

**NASDAQ: CEMI** 







RAPID tests for EARLIER treatments



Craig-Hallum 3rd Annual Alpha Select Conference September 27, 2012

### **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 Highlights**



- Develops, Manufactures & Markets Point-ofcare (POC) Diagnostic Tests, a \$10 Billion Market
- Partnered with Leading License & Distribution Partners in U.S. & South America
- Oral Fluid HIV Test Pending FDA Approval
- Pipeline Includes Syphilis, Hepatitis-C, HIV Self-Test & Potential Multiplex POC Testing Products
- Successive Record Revenues & Profits in 2009-2011 & Anticipated in 2012
- Seasoned Management Team, Strengthened in Q3 2012



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

Global Point-of-Care Test (POCT) Market



Total In-Vitro
Diagnostics Market

- •Rapid HIV Test Markets -\$200MM Globally
  - Oral Fluid HIV Test Pending FDA Approval
  - HIV OTC (Self-testing) Market Estimated at >\$250MM - Uniquely Positioned
- •Other New POCT Markets Targeted by Chembio
  - Hepatitis-C POCT Market
    - Estimated at >\$250MM
    - R&D, Initial External Studies
       Completed
  - Syphilis POCT Market
    - Estimated \$75MM
    - DPP® Syphilis Screen & Confirm Tests in EU and Brazil; U.S. Clinical Studies
  - Multiplex Tests

### Chembio Has Achieved Strong Growth in its FDA-Approved Lateral Flow HIV Tests Sold Globally











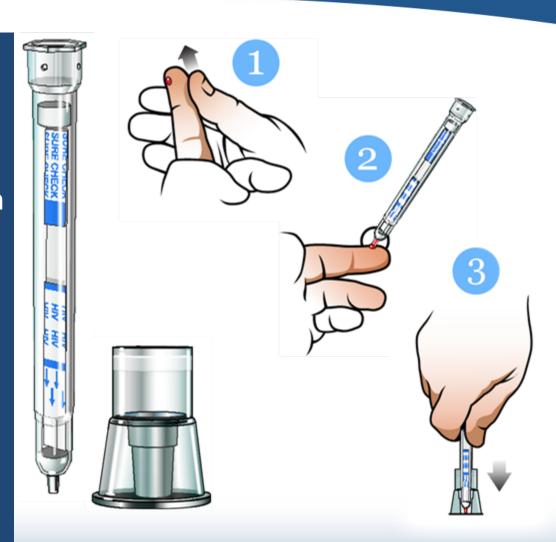


- Significant Growth & Increased Market Share in US
   Market Through Collaboration with Alere (NYSE: ALR)
- Opportunities to Grow Participation in International Markets via PEPFAR, Global Fund



### SURE CHECK® HIV & Development of the Overthe-Counter (OTC) Market For Self-Testing

- 10 Years Later, New POCT OTC Market Launch by Competitor in Q4 2012
- Chembio Product Already FDA-Approved & Distributed in US (Alere) and International Professional Market
- Pursuing FDA IDE to Begin OTC Studies in 2013, FDA Submissions 2014-2015



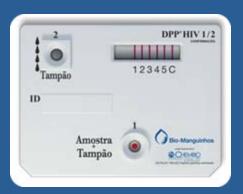


# Chembio's Patented Technology: Dual Path Platform (DPP®)

A Patented Platform Technology with a Multitude of Potential Diagnostic Applications

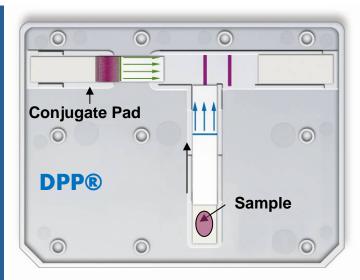
Improves Performance (Sensitivity and Specificity) v. Lateral Flow

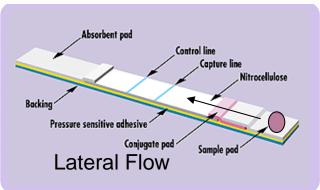
- Features Independent Sample Path and Direct Binding
- Enables Improved Multiplex Products



MULTIPLEX
DPP® HIV Confirmatory
Test Launched by
Chembio in Brazil;
Licensed to Bio-Rad
Worldwide

Foundational DPP Patent issued in U.S.; Additional patents issued or pending in U.S. & many foreign jurisdictions







### Successful Launch of DPP Products in Brazil

### Oswaldo Cruz Foundation (FIOCRUZ)

- •\$4.3MM Revenues in 2011
- •>\$9MM Anticipated in 2012

Possible New Products and Private Market Collaborations in Brazil









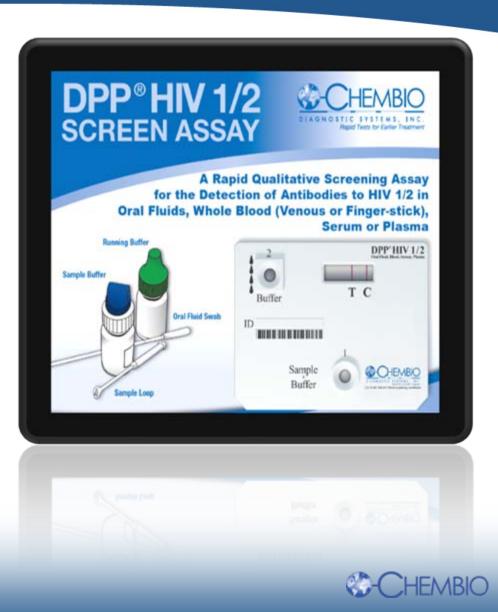




# DPP HIV Oral Fluid & Blood Rapid Test Pending FDA Approval

- Completed 3,000
   Patient Clinical Trial Q2
- Filed Final Module with FDA in June 2012
- PMA Approval
   Anticipated by End of

   2012
- CLIA Waiver/Launch in U.S. Professional Market 2013
- Potential OTC Trials & FDA Submission 2014-2016



### Pipeline: DPP® Syphilis Screen & Confirm Test

- First Dual POCT for Syphilis Enables Confirmation & Treatment At POC
- CE Marked October 2011, International Distribution being Established
- Pursuing US 510(K)
   Regulatory Clearance via
   De Novo Application
- HIV-Syphilis Combo Test

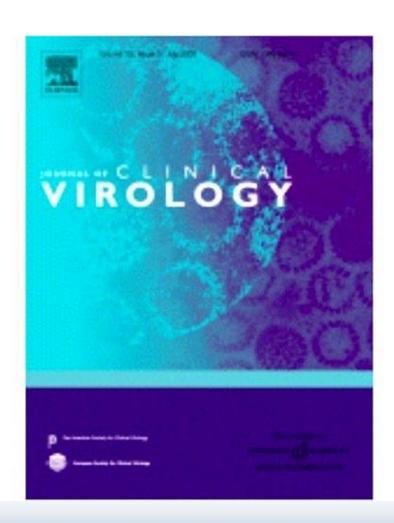


Developed in collaboration with the U.S. Centers for Disease Control



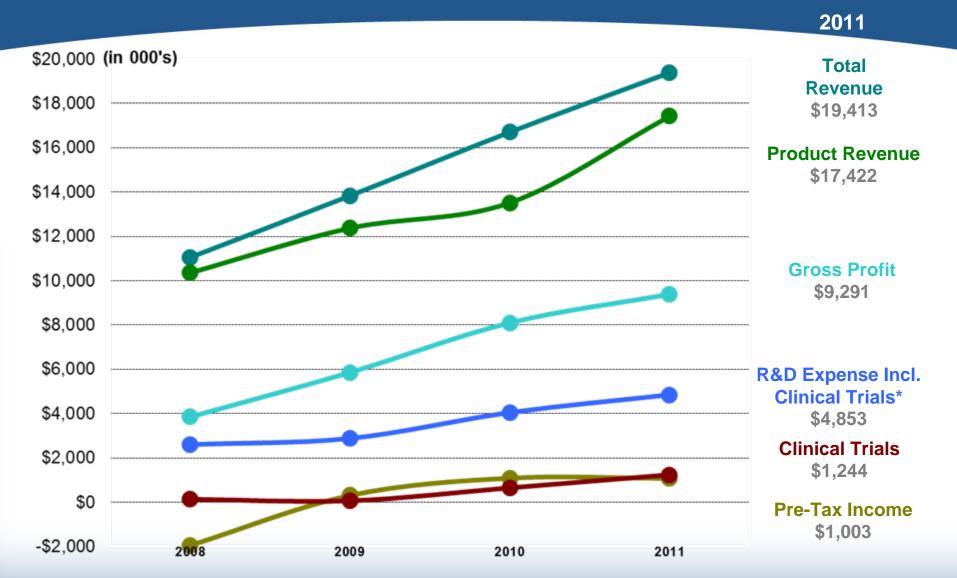
# Pipeline: Rapid Hepatitis C Point-of-Care Diagnostic

- Data Published in Journal of Clinical Virology shows Chembio's assay to be superior in assessing Hepatitis C among high-risk participants
- Recent CDC draft guidelines recommend HCV screening for all Americans born between 1945 and 1965—an estimated 70 million Americans
- Commence optimization studies of the assay 2H 2012
- Opportunity for strategic partnerships





#### **Selected Financial Data FY2008 - 2011**



<sup>\*</sup> Non-recurring 2010 \$1.5MM R&D Credit from the Affordable Care Act – excluded from 2010 R&D Exp. & 2010 Pre-Tax Income

### **Chembio Selected Financial Results Through Six Month Ended June 30, 2012**

•	1st Half 2012
	Revenues
	<b>Increased 75%</b>
	to \$12.7MM
	<b>Compared to</b>
	1st Half 2011

1st Half
 Operating
 Income of
 \$1.23MM
 Achieved by
 Strong DPP Brazil & US
 Market Gains

	Y٦	TD June		Y	TD June	
in (000's)	30	0, 2012		3	0, 2011	
Net Product Revenues	\$	12,174		\$	5,989	
Non-Product Revenues	\$	563		\$	1,260	
TOTAL REVENUES	\$	12,737		\$	7,249	
GROSS MARGIN	\$	5,904	46%	\$	3,977	55%
OPERATING COSTS:						
Research and development exp.	\$	2,358	19%	\$	2,455	34%
Selling, general and administrative exp.	\$	2,313	18%	\$	1,464	20%
	\$	4,671		\$	3,919	
INCOME FROM OPERATIONS	\$	1,233		\$	58	
OTHER INCOME (EXPENSES):	\$	(2)		\$	(5)	
NET INCOME-Before Taxes	\$	1,231	10%	\$	53	1%
Income tax (benefit) provision	\$	489		\$	-	
NET INCOME	\$	742	6%	\$	53	1%



### **Anticipate Continued Strong Year Over Year Revenue and Operating Results Improvements**

- 2<sup>nd</sup> Half 2012 Revenues Anticipated to be Comparable to 2<sup>nd</sup> Half 2011
  - Lower Q3 Shipments
    - US (CDC Grant) Funding Reallocation
    - Other International Orders Not Received in time for Q3 Shipment
  - Record Q4 backlog Includes \$1.5MM Order from Global NGO for New Chembio Market
  - Brazil Business Strong in Q3 & 4



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

#### (in millions except per share and daily volume data)

Ticker Symbol (NASDAQ)	СЕМІ
Price 9/22/12	\$4.22
52-Week High	\$5.30
52-Week Low	\$2.80
Outstanding Shares	8.00
Market Capitalization	\$33.8
Fully Diluted Shares	8.9
Management Holding	1.58
Average Daily Volume (3 months)	21,500

(\$ in millions)	Jun'12	Dec'11	Dec. '10
Cash	\$ 4,390	\$ 3,011	\$ 2,136
Total Current Assets	10,483	8,992	7,637
Total Assets	\$16,715	\$ 15,486	\$ 9,086
Total Current Liabilities	3,106	2,858	3,076
Total Liabilities	3,214	2,991	3,277
Total Equity	13,501	12,495	5,809
Total Liabilities & Stockholders' Equity	\$16,715	\$ 15,486	\$ 9,086

Options	Amt.	Avg. Ex. Price
578K held by Mgmt. & Board	764K	\$2.08



### **Leadership Strengthened**

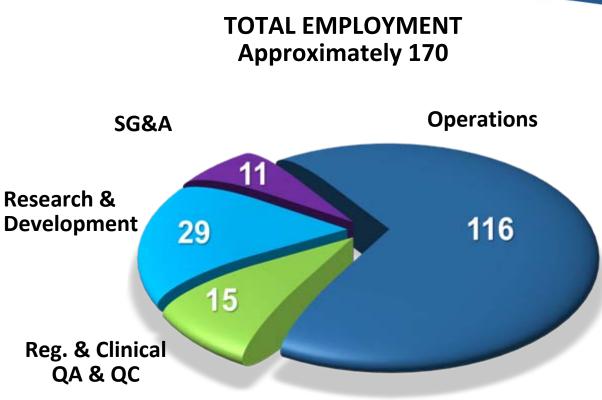
Executive		Joined Company
Lawrence Siebert	Chairman & CEO	2002
Richard Larkin	CFO	2003
Javan Esfandiari	SVP Research & Development	2000
Tom Ippolito	VP Regulatory & Clinical Affairs	2005
Sharon Klugewicz	VP QA/QC & Technical Operations	2012
Rick Bruce	VP Operations	2000
Michael Steele	VP Sales Marketing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

Independent Directors	Joined Board
Gary Meller, MD, MBA	2005
Katherine Davis, MBA	2007
Barbara DeBuono, MD, MPH	2011
Peter Kissinger, Ph.D	<b>2011</b>

#### **Organization & Facility**

- FDA & USDA-Approved
   Development & Manufacturing
   Facility
- All Company
   Operations in
   28,000 Sq. Ft.
   Leased Facility in









#### **Thank You**







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