

## RAPID Tests for EARLIER Treatment





**Annual Shareholders Meeting** 

September 22, 2011

### **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 obtain additional financing 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. 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



### **Chembio Overview**

- Develops, Manufactures and Markets Rapid Point-of-Care Test (POCT) Products
  - Current POCTs for HIV, Syphilis & Other Infectious Diseases, applicable to many other market segments
- Branded & Private Label (OEM) Strategy
  - Enabled by patented Dual Path Platform (DPP®)
  - Four products approved in Brazil 2010-11 now being launched by Brazilian OEM partner
  - Sure Check OTC Rapid HIV Test Initiative
- FDA & USDA Approved Leased Manufacturing Facility in Medford, NY
  - 130 Employees



## Leadership

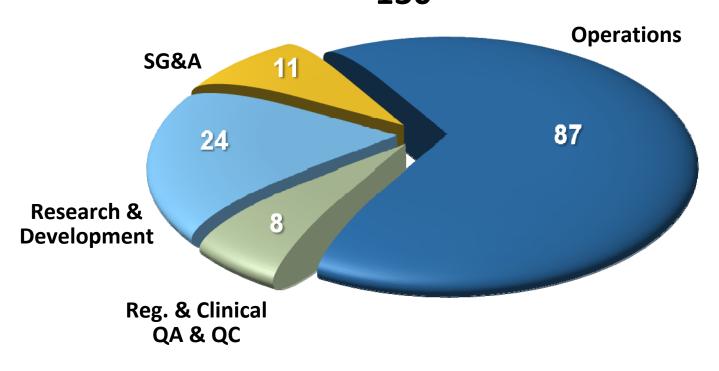
Executive		Joined Company
Lawrence Siebert	Chairman & CEO	2002
Richard Larkin	CFO	2003
Javan Esfandiari	SVP R&D	2000
Tom Ippolito	VP Regulatory, Clinical, QA/QC	2005
Rick Bruce	VP Operations	2000

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



### **Organization & Facility**





Fully Integrated FDA & USDA Approved Development & Manufacturing in 24,000 S/F Leased Facility in Medford, NY

### **Financial Overview**

- Five Year Compounded Annual Revenue Growth of 33%
- Gross Margin Expansion Actual and %/Sales

- 2006: \$1.60MM - 25%

- 2010: \$8.10MM - 48%

- 2010 6 Mos. YTD

\$3.40MM - 52%

- 2011 6 Mos. YTD

\$3.98MM - 55%

 Profitable 2009, 2010 and 2011YTD

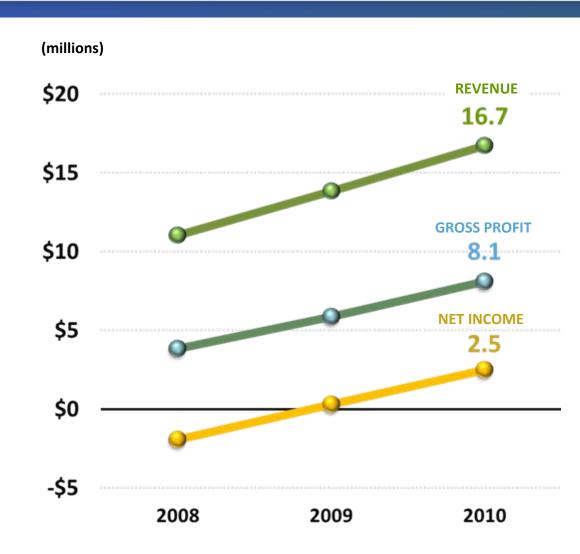




### **Financial Summary**

#### **FY2008-2010** Results

- Record Revenues and Earnings
- Improving Gross Margins
- Controlled Operating Expenses
- Operating Cash Flow Strengthened Balance Sheet





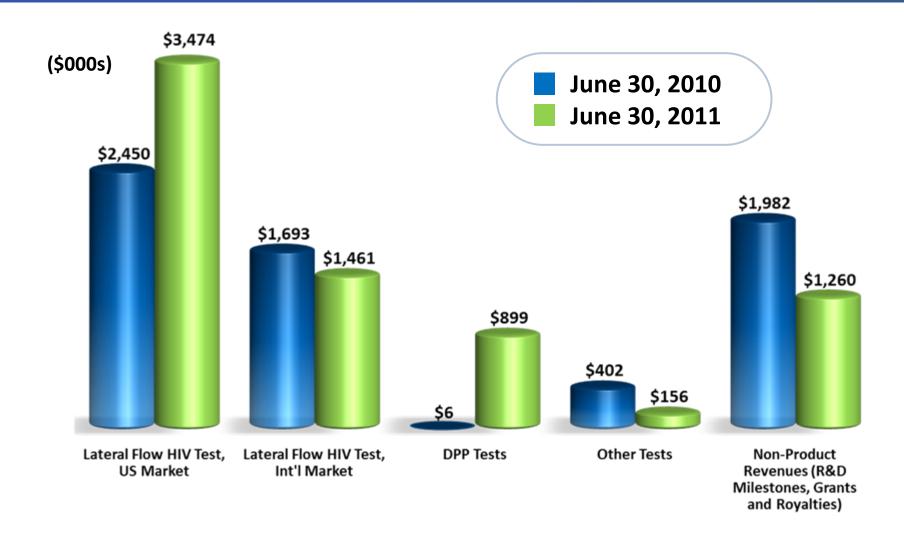
# Selected Comparative Operating Statement Items - 2010 vs. 2011

	3mos. June 30, 2011	3mos. June 30, 2010	June 30, 2011-YTD	June 30, 2010-YTD	December 31, 2010
Net Product Revenues	\$ 2,974,379	\$ 2,335,665	\$ 5,989,442	\$ 4,550,562	\$ 13,516,359
Non-Product Revenues	639,772	1,413,777	1,260,390	1,982,296	3,188,344
TOTAL REVENUES	\$ 3,614,151	\$ 3,419,442	\$ 7,249,832	\$ 6,532,858	\$ 16,704,703
GROSS MARGIN	<b>2,050,278</b> 57%	<b>2,094,966</b> 61%	3,976,620	55% <b>3,401,340</b>	<b>8,100,699</b> 48%
OPERATING COSTS:					
Research and development expenses	1,164,872 32%	791,596 23%	2,455,014	34% 1,592,354	24% 2,586,308 15%
Selling, general and administrative expense	688,259 19%	680,014 20%	1,463,630	20% 1,341,862	21% 2,940,721 18%
	1,853,131	1,471,610	3,918,644	2,934,216	5,527,029
INCOME FROM OPERATIONS	197,147	623,356	57,976	467,124	2,573,670
OTHER INCOME (EXPENSES):	(2,308)	(1,439)	(5,434)	(2,533)	(60,326)
NET INCOME	<b>194,839</b> 5%	<b>621,917</b> 18%	52,542	1% 464,591	7% <b>2,513,344</b> 15%

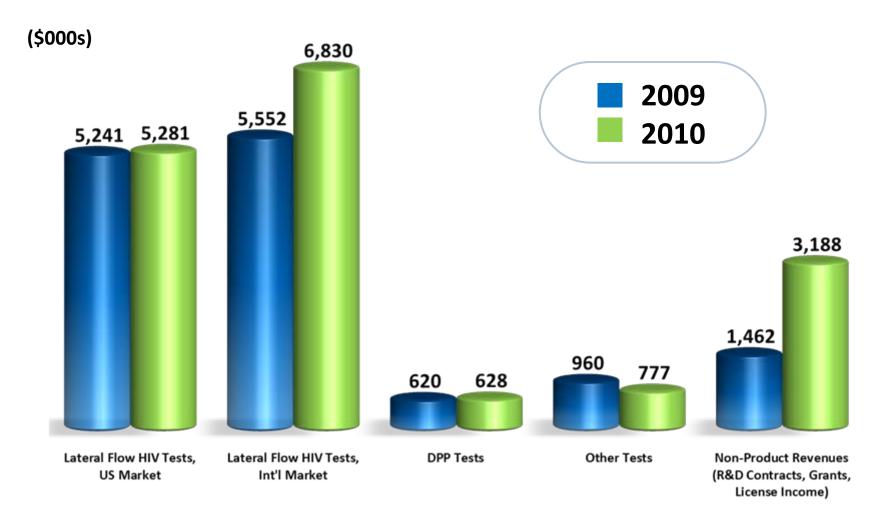
### U.S. Rapid HIV Test Market Chembio U.S. Sales Up 42% YTD vs. 2010

	Clearview Complete	Clearview STAT PAK®	DPP® HIV Screen	OraQuick	Uni-Gold
		Charles on 17 Harrison	Devisor T C  Devisor Structure Struc		
Manufacturer	Chembio	Chembio	Chembio	Orasure Technologies, Bethlehem PA	Trinity Biotech, Dublin Ireland
Current or Planned Distribution	Private Label for Alere Direct & Distribution	Private Label for Alere Direct & Distribution	Direct & Distributors	Direct sales force	Direct sales force & distributors
FDA Approval Date	2006	2006	Clinical trials	2003	2003
Technology	Lateral Flow	Lateral Flow	Dual Path Platform (DPP®)	Lateral Flow	Lateral Flow
Est. US Market Shr.	8%	12%	N/A	65%	15%
FDA Sensitivity	99.7%	99.7%	TBD	99.3%OF/99.6% WB	100%
FDA Specificity	99.9%	99.9%	TBD	99.8%OF/100% WB	99.7%
Features					
Sample Types	All Blood Matrices	All Blood Matrices	Blood & Oral Fluid Claims being pursued	Oral Fluid and all blood matrices except serum	All Blood Matrices
True IgG Control	Υ	Υ	Υ	Υ	N
Sample Size (in microliters)	<5	<5	<5	<5	40
HIV-2	Υ	Υ	Υ	Υ	N

## Revenue Growth by Category: Q2'10 YTD vs. Q2'11 YTD



### Revenue Growth by Category: 2009 vs. 2010



### **Selected Balance Sheet Data**

(\$000s)	Ju	ıne'11	D	ec. '10	D	ec. '09	D	ec. <b>'08</b>
Cash	\$	2,139	\$	2,136	\$	1,068	\$	1,212
Accounts Receivable		1,643		3,946		1,776		809
Inventories		2,917		1,349		1,556		1,819
Total Current Assets		6,914		7,637		4,667		4,068
Net Fixed Assets		778		813		580		881
Other Assets		743		636		1,068		968
Total Assets	\$	8,435	\$	9,086	\$	6,315	\$	5,915
Total Current Liabilities		2,079		3,076		3,173		2,402
Total Liabilities		2,238		3,277		3,227		3,338
Total Equity		6,197		5,809		3,088		2,577
Total Liabilities & Stockholders Equity	\$	8,435	\$	9,086	\$	6,315	\$	5,915

# OEM: Progress on Four DPP® OEM Contracts with FIOCRUZ

- 2010 Annual Meeting Status
  - Four DPP® Products Completed
  - Three DPP® Products Submitted for Regulatory Approval
  - Anticipated All Four DPP® Product Approvals in 2010
    - Significantly Longer Process than Expected
- 2011 Annual Meeting Status
  - All Five DPP® Products Approved
    - Leptospirosis DPP® Product Approved August
  - Completed Shipments of Other Four DPP® Products during Q3 with more anticipated in Q4
    - Still anticipate >\$3MM 2011 DPP® Product Revenues



# OEM: Multiplex DPP® OEM Development Contracts with BIO-RAD

- 2010 Annual Meeting Status
  - Bio-Rad Completing Product Development Phase in Current Q2
     2010
  - Multiplex Influenza Test Awarded \$900K Contract
- 2011 Annual Meeting Status
  - Bio-Rad:
    - Completed all requirements for recognition of license fee, technology transfer, supporting regulatory submission activity
  - Multiplex Influenza Test:
    - Prototypes delivered within specification
    - Anticipate new contract award to continue development



# CHEMBIO BRANDED DPP® PRODUCT PIPELINE DPP HIV 1/2 Screen Assay for Oral Fluid

- 2010 Annual Meeting Status
  - Approved by PEPFAR for all blood matrices & oral fluid

- 2011 Annual Meeting Status
  - US Clinical Studies Commenced and Nearly Completed
  - Anticipated 2012 Approval



# CHEMBIO BRANDED DPP® PRODUCT PIPELINE DPP Syphilis Screen & Confirm

#### 2010 Annual Meeting Status

- WHO Phase I Study Complete
- Contracts Pending for FDA clinical trials
- Submitting for CE Mark

### 2011 Annual Meeting Status

- Product Validation Was Delayed for One Year
- CE Mark Submitted Q3 2011
- Clinical Trials Commenced Q3 2011
- WHO Phase II Study Complete
  - Study Report being finalized



### **DPP HCV & INFLUENZA A/B**

- 2010 Annual Meeting Status
  - HCV
    - CDC Laboratory and Field Studies Concluded
  - INFLUENZA
    - Prototype Completed
- 2011 Annual Meeting Status
  - HCV
    - CDC Data Published Confirming Good Prototype Performance
    - Uncertain Outlook for US HCV Rapid Testing
  - INFLUENZA
    - Product Development Completed
    - New Regulatory Standards for CLIA waiver



### **Other Contract Development and Grant Awards**

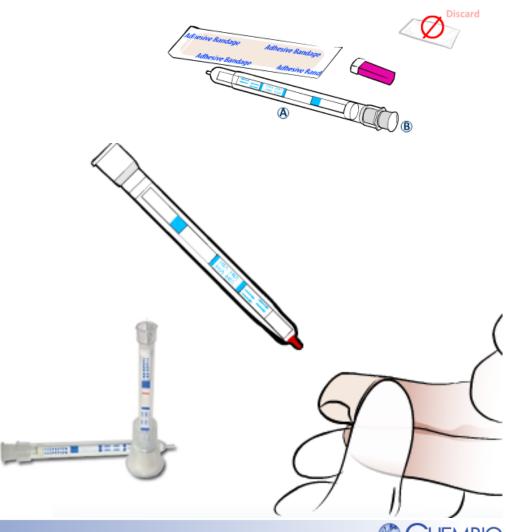
- 2010 Annual Meeting Status
  - NIH \$2.9MM 3 year Phase II Leptospirosis Grant Awarded June 2009

- 2011 Annual Meeting Status
  - \$1.467MM in Qualified Therapeutic Discovery Project Grants Awarded Q3 2010
  - NIH \$2.4MM 3 year Phase II Tuberculosis Grant Awarded March 2011



### NEW INITIATIVE in 2011: SURE CHECK® HIV OTC -IDE Submission 2011

- Completed Marketing Study and Flex Studies
- Pre-IDE Meeting with FDA Scheduled Q4
- Anticipate having timetable for initiation of clinical studies by Q1 2012



### **CEMI Selected Share Data**

Increase of 90% Since July 2010; 300% Since July 2009; 0% Since Oct. 2006

(in millions except per share data)

Ticker Symbol (OTC-QB)	CEMI.QB
Price 9/20/2011	\$0.400
52-Week High	\$0.580
52-Week Low	\$0.210
<b>Outstanding Shares</b>	63.3
Market Capitalization	\$25.3
Fully Diluted Shares	69.8
Management Holding	11.6
Average Daily Volume (3 months)	53,439

Options and Warrants	Amt.	Avg. Ex. Price
Options (3.89 MM held by mgmt. & board)	5.42	\$0.192
Warrants (MM) - Exp. Dates		
10/6/2011	1.17	\$0.454
2/5/2012	0.07	\$0.810
Total Options & Warrants	2.41	\$0.254





## **Actions Being Pursued to Enhance Shareholder Value**

- Continue Delivering Improved Fundamental Operating Results
- Consider, Under Right Circumstances, Reverse Split to Qualify for NASDAQ or AMEX to Develop Interest in CEMI from a Broader Spectrum of Investors





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