



# **Investor Presentation August 4, 2010**



#### **Forward Looking Statements**



Statements contained herein that are not historical facts are forwardlooking 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 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. 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** 







- Medford, NY Manufacturer of Point-of-Care Rapid Diagnostic Tests
- Five Year Revenue CAGR of 33%
- 2009 Total Revenues of \$13.8MM \$309K Net Income
   v. \$11.0MM Rev. \$1.9MM Net Loss in 2008
  - 2010 Six Mos. YTD Revenues \$6.5MM and \$464K Net Income
     vs. \$5.9MM and \$(215K) in 2009
- Revenues from FDA Approved Rapid HIV Tests
   Marketed in U.S. by Alere (formerly Inverness Medical)
   Increased 148% in 2009 to \$5.2MM
  - 22% in Six Months Ended 6/30/2010 to \$2.5MM
- \$739K & \$1.243MM YTD in License and R&D Revenues Related to Chembio's Patented DPP® Technology

#### **Organization & Management Team**



Lawrence Siebert, CEO & Chairman

Richard Larkin, CFO

Javan Esfandiari, Sr. VP R&D

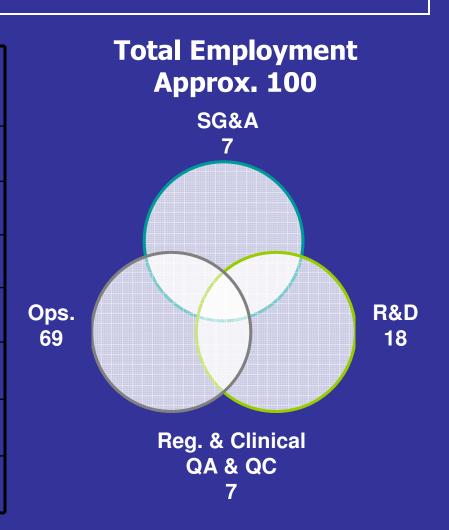
Rick Bruce, VP Operations

Tom Ippolito, VP Reg., QA/QC

Sandy Speer, Dir. Client Serv.

Dr. Gary Meller, Director

Katherine Davis, Director



## Regulatory Approvals Provide Access to Large, Diverse & Global POCT Markets



### U.S. Food and Drug Administration

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Two FDA-Approved PMA's



USDA-Approved Facility & Product



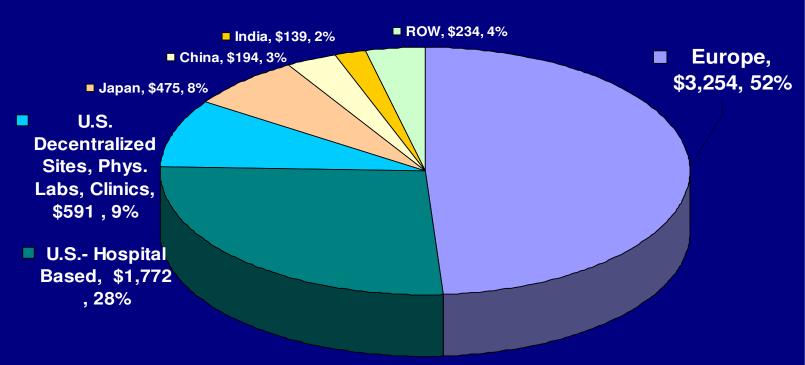
Licenses
ISO Certified for
Global Markets



#### \$7B Global Point-of-Care Test (POCT) Market

### Worldwide Distribution of POCT Sales (in \$ Millions) and Worldwide Market Shares





At 7% Projected Increases, even with Large Low-Growth Segments (e.g., Glucose), Global POCT Market is Fastest Growing Segment of \$39.5B In-Vitro Diagnostics Market, Projected to Reach \$8.8B by 2012

#### **POCT Market Drivers**



- Reduce Patient Stays and Costs, Improve Patient
   Outcomes with Prompt & Early Diagnosis
  - Improve Therapeutic Intervention
  - Prevent Needless Admissions
  - Simplify Testing Procedures to Reduce Testing Costs
  - Avoid Delays from Central Lab Batching
  - Eliminate Need for Return Visit (s)







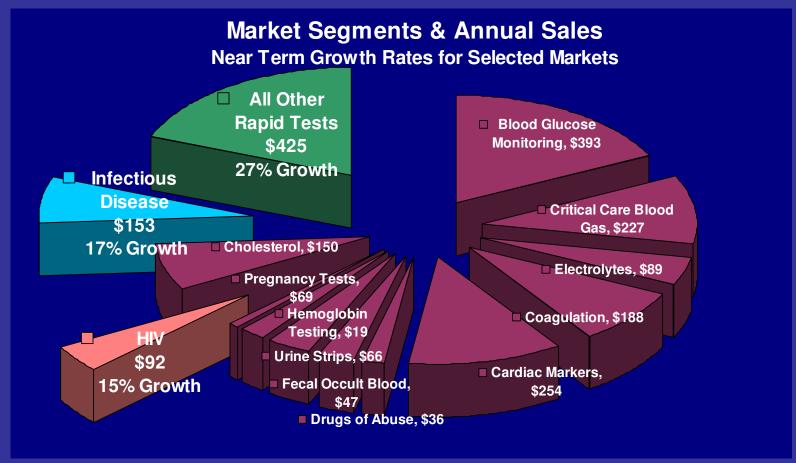




Point of Care Single and Multiplex Test Development, Manufacturing, & Licensing

## Our Current LF and Planned DPP® Products Participate in Large & Growing U.S. POCT Market Segments



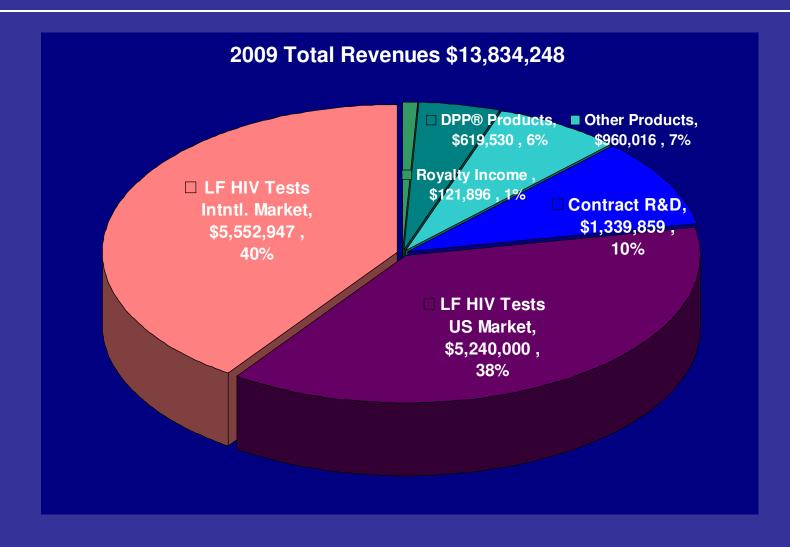






#### **2009 Revenue Composition**

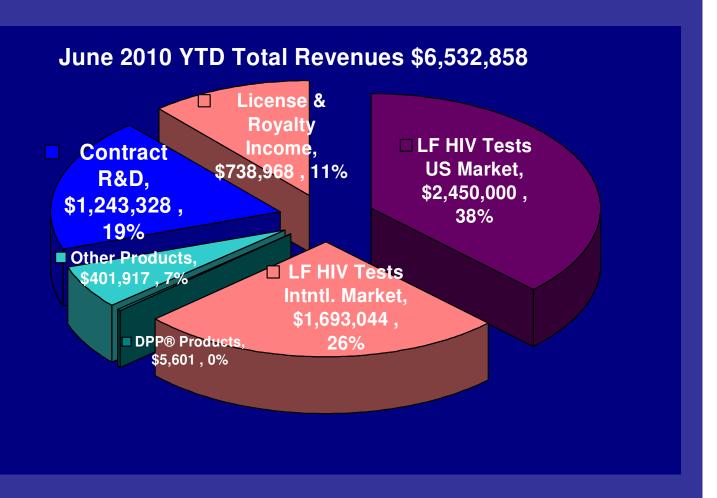




#### **2010 YTD Revenue Composition**

**UNAUDITED** 







#### **FDA Approved Rapid HIV Tests**

Distributed in US Exclusively by Alere (formerly Inverness Medical)



- 148% Revenue Increase in 2009 -\$5.3MM v. \$2.1MM in 2008; 22% 2010 Six Months YTD
  - Gains Based Upon Market Expansion and Increased Market Share; New National HIV Strategy Announced July 2010 to Increase Knowledge of HIV Status
- Competitive Features
  - CLIA Waived
  - Two Formats
  - 99.7% Sensitivity;99.9% Specificity
  - ProprietaryFormulationEnables 24 MonthStability
  - Strong MarketingPartner



# Chembio's Rapid HIV Tests are Distributed Globally





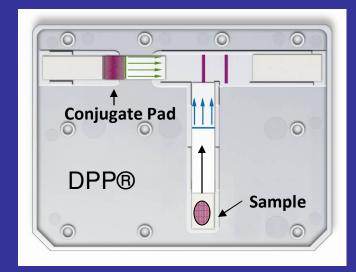
- Approved for Procurements by UN,WHO, CDC/USAID (PEPFAR)
- Registered/Approved in several countries in South America, Asia, and Africa
- Projected 2010 Intl.
   HIV Rev. Increase of 25% to \$4.25MM

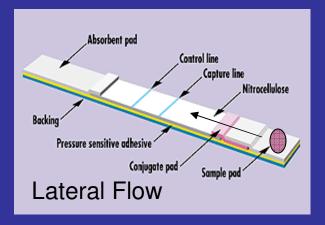
#### PATENTED DUAL PATH PLATFORM (DPP®)

KEY DESIGN AND PERFORMANCE ADVANTAGES vs. LATERAL FLOW



- Independent Sample Flow Path Enables Improved Sensitivity & Use of More Challenging Sample Types
- Improved Multiplexing Facilitated by Direct Binding, Uniform Delivery of Samples
- US Patent #7,189,522.
   Patent Protection Pending
   Worldwide



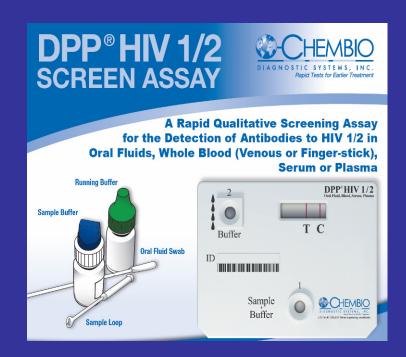




### DPP® HIV 1/2 Oral Fluid Assay



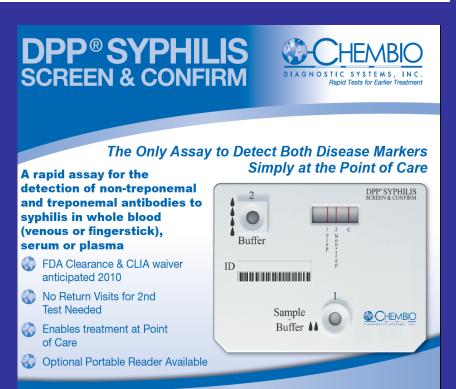
- \$60MM/6MM Unit US Market Growing ~15%/Year
- International Studies
   Completed in 2009
- US Clinical Trials
   Commenced Q1 2010
- Anticipate PMA approval late-2011
- OTC Opportunity



#### **DPP® Syphilis Screen & Confirm**



- First POCT For Syphilis
   In US Estimate
   \$30MM Market
- Provides Better Indication Of Active Disease
- Enables Confirmation& Treatment At POC
- Pre-natal Testing
- International Evaluation Ongoing
- Anticipate 510(K)
   Clearance in Mid-2011



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

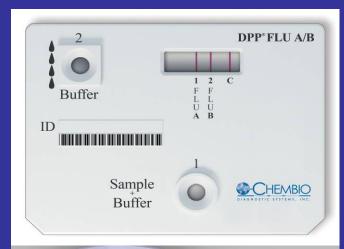


### In Development: DPP® INFLUENZA

Multiplex Flu A & B Test & 6 Strain Immunity Test



- Large Established Market for Flu A&B tests
- Chembio's First Antigen
   Detection Test with DPP
- Prototype Shows Improved Performance v. Established Tests
- In Addition: \$900,000
   Contract signed Dec. 2009
   with CDC Contractor for 6-band Multiplex Immune
   Status Test

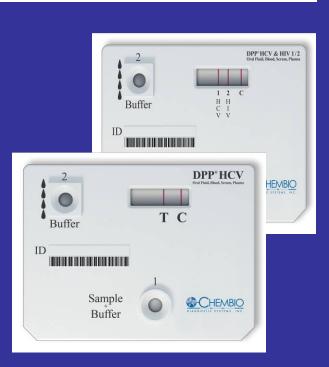




# In Development: Hepatitis-C (HCV) & HIV/HCV Comb. Oral Fluid



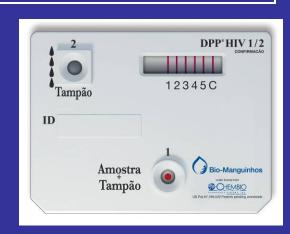
- Estimated 3MM HCV Infections in US
  - Only 22% Diagnosed
  - 25% Co-infection with HIV
  - Major Cause of Liver Disease
  - New therapeutics from Vertex,
     etc. will drive demand for Dx
- No HCV Point-of-Care Test in US
- Chembio Participating in Pre-Clinical CDC Study with both prototypes – Expect Data in First Half 2010



#### **OEM Contracts with FIOCRUZ**



- Four Products Under OEM Agreements with FIOCRUZ
  - Based on Successful \$8MM
     Tech. Transfer Program
     Completed 2004-2009
- Anticipate Regulatory
   Approval in Brazil of Four
   Products in 2010
  - Potential Total Revenues of \$12MM in 2010-2013



#### **OEM Products Overview**



	2009	2010	2011	
FDA Approved LF HIV Tests - Inverness	\$5.3MM Revenues (148% Incr. v. 2008)	Exclusive Agreement with Inverness Medical through 2016 for US Market Royalties phase		
LF HIV Test - Brazil	Completed 5 Year, \$8MM Program; Began royalty phase			
4 DPP® OEM Products for Brazil	2 Submitted for Regulatory Approval	Anticipated Approval of 4 Products & Initial OEM Product Revenues	OEM Product Sales	
Multiplex Influenza Immune Status Test - CDC	Contract signed Dec. 2009	Product Development	TBD	
Multiplex DPP Product - Bio- Rad	Entered License Agreement & Phase II of Development	Development to be completed mid-2010	regulatory phase	

Three Year, \$3MM Phase II NIH Grant for Leptospirosis Awarded June 2009. Several Other Grants Active and Additional Grant Applications Pending

#### **Chembio Branded Products Pipeline**

DPP-HIV 1/2 12345C
DIVINVIZA
Sample Buffer
Sample duffer 11 O SCHOMBO

	2009	2010	2011
DPP® HIV Oral Fluid Rapid Test	International Studies Completed	US Clinical Studies & FDA PMA Filing; International launch	U.S. Launch
DPP® Syphilis Screen & Confirm	International Studies Commenced	US Clinical Studies & FDA 510(k) Submission	U.S. Launch
DPP® Influenza A/B DPP® Hepatitis C	Initial Development Prototype	Complete Development	Regulatory & Commercial Timelines TBD

Completion of HIV & Syphilis Clinical Studies to achieve 2011 Launch will require additional capital



#### **Our Target Markets**



#### **U.S. Market Estimates for Current and Future Chembio Rapid Tests**

Market estimates based on sales value to end users (e.g., health professsionals or consumers)

Existing Markets	Est. of U.S. Annual Market Size	Growth Rate	Current POCTs in U.S.	Chembio Products in Market	DPP® Products in Development	Comments	Companies w/ Competitive Rapid Tests in U.S. Market	Notes
HIV Tests - Professional Market	\$60,000,000	15%	4	2	1	Oral Fluid test in clinical trials	OSUR, TRIB	1
Influenza A-B Antigen Detection  New Markets	\$140,000,000	20%	4	0	1	In development	IMA, BD, QDEL	2
Syphilis	\$30,000,000	unknown	0	0	1	Clinicals to start in Q3	None	3
HIV Tests - OTC Market	\$80,000,000	unknown	0	0	2	Whole blood "barrel" test could start FDA trials now; oral fluid needs FDA PMA approval first (2011)	OSUR in Trials	4
Hepatitis-C	\$45,000,000	unknown	0	0	2	In development	OSUR in Trials	5

#### **Notes to Market Estimates**

- 1 Based on estimate of 6 million tests @ \$10 ASP\*. Market growth at 10-20%/annum; Chembio's current products marketed exclusively by
- 2 Analyst Report
- 3 Based on estimate of 3 million tests @ \$10 ASP\*
- 4 Based on estimate of 4 million tests @ \$20 ASP\* (15% of analyst estimate)
- 5 Based on estimate of 3 million tests @ \$15 ASP\*
- \* ASP Average Selling Price

Completion by Chembio of development, regulatory approval and commercial launch subject to several conditions as set forth in Chembio's SEC filings



#### **Selected Comparative Historical Financial Results**



	For the Years Ended			
\$(000s)	2009	<u>2008</u>	2007	<u>2006</u>
Total Revenues	\$13,834	\$11,050	\$ 9,231	\$ 6,503
Cost of sales	7,974	7,198	6,435	4,894
<b>Gross Profit</b>	5,860	3,852	2,796	1,609
	42.4%	34.9%	30.3%	24.7%
R&D Expense	2,884	2,605	1,907	1,402
SG&A Expense	2,659	3,317	3,765	4,787
Operating Income (Loss)	317	(2,071)	(2,876)	(4,580)
Other Inc. (Expense)	(8)	122	249	(415)
Net Income (Loss) - Stkhldrs	309	(1,949)	(2,627)	(4,995)
Pref. Stock Expenses	-	-	5,645	3,210
Net Loss	\$ 309	\$ (1,949)	\$ (8,272)	\$(8,205)
Net Income (Loss) - per Share	\$ 0.00	\$ (0.03)	\$ (0.57)	\$ (0.80)
Avg. No. Shares (Millions)	61.946	61.267	14.608	10.293
Working capital	\$ 1,494	\$ 1,664	\$ 3,229	\$ 5,113
Total assets	6,315	5,915	6,585	7,907
Total liabilities	3,227	3,338	2,322	2,297
Equity (Deficit)	3,088	2,577	4,263	(940)



#### **Selected Comparative Historical Financial Results**



	For the three	months ended	For the six months ended		
	June 30, 2010	June 30, 2009	June 30, 2010	June 30, 2009	
Net product sales	\$2,335,665	\$3,051,385	\$4,550,562	\$5,320,801	
License and royalty income	\$717,472	\$52,322	\$738,968	\$52,322	
Research grant income	\$696,305	\$269,817	\$1,243,328	\$545,999	
Total Revenues	\$3,749,442	\$3,373,524	\$6,532,858	\$5,919,122	
Gross Profit	\$2,094,966	\$1,361,945	\$3,401,340	\$2,360,634	
Research and development	\$791,596	\$702,986	\$1,592,354	\$1,350,358	
SG&A	\$680,014	\$542,449	\$1,341,862	\$1,218,262	
Income (loss) from operations	\$623,356	\$116,510	\$467,124	(\$207,986)	
Net income (loss)	\$621,917	\$109,939	\$464,591	(\$215,294)	
Basic earnings (loss) per share	\$0.01	\$0.00	\$0.01	(\$0.00)	
Diluted earnings (loss) per share	\$0.01	\$0.00	\$0.01	(\$0.00)	
Weighted average number of					
shares outstanding, basic Weighted average number of	62,070,736	61,944,901	62,028,450	61,944,901	
shares outstanding, diluted	70,614,048	74,814,205	71,340,820	61,944,901	



### **Selected Balance Sheet Data**



	June 30, 2010	December 31, 2009
	(UNAUDITED)	
CURRENT ASSETS:		
Cash	\$746,848	\$1,068,235
Accounts receivable, net of allowances	1,817,284	1,776,327
Inventories	1,849,708	1,555,903
Other current assets	300,790	266,637
TOTAL CURRENT ASSETS	4,714,630	4,667,102
NET FIXED ASSETS	853,181	580,213
OTHER ASSETS		
Deposits on manuf. equipment	52,824	338,375
License agreements and other assets	686,226	729,560
	\$6,306,861	\$6,315,250
TOTAL CURRENT LIABILITIES	\$2,378,665	\$3,173,132
TOTAL OTHER LIABILITIES	241,460	54,204
TOTAL LIABILITIES	2,620,125	3,227,336
TOTAL STOCKHOLDERS' EQUITY	3,686,736	3,087,914
	\$6,306,861	\$6,315,250



#### **CEMI Selected Share Data**



Ticker Symbol (OTCBB)		CEMI	
Price 7/30/10		\$0.260	
52 Week High		\$0.390	
52 Week Low		\$0.122	
Outstanding Shares (MM)		62.0	
Market Capitalization (MM)		\$16.1	
Fully Diluted (FD) Shares (MM)		70.6	
Management Holding (MM)-FD		11.4	
Average Volume (3 Mos)		61,769	
Options and Warrants (MM)			Avg. Ex. Price
Options (MM) (4.11MM held by ma	gmt. &		
board)		5.96	\$0.166
Warrants (MM) - Exp. Dates			
	10/6/2011	2.64	\$0.482
	2/5/2012	0.07	\$0.810
Total Warrants (MM)		2.71	
Total Options & Warrants (MM)		8.67	







www.chembio.com