



DIAGNOSTIC SYSTEMS, INC.

*Rapid Tests for Earlier Treatment*



# Investor Presentation

May 6, 2010



# 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



- Medford, NY Manufacturer of Point of Care Rapid Diagnostic Tests
- 2009 Total Revenues of \$13.8MM - \$309K Net Income v. \$11.0MM Rev. - \$1.9MM Net Loss in 2008
- Five Year Revenue CAGR of 33%
- 148% Revenue Increase, to \$5.3MM in 2009, of FDA Approved Rapid HIV Tests Marketed in U.S. by Inverness Medical
- New OEM & Branded Product Pipeline Utilizing 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**

**Total Employment  
Approx. 100**

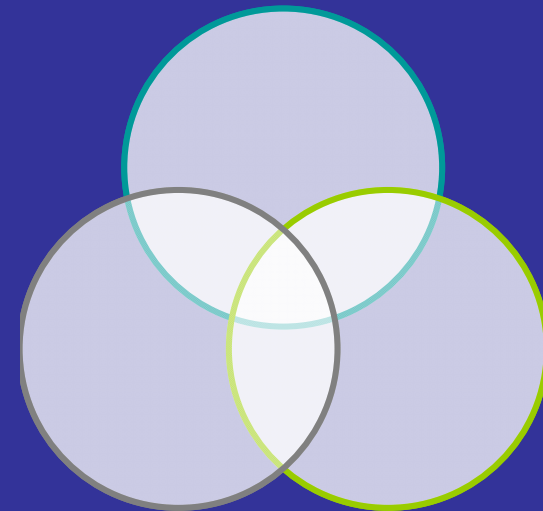
**SG&A**

**7**

**Ops.  
69**

**R&D  
18**

**Reg. & Clinical  
QA & QC  
7**



# 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**



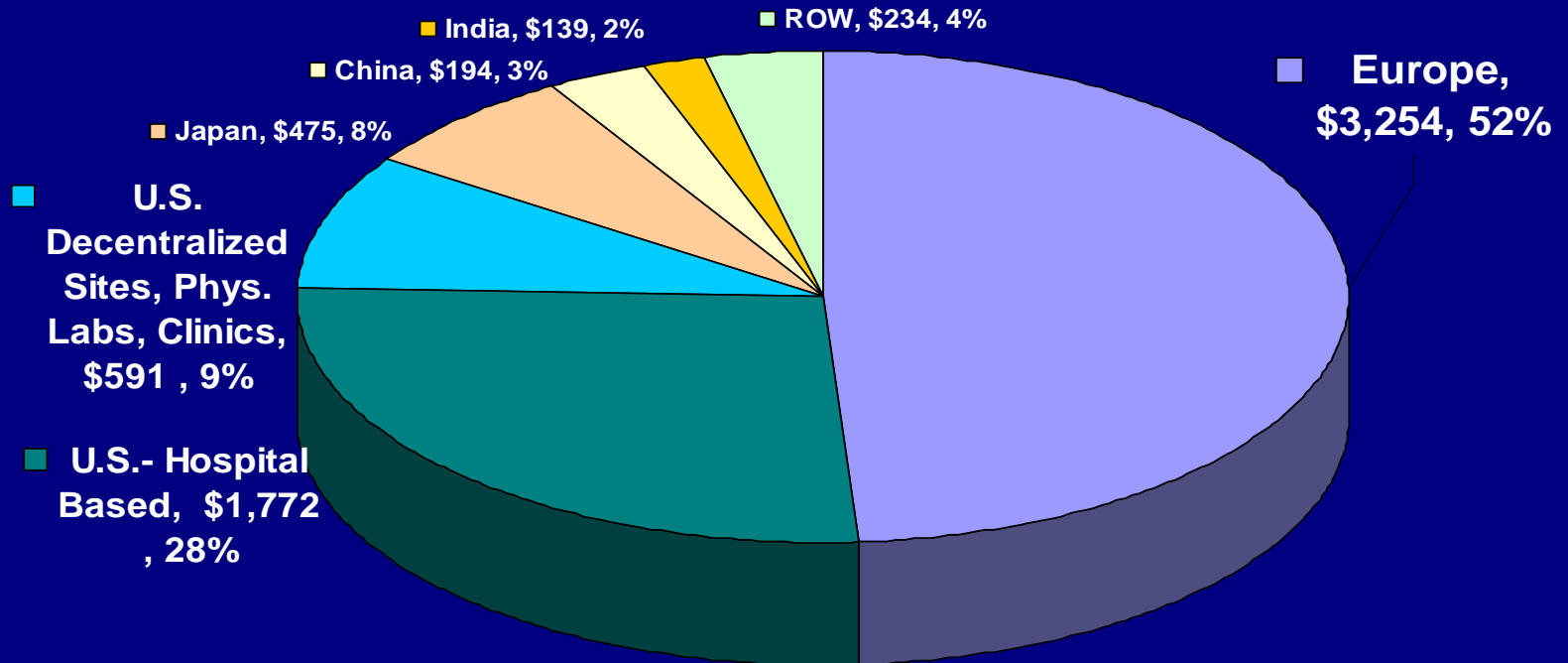
**USDA-Approved  
Facility & Product**



**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

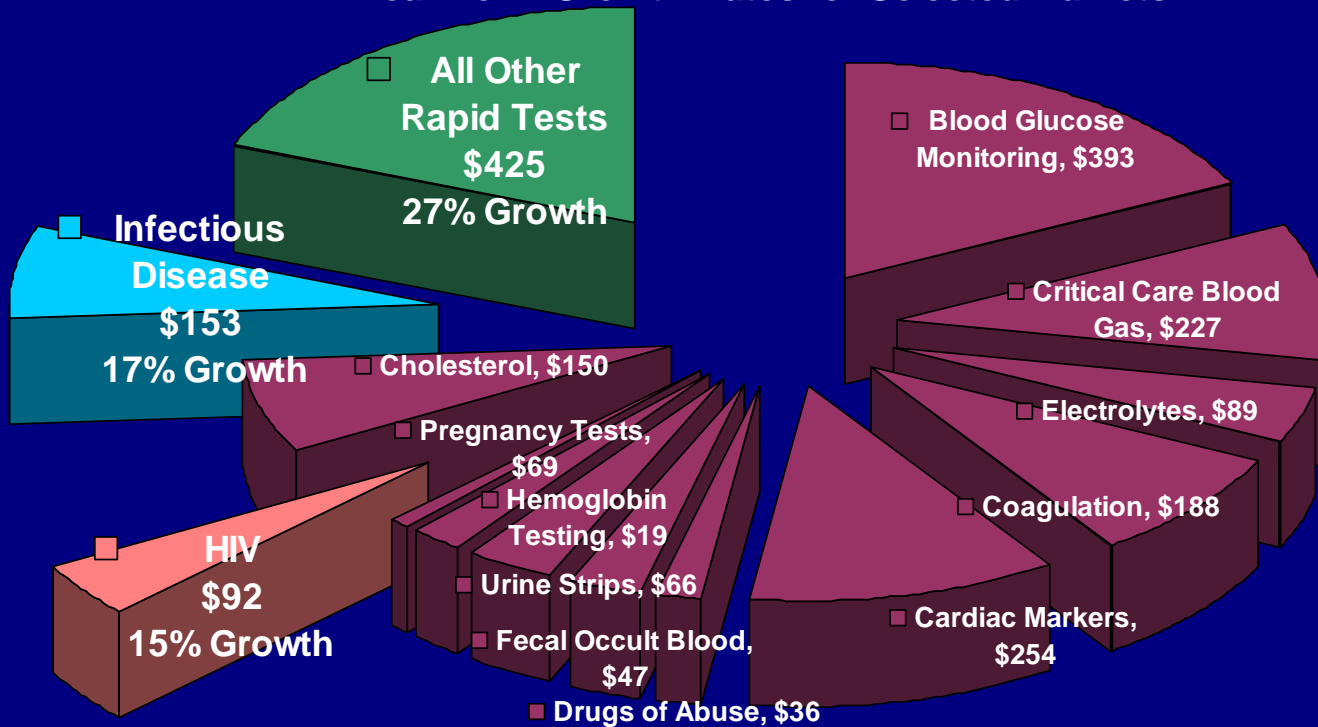
- Reduce Patient Stays and Costs, Improve Patient Outcomes with Prompt & Early Diagnosis
  - Improve Therapeutic Intervention
  - Prevent Needless Admissions
  - Simplify Testing Procedures to Reduce Testing Costs
  - Avoid Delays from Central Lab Batching
  - Eliminate Need for Return Visit (s)



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

**Market Segments & Annual Sales**  
Near Term Growth Rates for Selected Markets

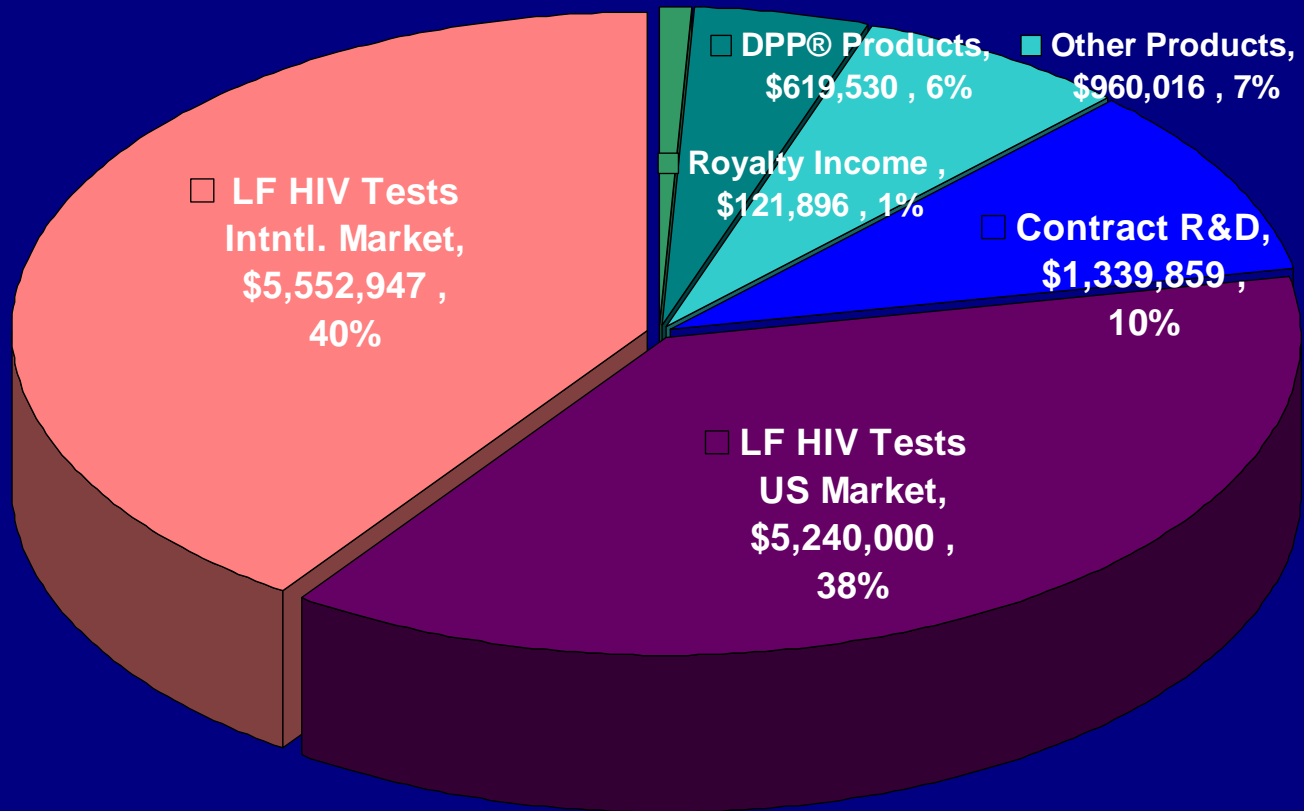


Source: Independent Market Research Report



# 2009 Revenue Composition

2009 Total Revenues \$13,834,248



# FDA Approved Rapid HIV Tests

## Distributed in US Exclusively by Inverness Medical

- **148% Revenue Increase in 2009 - \$5.3MM v. \$2.1MM in 2008**
  - Gains Based Upon Market Expansion and Increased Market Share
- **Competitive Features**
  - CLIA Waived
  - Two Formats
  - **99.7% Sensitivity; 99.9% Specificity**
  - Proprietary Formulation Enables 24 Month Stability
  - Strong Marketing Partner



# 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

## HIV 1/2 STAT-PAK™ Dipstick Rapid Assay

### HIV 1/2 STAT-PAK® Rapid Assay

A rapid qualitative screening assay for the detection of antibodies to HIV 1 & 2 in human serum, plasma or whole blood

Convenient and Cost Effective

the detection of  
plasma or whole blood

## SURE CHECK® HIV



Collect • Process • Analyze

3 in 1

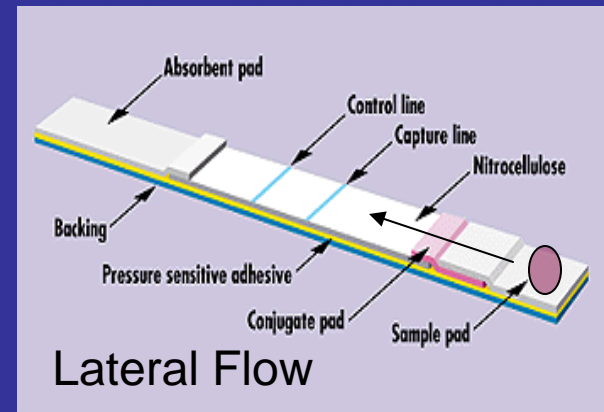
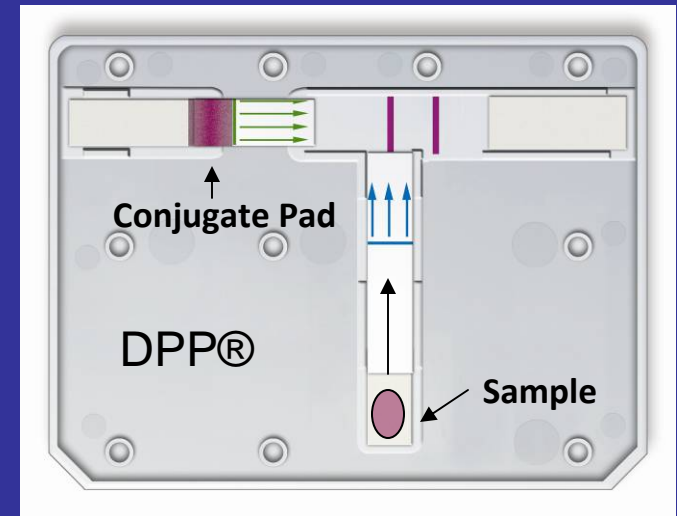
- Sample collection, processing and analysis in one device
- Individually packaged for use as needed
- Fingerstick sample
- Uses only 3µl of whole blood
- On-site results in minutes
- Room temperature storage

—This product not approved for use in the U.S.

# PATENTED DUAL PATH PLATFORM (DPP®)

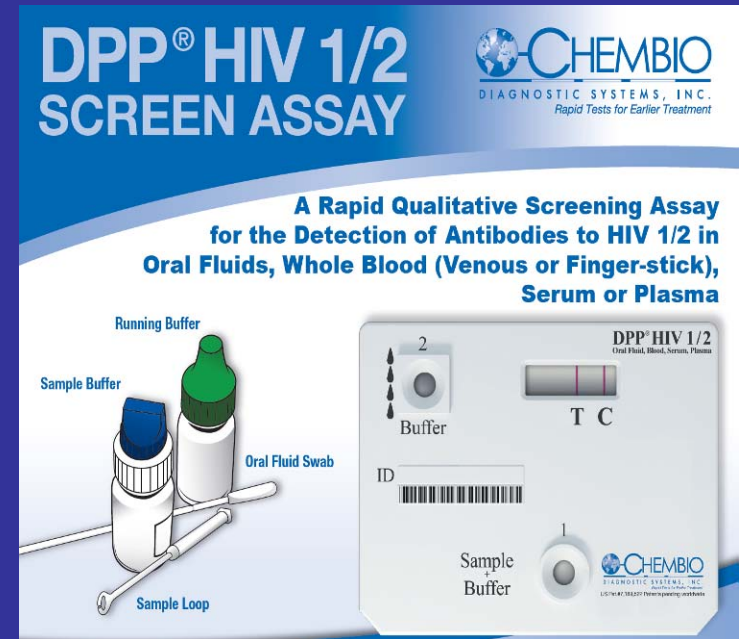
KEY DESIGN AND PERFORMANCE ADVANTAGES vs. LATERAL FLOW

- 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 Commencing Q1 2010
- Anticipate PMA approval mid-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 Early 2011

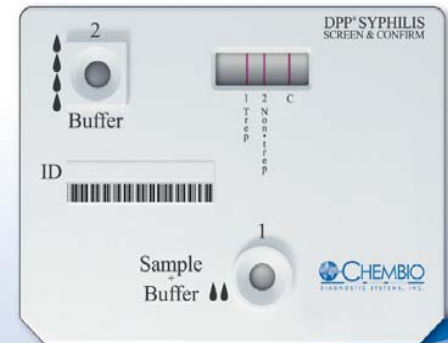
**DPP® SYPHILIS  
SCREEN & CONFIRM**

**CHEMBIO**  
DIAGNOSTIC SYSTEMS, INC.  
Rapid Tests for Earlier Treatment

*The Only Assay to Detect Both Disease Markers  
Simply at the Point of Care*

**A rapid assay for the detection of non-treponemal and treponemal antibodies to syphilis in whole blood (venous or fingerstick), serum or plasma**

- FDA Clearance & CLIA waiver anticipated 2010
- No Return Visits for 2nd Test Needed
- Enables treatment at Point of Care
- Optional Portable Reader Available

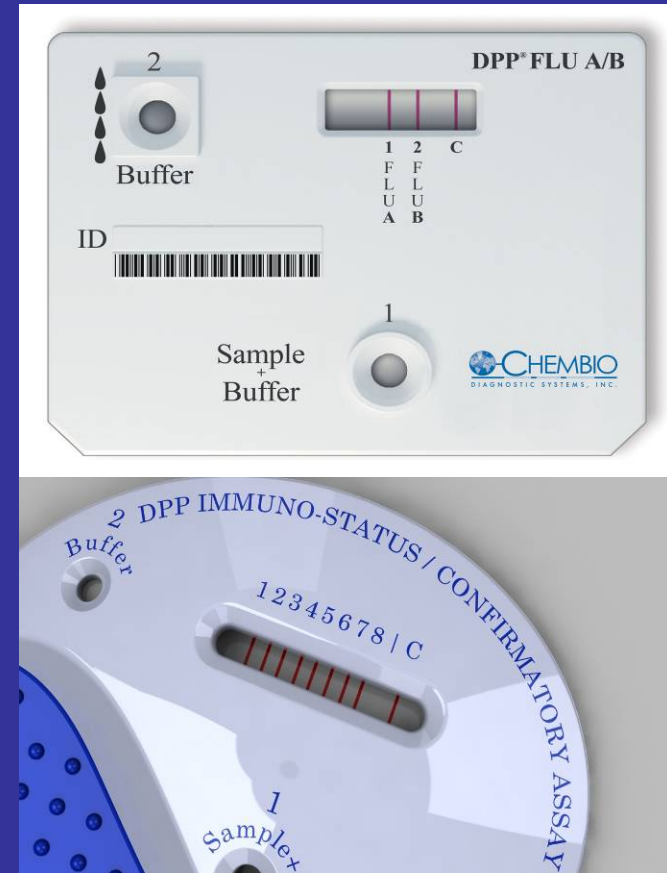


**Developed in collaboration  
with the U.S. Centers for  
Disease Control**

# In Development: DPP<sup>®</sup> INFLUENZA

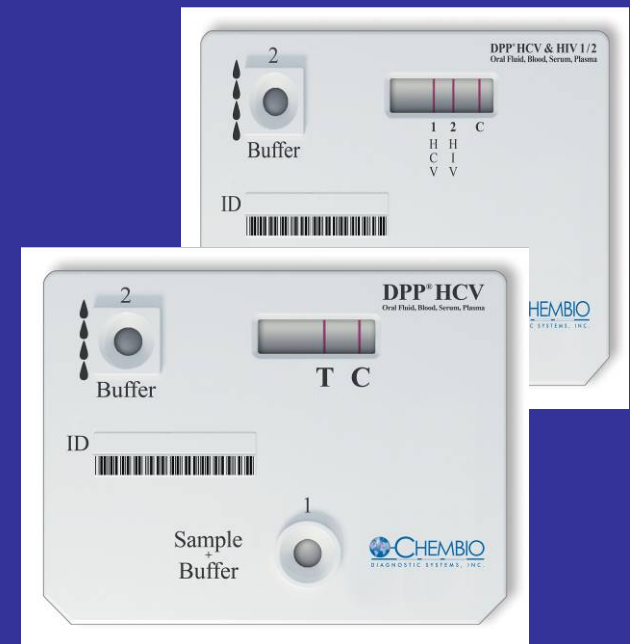
Multiplex Flu A & B Test & 6 Strain Immunity Test

- 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 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 Revenues of ~\$2MM 2010 and ~\$10MM 2011-2013



# OEM Products Overview

	2009	2010	2011
FDA Approved LF HIV Tests - Inverness	\$5.3MM Revenues (148% Incr. v. 2008) Completed 5 Year, \$8MM Program; Began royalty phase	Exclusive Agreement with Inverness Medical through 2016 for US Market	
LF HIV Test - Brazil			Royalties 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

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

	Est. of U.S. Market Size	Growth Rate	Current POCTs in U.S.	Chembio Products in Market	DPP® Products in Development	Comments	Companies w/ Competitive Rapid Tests in US Market	
<b><u>Existing Markets</u></b>								
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	\$140,000,000	20%	4	0	1	In development	IMA, BD, QDEL	2
<b><u>New Markets</u></b>								
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	\$150,000,000	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
- 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

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

## 2006-Q1'10

\$(000s)	Three Mos Ended		For the Years Ended			
	Mar 31 2010	Mar 31, 2009	2009	2008	2007	2006
Total Revenues	\$ 2,783	\$ 2,546	\$ 13,834	\$ 11,050	\$ 9,231	\$ 6,503
Cost of sales	1,477	1,547	7,974	7,198	6,435	4,894
Gross Profit	1,306	999	5,860	3,852	2,796	1,609
	46.9%	39.2%	42.4%	34.9%	30.3%	24.7%
R&D Expense	801	647	2,884	2,605	1,907	1,402
SG&A Expense	661	676	2,659	3,317	3,765	4,787
Operating Income (Loss)	(156)	(324)	317	(2,071)	(2,876)	(4,580)
Other Inc. (Expense)	(1)	(1)	(8)	122	249	(415)
Net Income (Loss) - Stkhldrs	(157)	(325)	309	(1,949)	(2,627)	(4,995)
Pref. Stock Expenses	-	-	-	-	5,645	3,210
Net Loss	\$ (157)	\$ (325)	\$ 309	\$ (1,949)	\$ (8,272)	\$ (8,205)
Net Income (Loss) - per Share	\$ (0.00)	\$ (0.01)	\$ 0.00	\$ (0.03)	\$ (0.57)	\$ (0.80)
Avg. No. Shares (Millions)	61.986	61.945	61.946	61.267	14.608	10.293
Working capital	\$ 1,431	\$ 1,334	\$ 1,494	\$ 1,664	\$ 3,229	\$ 5,113
Total assets	5,864	5,697	6,315	5,915	6,585	7,907
Total liabilities	2,856	3,429	3,227	3,338	2,322	2,297
Equity (Deficit)	3,008	2,268	3,088	2,577	4,263	(940)



# Selected Balance Sheet Data

(\$000s)

## Balance Sheet Data

	Mar. '10	Dec. '09
Cash	\$ 798	\$ 1,068
Accts. Receivable	1,178	1,776
Inventories	1,980	1,556
Other Current Assets	285	267
Total Current Assets	4,241	4,667
Net Fixed Assets	850	580
Other Assets	773	1,068
Total Assets	5,864	6,315
Total Current Liab.	2,810	3,173
Total Other Liab.	46	54
Total Liabilities	2,856	3,227
Total Equity	3,008	3,088
Total Liabilities & Shareholders Equity	\$ 5,864	\$ 6,315



# CEMI Selected Share Data

Ticker Symbol (OTCBB)		CEMI
Price 4/30/10		\$0.230
52 Week High		\$0.390
52 Week Low		\$0.100
Outstanding Shares (MM)		62.0
Market Capitalization		\$14.3
Fully Diluted (FD) Shares		70.7
Management Holding-FD		11.2
Average Volume (3 Mos)		130,000
Options and Warrants (MM)		
Options (4.11MM held by mgmt. & board)		5.96
Warrants - Exp. Dates		
	10/6/2011	2.64
	2/5/2012	0.07
Total Warrants		2.71
Total Options & Warrants		8.67





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[www.chembio.com](http://www.chembio.com)

