

# Rodman & Renshaw 11<sup>th</sup> Annual Healthcare Conference September 11, 2009



## **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 Based, FDA (PMA), USDA and ISO 13.485 certified manufacturer of proprietary point of care tests
- Growing base business of rapid tests for HIV marketed in the US and globally based on lateral flow technology
- New Product Pipeline Enabled by Patented Dual Path Platform (DPP®) Rapid, Point-of-Care-Testing (POCT) Platform
- 24% 5-Year CAGR of Sales Achieved Profitability in Q2-09 on \$3.4MM Quarterly Revenues











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



## **Organization & Management Team**



Lawrence Siebert, President
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** 

**Total Employment** Approx. 100 SG&A Ops. R&D 69 18 Reg. & Clinical QA & QC



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





Two FDA-Approved PMA's



USDA-Approved Facility & Product Licenses

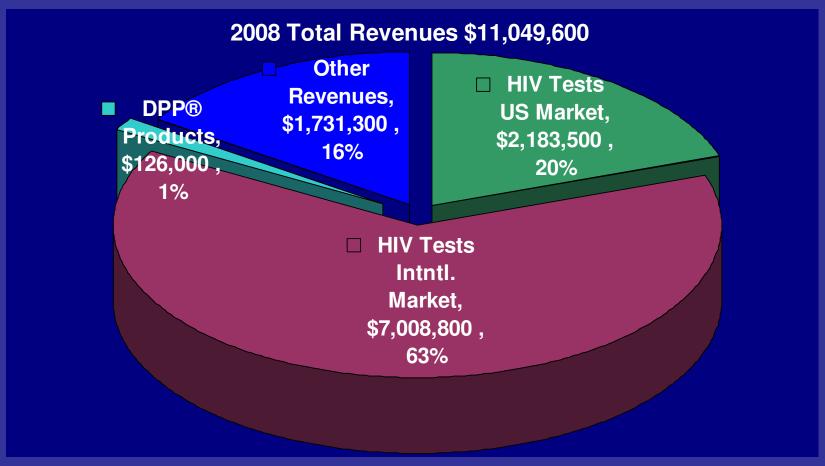


ISO Certified for Global Markets



# Overview of Current Products & Revenue 2008

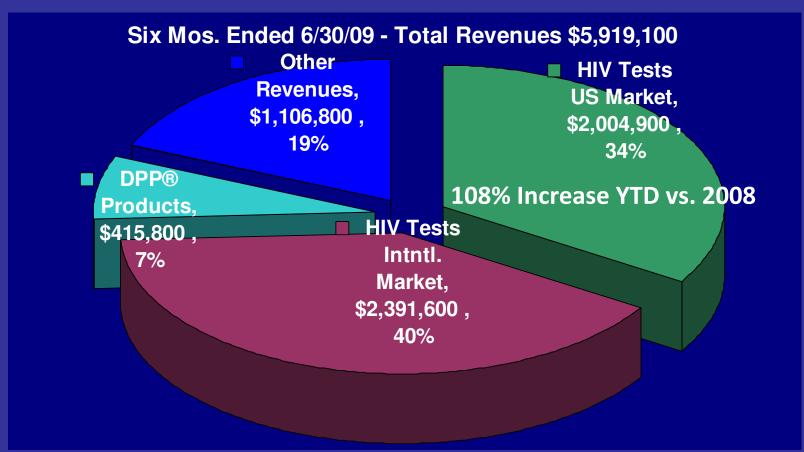






# Overview of Current Products & Revenue YTD Increases from U.S. Market, DPP® and R&D Contracts

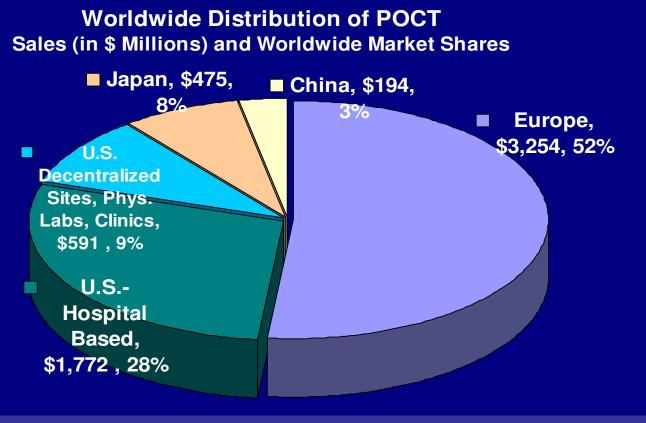






## \$6.7B Global Point of Care Test (POCT) Market





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

Source: Independent Market Research Report



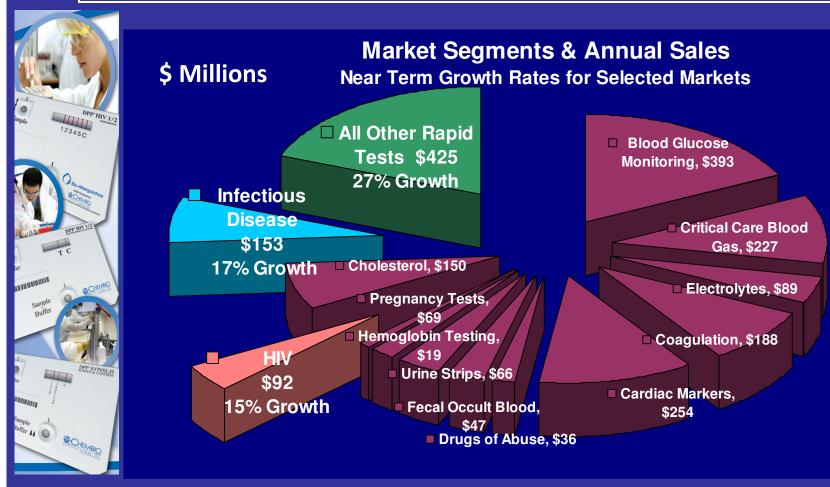
## **POCT Market Drivers**



- 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)



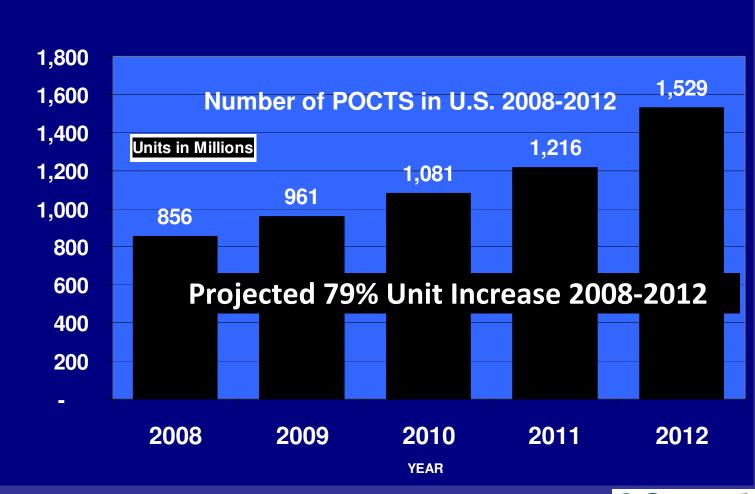
# Estimated \$2.2B U.S. POCT Market in 2008 Our Current and Planned Products Participate in Large & Growing US POCT Market Segments





## U.S. Market 2008-2012 Projected Number of POCTs



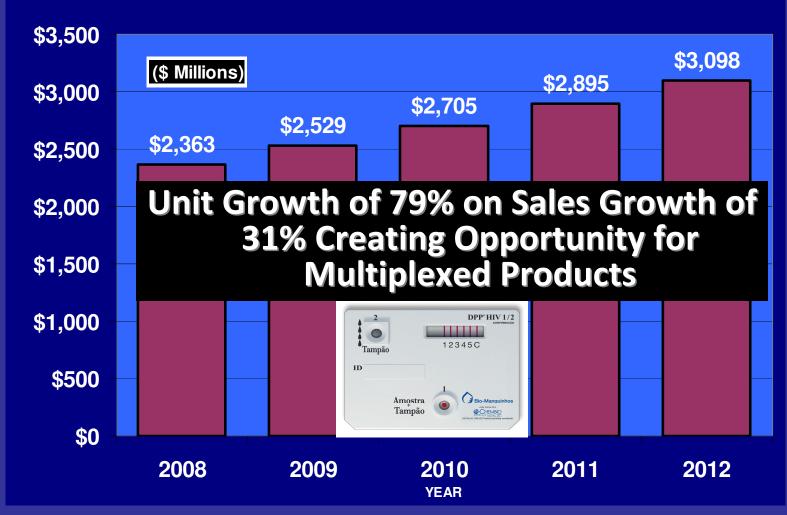






# Estimated Projected Annual Sales of U.S. POCTs 2008-2012







## **Products & Pipeline**



	R&D	Pre-Clinical	Validation	Clinical	Commercial	Est. US Mkt	# of U.S.
	NOD	r re-cirrical	Valluation	Testing	Product(s)	Size	Compet.
HIV and Other	CFM	Llateral flow	product reve	enues of \$5.	0 MM @6/30 YTD		
Lateral Flow Rapid	CEMI lateral flow product revenues of \$5.0 MM @6/30 YTD include \$2MM in U.S. rapid HIV tests		\$15MM	1			
Lateral How Napid			· γ= •	····	- 10515	(blood)	-
Tests; Contract R&D							
	DPP®	Product Pip	eline				
3 OEM Products for					Est. \$12MM Min.		
					Purchases 2009-	NA	n/a
Brazil MOH					2012	_	
HIV Oral Fluid						\$35 MM	1
						(oral fluid)	
Syphilis Screen &						ĆEO BABA	0
Confirm						\$50 MM	0
Hepatitis -C (HCV) &						\$50 MM	0
Combo HIV/HCV						ŞSU IVIIVI	U
Influenza	$\longrightarrow$					\$250 MM	6
Global Health					Donor Funded Dem	and	n/a
Products					Donor Funded Dem	anu	n/a



## **FDA Approved Rapid HIV Tests**



- 108% US Market Revenue Growth YTD
  - Estimated 10-15% Market Share
  - Gains Based Upon Competitive Features & Increasing
     Adoption of CDC Recommendations for Routine HIV Testing
- 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
- CE Mark Pending

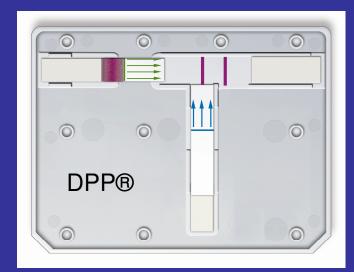


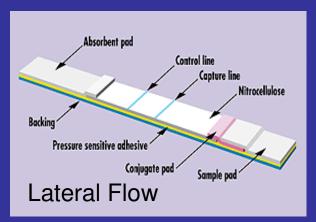
#### **DPP® DUAL PATH PLATFORM**

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 Screen Assay



- Designed for Use with Oral Fluid & Blood
- \$50MM/5MM Unit US Market Growing 15-20%/Year
- Opportunity to Gain Market Share from Sole Competitor
- US Clinical Trials
   Commencing Q4 2009

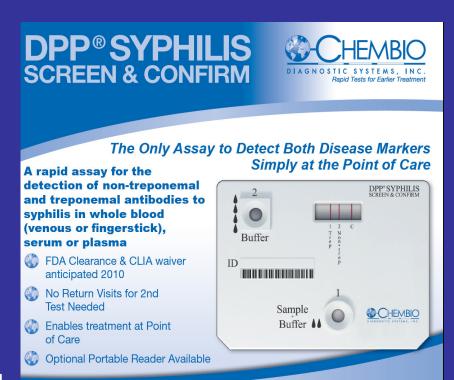




## **DPP® Syphilis Screen & Confirm**



- First POCT For Syphilis In US
- Provides Better Indication Of Active Disease
- Enables Confirmation& Treatment At POC
- Pre-natal Testing
- Comparable To US HIV Market Dynamic
- FDA Pre-IDE Submitted
   Q3



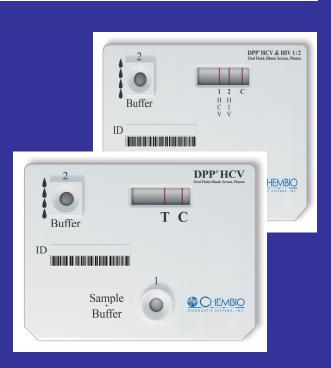
Developed in collaboration with the U.S. Centers for Disease Control



## Hepatitis-C (HCV) & HIV/HCV Comb.



- 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





## **INFLUENZA**

#### **MULTIPLEX ANTIGEN & IMMUNITY TESTS**



- Current Lateral Flow Rapid Tests Need Improvement
- Initial Data Show Improved
   Performance with DPP®
- Multiplex Immune
   Status Serology Test
   H1N1 Project





## **DPP® Global Health Products**



- Five Band POC HIV Confirmatory Test Being Launched in Brazil
- Three Year \$3MM NIH SBIR Phase II Grant for Human Leptospirosis



DPP® Point of Care Test	Collaborating Organization
Tuberculosis	FIND
Malaria	FIND
HIV 1/2 Confirmatory Test	FIOCRUZ
Neglected Diseases: Leishmaniasis, Chagas, Leptospirosis, Leprosy	IDRI, NIH, FIOCRUZ



## Portable Readers with DPP®



- Hand Held & Desktop Models
- Sharper Test Results with DPP® improve reader performance
- Eliminates Interpretation Errors
- Multiplex Test Results recorded and printed
- USB connection for Data export. A/C and Rechargeable Battery Power





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## **Specialty Veterinary Products**



- Companion Animals
  - Canine Leishmaniasis -Brazil
- Research Laboratory Applications
- Veterinary TB
  - Two USDA Approved
  - Cervid TB Pending USDA
     Approval

#### 



## Selected Comparative Historical Financial Results 2008 v. 2009YTD

DPP-HIV 1/2 12345C
T C
Sample Buffer
Sample 1 Duffer 11

	For the Years Ended			
\$(000s)	2008	2007	2006	2005
Total Revenues	\$11,050	\$9,231	\$6,503	\$3,941
Cost of sales	7,198	6,435	4,894	2,996
<b>Gross Profit</b>	3,852	2,796	1,609	945
	34.9%	30.3%	24.7%	24.0%
R&D Expense	2,605	1,907	1,402	1,365
SG&A Expense	3,317	3,765	4,787	2,878
Operating Income (Loss)	(2,071)	(2,876)	(4,580)	(3,298)
Other Inc. (Expense)	122	249	(415)	46
Net Income (Loss) - Stkhldrs	(1,949)	(2,627)	(4,995)	(3,252)
Pref. Stock Expenses	-	5,645	3,210	3,517
Net Loss	(\$1,949)	(\$8,272)	(\$8,205)	(\$6,769)
Net Income (Loss) - per Share	(\$0.03)	(\$0.57)	(\$0.80)	(\$0.88)
Avg. No. Shares (Millions)	61.267	14.608	10.293	7.705
Working capital	\$1,664	\$3,229	\$5,113	\$4,708
Total assets	5,915	6,585	7,907	7,075
Total liabilities	3,338	2,322	2,297	1,964
Equity (Deficit)	2,577	4,263	(940)	1,053



# Selected Comparative Historical Financial Results 2005-2008



	Three Mo	s Ended	Six Mos	Ended
\$(000s)	6/30/09	6/30/08	6/30/09	6/30/08
Total Revenues	\$3,374	\$2,718	\$5,919	\$5,083
Cost of sales	2,012	1,706	3,558	3,238
Gross Profit	1,362	1,012	2,361	1,845
	40.4%	37.2%	39.9%	36.3%
R&D Expense	703	567	1,350	1,194
SG&A Expense	542	810	1,218	1,828
Operating Income (Loss)	117	(365)	(208)	(1,177)
Other Inc. (Expense)	(7)	2	(7)	16
Net Income (Loss) -				
Stkhldrs	110	(363)	(215)	(1,161)
Pref. Stock Expenses		-	-	-
Net Income (Loss)	\$110	(\$363)	(\$215)	(\$1,161)
Net Income (Loss) - per				
Share	\$0	(\$0)	(\$0)	(\$0)
Avg. No. Shares (Millions)	61.945	60.616	61.945	60.577
Working capital	\$1,601	\$1,827	\$1,601	\$1,827
Total assets	6,167	6,219	6,167	6,219
Total liabilities	3,714	2,894	3,714	2,894
Equity (Deficit)	2,453	3,325	2,453	3,325
				40.0



## **Selected Balance Sheet Data**



(\$000s)		
<b>Balance Sheet Data</b>	June '09	Dec. '08
Cash	\$1,859	\$1,212
Accts. Receivable	611	809
Inventories	1,653	1,819
Other Current Assets	247	225
Total Current Assets	4,370	4,066
Net Fixed Assets	704	881
Other Assets	1,093	968
Total Assets	\$6,167	\$5,915
Total Current Liab.	\$2,769	\$2,402
Total Other Liab.	945	936
Total Liabilities	3,714	3,338
Total Equity	2,453	2,577
Total Liabilities &		
Shareholders Equity	\$6,167	\$5,915
Working capital	\$1,601	\$1,664



## **Selected Share Data**



Ticker Symbol	CEMI	
Price 8/31/09	\$0.18	
52 Week High	\$0.21	
52 Week Low	\$0.08	
Common Stock Held by Management	8.8MM	
Total Issued & Outstanding Shares	61.9MM	
Market Capitalization	11.1MM	
Average Volume (3 Mos)	59,000	
		Avg. Exerc. Price
Options Warrants	5.7MM	\$0.16
Expire 1/28/2010	5.0MM	\$0.47
Expire 10/5/2011	2.6MM	\$0.48
Expire 2/5/2012	0.1MM	\$0.81







www.chembio.com

