



RAPID tests for EARLIER treatments



**Investor Presentation** 

**May 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 forwardlooking 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 forwardlooking 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**

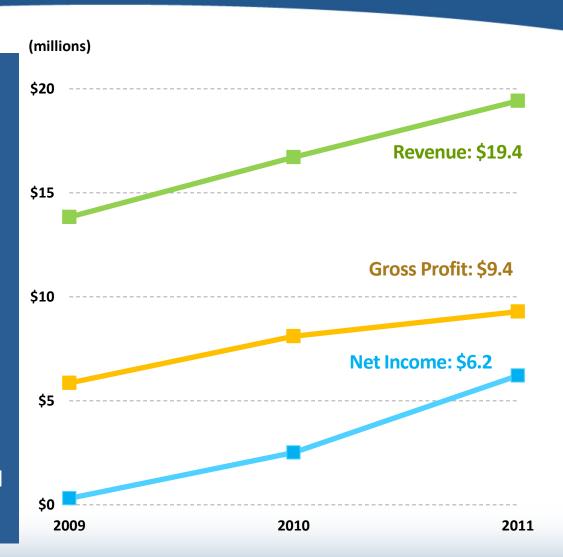


- Develops, Manufactures & Markets Point-of-Care Diagnostic Tests Participating in \$10 billion POC test market
- Partnered with leading license and distribution partners in U.S. and South America
- Robust pipeline of POC diagnostics for infectious diseases based on lateral flow and proprietary DPP® platforms
- New opportunities for strategic partnerships with HIV Self-Tests, Hepatitis-C, Multiplex DPP® POC Testing Products
- Record Revenues and Income in 2009-2012YTD
- Seasoned management team with relevant industry and financial experience



### Financial Summary - FY2009-2011 Results

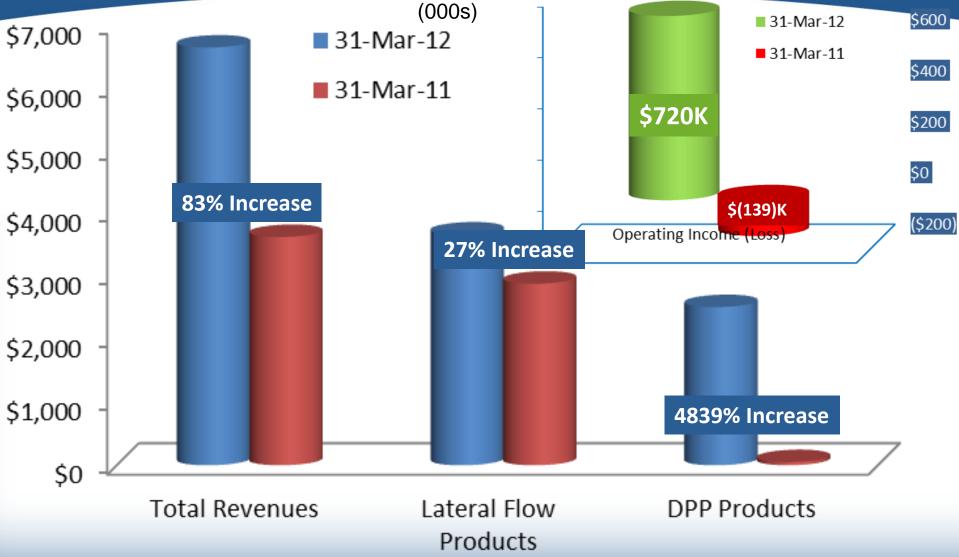
- Product Revenue Growth of 40.8% over period to \$17.4MM in 2011
- Gross Margin Growth of 60% over period to \$9.4MM in 2011
- Non-Recurring Items
   Included in Net Income
  - \$1.5MM QTDP grant in 2010 credited to R&D expense
  - \$.3MM 2010 Expense related to possible strategic transaction
  - 2011 Recognition of deferred tax asset valuation allowance of \$5.1MM





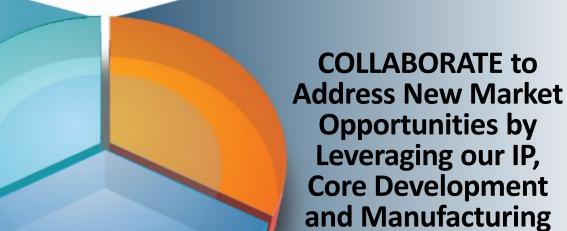
# Three Months Ended March 31, 2011 & 2012 Selected Financial Results

\$800



### **Our Business Strategy**





**Competencies** 

CONTINUE to Increase Revenue and Profitability Growth to Drive Shareholder Value

**CHEMBIO** 

### 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
- Potential HIV OTC (Self-testing) Market Estimated at >\$250MM
- 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
  - Veterinary POCT



# Lateral Flow Technology

# Product Portfolio At a Glance In-Licensed Lateral Flow Technology

**SURE CHECK HIV 1/2 OTC** 

**Clinical Testing** Marketed Feasibility Testing **Chembio HIV 1/2 STAT PAK OUS Chembio Clearview HIV 1/2 STAT PAK US - Alere SURE CHECK HIV 1/2 OUS - Chembio Clearview Complete HIV 1/2 US - Alere** 



# **Dual Path Platform Technology**

### Product Portfolio At a Glance Chembio Patented Dual Path Platform Technology

Clinical Testing Marketed R&D **Brazil-FIOCRUZ DPP HIV Confirmatory Bio-Rad US & ROW Brazil-FIOCRUZ DPP Syphilis Screen** Licensed Leptospirosis **Brazil-FIOCRUZ** or OEM Leishmaniasis **Brazil-FIOCRUZ** DPP HIV 1/2 **Brazil-FIOCRUZ Completing Q2 2012 DPP Syphilis Screen & Confirm Branded Products HCV Pre-Natal** Veterinary

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



# **Essential Tool in Prevention Efforts Globally**

- 50,000 new cases of HIV annually still in U.S.
- Estimated that >20% of HIV-positive individuals in U.S. unaware of their status

# Marketed Exclusively in U.S. Professional Market by Alere, Inc.

- Chembio's U.S. market sales (to Alere) increased by 36.5% in 2011 to \$7.2MM
- Profit Share Structure Based on ASP
- Estimated 20%+ U.S. market share
- Sold through distribution ex-U.S.





## FDA's BPAC\* Recommended Approval Of In-Home HIV Test \*Blood Products Advisory Committee

- Will Help Avert More Infections By Enabling Self-testing
- Chembio Is Uniquely Positioned To Participate In This New Market
- Barrel Product Currently Sold In U.S, Professional Market By Alere Already Unitized
- Anticipate Receiving FDA Investigational Device Exemption In 2012 To Begin Studies In 2013





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

A Patented Platform Technology with a Multitude of Potential Diagnostic Applications

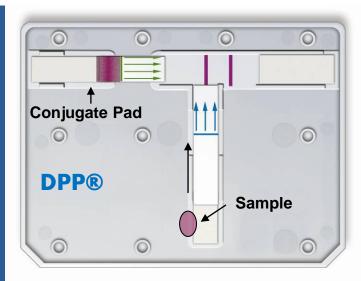
Improves Performance (Sensitivity and Specificity) v. Lateral Flow

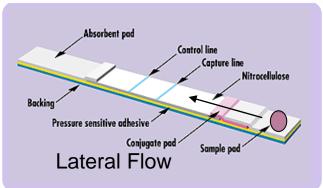
- Features Independent Sample Path and Direct Binding
- Enables Improved Multiplex Products



MULTIPLEX
DPP® HIV
Confirmatory Test
Launched in Brazil

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

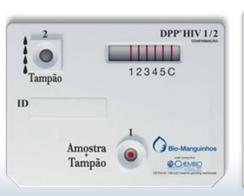






# OEM Collaboration with Brazil's Oswaldo Cruz Foundation (FIOCRUZ) for DPP® - 5 Products Approved 2010-2011

- Five Contracts with Aggregate \$23MM of Minimum Purchases, All Products Approved in Brazil 2010-11
- \$4.3MM Revenues in 2011 >\$9MM Anticipated in 2012
- Possible New Products and Collaborations with FIOCRUZ & Others in Brazil





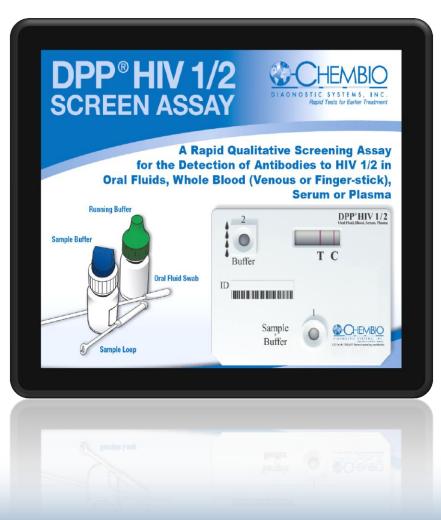






# Branded Product: DPP® HIV Screening Assay For Use with Oral Fluid or Blood Samples

- Clinical Trials
   Completed April 2012
- Final Module
   Submission June 2012
- Anticipated FDA PMA Approval in 2012
- Market Launch 2013
- Improved Performance
   & Unique Features





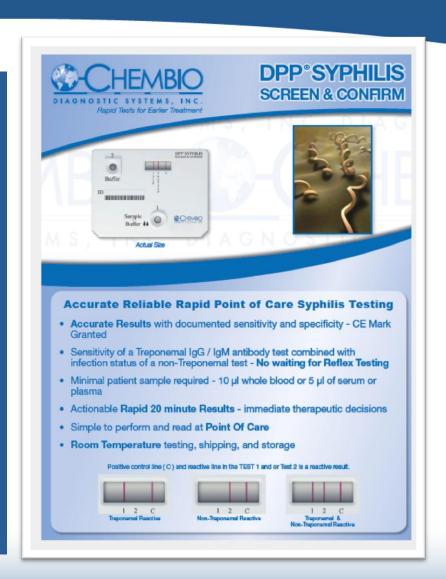
# U.S. Rapid HIV Test Market\* - Solid Growth Since 2006 with New CDC Testing Recommendations

	Complete (US) Sure Check® (Intl)	HIV 1/2 STAT-PAK®	DPP® HIV 1/2	OraQuick® Advance	Uni-Gold®		
Manufacturer	Chembio Diagnostics	© © Chembio	Chembio	Orasure	Trinity		
Location	NY Alere in US;	Diagnostics NY	Diagnostics NY	Technologies PA	Biotech Dublin, IR		
Marketing	Distribution ex-US	Alere in US; Distribution ex-US	TBD	Direct US Distribution Ex- US	Direct & Distr. US Distr. Ex-US		
FDA Approval Date	2006	2006	Anticipated by End of 2012	2003	2003		
Technology	Lateral Flow	Lateral Flow	Patented Dual Path Platform DPP®	Lateral Flow	Lateral Flow		
Key Features	Unitized Barrel Device; 2.5µl sample	5 μl sample size Standard Cassette	Patent-Pending Samptainer ™ Closed Sample System Earlier detection in seroconversion panels		50 µl sample size Doesn't detect HIV-2		
Sample Types	All Blood Matrices	All Blood Matrices	Oral Fluid & All Blood Matrices	Oral Fluid, Whole Blood, Plasma; not serum	All Blood Matrices		
Est. US Mkt. Shr. *Does not include	10% tests that are not CLIA waive	<b>15%</b>	N/A	62%	13%		

### **Branded Product: DPP® Syphilis Screen & Confirm**

- First Dual POCT for Syphilis Enables Confirmation & Treatment At POC
- CE Marked October 2011, International Distribution being Established
- US 510(K) Clinical Trials 2012

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





# Three Months Ended March 31, 2012 & 2011

in (000's)  Years Ended Dec. 2011 & 2010 Selected Financial Results  3 Mo. Mar. 31, 2012 3 Mo. Mar. 31, 2012					
in (000's)	3 Mo. Mar. 31, 2012	3 Mo. Mar. 31, 2011			

\$

\$

6,363

6,653

3,333

1,379

1,234

2,613

720

(1)

719

285

433

290

50%

12%

19%

11%

7%

\$

3,015

3,636

1,926

1,290

775

2,065

(139)

(142)

(142)

(3)

53%

35%

21%

-4%

-4%

621

**Net Product Revenues** 

Non-Product Revenues

**TOTAL REVENUES** 

**GROSS MARGIN** 

**R&D** Expenses

**SG&A Expenses** 

**NET INCOME** 

**INCOME FROM OPERATIONS** 

**OTHER INCOME (EXPENSES):** 

Income tax (benefit) provision

**NET INCOME-Before Taxes** 

**OPERATING COSTS:** 

	Dec. 2011 & 2010 ancial Results	
in (000's)	3 Mo. Mar. 31, 2012	3 Mo. Mar. 31, 2011

Y/E Dec. 31, 2011

17,422

1,966

19,388

9,390

4,878

3,424

8,302

1,088

(12)

1,076

(5,133)

6,209

48%

25%

18%

6%

32%

Ś

Y/E Dec. 31, 2010

13,516

3,188

16,705

8,101

2,586

2,941

5,527

2,574

(15)

2,559

2,513

46

48%

15%

18%

15%

15%

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

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

Ticker Symbol (OTC-QB)	СЕМІ
Price 4/30/12	\$0.490
52-Week High	\$0.570
52-Week Low	\$0.210
Outstanding Shares	63.9
Market Capitalization	\$31.3
Fully Diluted Shares	69.7
Management Holding	12.5
Average Daily Volume (3 months)	32,500

(\$ in millions)	Mar'12	Dec'11	Dec. '10
Cash	\$ 2,954	\$ 3,011	\$ 2,136
Total Current Assets	10,033	8,992	7,637
Total Assets	\$16,360	\$ 15,486	\$ 9,086
Total Current Liabilities	3,133	2,858	3,076
Total Liabilities	3,254	2,991	3,277
Total Equity	13,106	12,495	5,809
Total Liabilities & Stockholders' Equity	\$16,360	\$ 15,486	\$ 9,086

Options	Amt.	Avg. Ex. Price
4.31MM held by Mgmt. & Board	5.82MM	\$0.229



### **Anticipated Milestones 2012-13**

### Product Revenues & Operating Results

- Full Year of New Products
   Launched in Brazil through
   FIOCRUZ
- Launch of DPP® HIV & Syphilis Tests in Global & US Markets
- Increased Lateral Flow HIV Test Sales in U.S. & Global Markets

### Potential New Products & Marketing Collaborations

 Developments Related to Potential New Branded and/or OEM Products & Related Strategic Collaborations



### **Development Programs**

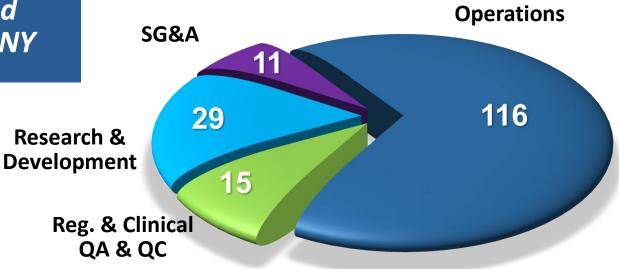
- •DPP® HIV Oral Fluid Test
  - Milestones Toward FDA Approval
- Sure Check HIV OTC
  - IDE, Clinical Trials
- Hepatitis-C Product
  - Developments, Studies
- Syphilis Screen & Confirm
- Others
  - •HIV/Syphilis Combo
  - New Multiplex Tests



### **Organization & Facility**

 FDA & USDA- Approved Development & Manufacturing Facility

 28,000 Sq. Ft. Leased Facility in Medford, NY Approx. 170





### Leadership

Executive		Joined Company				
Lawrence Siebert	Chairman & CEO	2002				
Richard Larkin	CFO	2003				
Javan Esfandiari	SVP R&D	2000				
Tom Ippolito	VP Regulatory, Clinical, QA/QC	2005				
Rick Bruce	VP Operations	2000				

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



### **Investment Highlights**



- Develops, Manufactures & Markets Pointof-Care Diagnostic Tests Participating in \$10 billion POC test market
- Partnered with leading license and distribution partners in U.S. and South America
- Robust pipeline of POC diagnostics for infectious diseases based on lateral flow and proprietary DPP® platforms
- New opportunities for strategic partnerships with HIV Self-Tests, Hepatitis-C, Multiplex DPP® POC Testing Products
- Record Revenues and Income in 2009-2012YTD
- Seasoned management team with relevant industry and financial experience





# Thank You Additional Slides







RAPID tests for EARLIER treatments

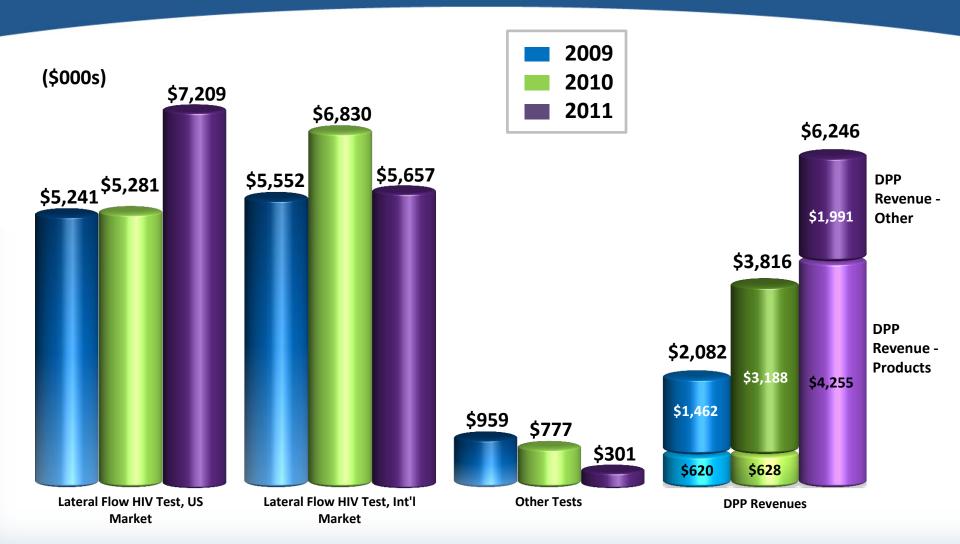


# **Comparative Selected Operating Results 2006-2011**

(in 000s)	2011		2010		2009		2008		2007		2006	
REVENUES:												
Net Product sales	\$ 17,422		13,516		12,372		10,356		8,765		6,294	
Non-product revenues	1,966		3,189		1,462		694		466		208	
TOTAL REVENUES	19,388		\$ 16,705		\$ 13,834		\$ 11,050		\$ 9,231		\$ 6,502	
Cost of sales	9,998		8,604		7,974		7,198		6,435		4,894	
GROSS MARGIN	9,390	48%	8,101	48%	5,860	42%	3,852	35%	2,796	30%	1,608	25%
OVERHEAD COSTS:												
Research and development expenses	4,878	25%	2,586	15%	2,884	21%	2,606	24%	1,907	21%	1,401	22%
Selling, general and administrative expenses	3,424	18%	2,941	18%	2,659	19%	3,317	30%	3,765	41%	4,787	74%
	8,302		5,527		5,543		5,923		5,672		6,188	
INCOME (LOSS) FROM OPERATIONS	1,088		2,574		317		(2,071)		(2,876)		(4,580)	
OTHER INCOME (EXPENSES):												
Other income (expense)			(4)		(7)		96		121		(57)	
Interest income	6		4		9		34		145		29	
Interest expense	(19)		(15)		(10)		(8)		(17)		(387)	
	(13)		(15)		(8)		122		249		(415)	
NET INCOME (LOSS) BEFORE INCOME TAXES	1,075		2,559		309		(1,949)		(2,627)		(4,995)	
Income tax (benefit) provision	(5,133)		46		-		-		-		-	
NET INCOME (LOSS)	6,208	32%	2,513	15%	309	2%	(1,949)	-18%	(2,627)	-28%	(4,995)	-77%
Pref. Divid. '06/07, beneficial conversion feature in 2006 and effect of conversion in 2007									5,645		3,210	
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ 6,208		\$ 2,513		\$ 309		\$ (1,949)	-18%	\$ (8,272)	-90%	\$ (8,205)	-126%
Basic income (loss) per share	\$ 0.10		\$ 0.04		\$ 0.00		\$ (0.03)		\$ (0.57)		\$ (0.80)	
Diluted income (loss) per share	\$ 0.09		\$ 0.04		\$ 0.00		\$ (0.03)		\$ (0.57)		\$ (0.80)	
Weighted average number of shares outstanding, basic	62,998		62,103		61,946		61,267		14,608		10,293	
Weighted average number of shares outstanding, diluted	68,450		70,921		75,042		61,267		14,608		10,293	

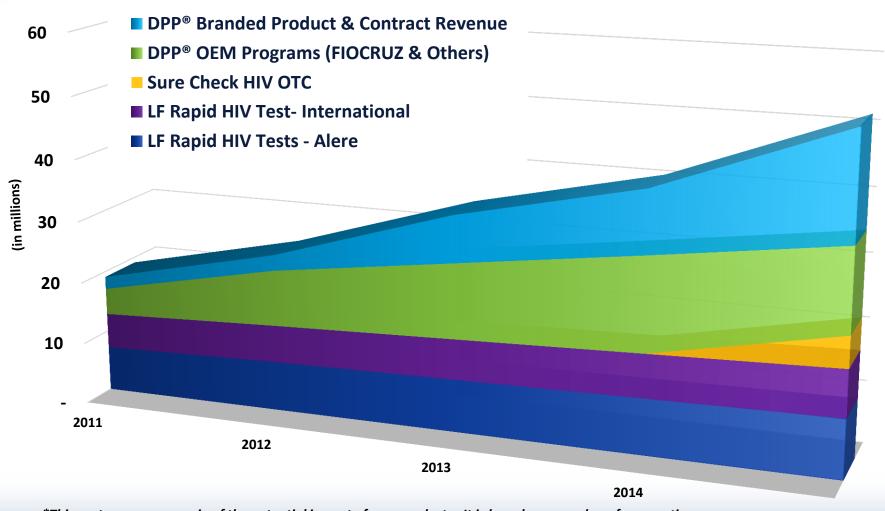


### **Revenue Growth by Category: 2009-2011**





# Potential Impact of OEM & Branded Products on Revenue\*







2015