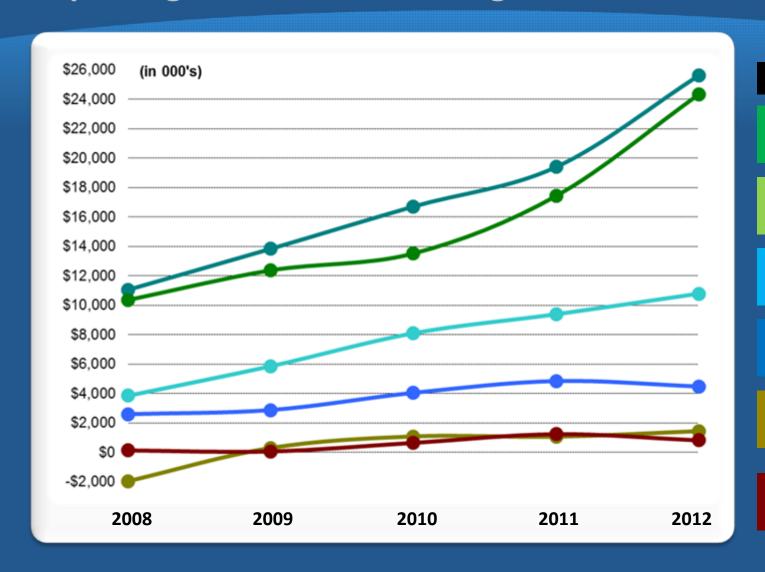
- Data Published in Journal of Clinical Virology showed good performance of Chembio's 1st Generation Prototype Assay
- Completed Feasibility to Establish Performance Comparable to Only POCT HCV Test – 2013 R&D to incorporate additional value-added features
- Recent CDC recommendations for testing on everyone born between 1945-1964
- Anticipated Timeline
  - Development & Clinical Trials 2013-2014
  - US Market Launch Anticipated 2015







# Selected Financial Data FY2008 –2012 Reporting Record Revenues Again for FY2012



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



# Strong Revenue & Operating Income Growth Q1 2013 and Years ended 2012 and 2011

	3	Mos Ended		3	Mos Ended		Υ	ear Ended		Υe	ear Ended	
in (000's)	Ma	arch 31, 2013		Ma	arch 31, 2012		De	ec 31, 2012		De	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%

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

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)	Mar'13	Dec'12	Dec'11
Cash	\$2,599	\$2,952	\$3,011
Total Current Assets	11,234	11,009	8,992
Total Assets	\$17,473	\$17,335	\$15,486
Total Current Liabilities	3,213	3,378	2,858
Total Liabilities	3,213	3,460	2,991
Stockholders' Equity	14,260	13,875	12,495
Total Liabilities & Stockholders' Equity	\$17,473	\$17,335	\$15,486







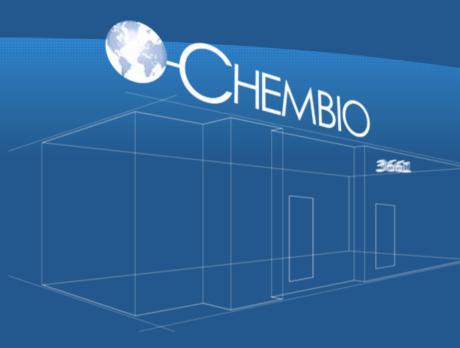
#### Leadership

Executive		<b>Joined Company</b>
Lawrence Siebert	Chairman & CEO	2002
Richard Larkin	CFO	2003
Javan Esfandiari	SVP Research & Development	2000
Tom Ippolito	VP Regulatory & Clinical Affairs	2005
Sharon Klugewicz	VP QA/QC & Technical Operations	2012
Rick Bruce	VP Operations	2000
Michael Steele	VP Sales Marketing & Bus. Dev.	2012
Independent Directors		<b>Joined Board</b>
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









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