



NASDAQ: CEMI



**RAPID** tests for  
**EARLIER** treatment

Investor Presentation

September 2013



# 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 develop, manufacture, market and finance new products 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. 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.

- Develops, Manufactures & Markets Point-of-Care Diagnostic Tests (POCTs) – Global Sales
- \$25.6MM 2012 Revenues - Profitable
  - Anticipate Record Revenues in Second Half 2013
- Patented DPP® - A Platform POCT Technology
  - Oral Fluid HIV Test – FDA-Approved - CLIA waiver pending
- Strong Product Pipeline of Multiplex DPP Products
  - HIV-Syphilis & Syphilis Screen & Confirm Tests for International and U.S. Markets
  - HCV Ab & HIV Ag-Ab Test
  - New Technologies for Multiplex Products
  - New Collaboration in Brazil with LabTest

# Our Vision & Mission



**We are a provider of Point-of -Care diagnostic tests and solutions, helping people live longer and healthier lives.**

Our Mission is to become a key provider in the market for rapid diagnostic Point of Care (POC) testing, through the development, manufacture, and commercialization of proprietary technology with superior performance and technical service.



# Chembio Products are well Positioned Globally for Growth...

## USA

- Distribution through Alere (36% FY12 revenue)
- DPP® HIV PMA approval (Dec'12) / CLIA pending
- Funded Research Collaborations with CDC, DOD, NIH

## EU

- CE mark approval for SURECHECK® (July'13)
- CE mark for STATPAK®, DPP® HIV HIV/Syphilis pending

## AFRICA

- Procurements primarily funded by PEPFAR, Global Fund, and WHO
- Sales channel ; NGO-direct & through distributors (11% FY12 revenue)
- Commercial resource deployment

## SOUTH/CENTRAL AMERICA

- Strong OEM Partnerships (FIOCRUZ, Labtest); Branded products sold to NGOs, private distributors (>50% FY12)

# Chembio's Pipeline: \$650MM Total Addressable Market

Chembio Pipeline POCT	Total Market Opportunity	Targeted Launch
HIV POCT - U.S.	\$75 MM	Q1 -2014
HIV-Syphilis & Syphilis Screen-Confirm POCTs- U.S.	\$75 MM	2H -2014
Hepatitis C POCT – U.S.	\$100 MM	2016
Combined Estimated Market for Above – ex-U.S.	\$400 MM	~\$16MM in 2012; Significant Growth Opportunities with Current and New Products
<b>Total:</b>	<b>\$650 MM</b>	



# Chembio POCT Market Opportunities: HIV Rapid POCTS

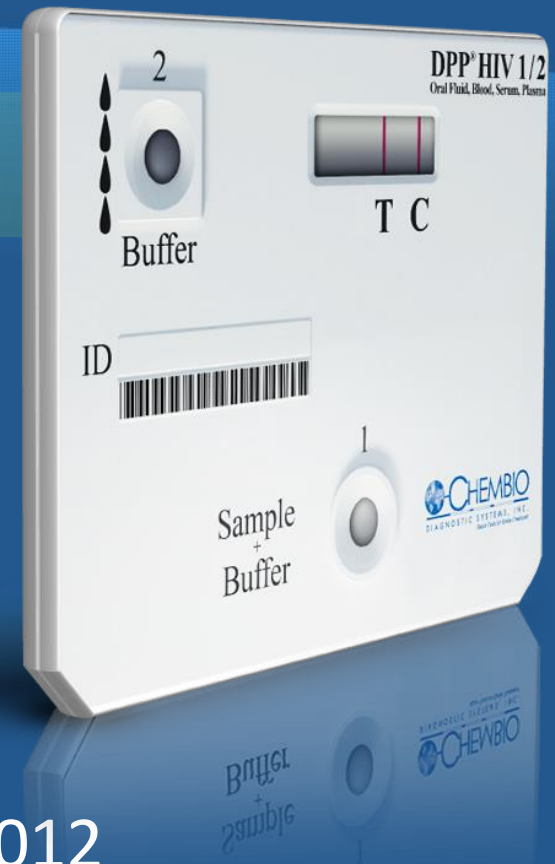
## Established, Growing Markets

### U.S.

- ~50,000 New Infections in 2012
- USPSTF Recommends Routine Testing
  - ACA Expanding Coverage by 25MM+

### International

- 2.5 MM New Infections Worldwide in 2012
- Designation in PEPFAR & Other Donor-Funded Countries' Testing Protocols



# Chembio POCT Market Opportunities: Syphilis & HCV POCTS

## HIV-Syphilis POCT – New Market Opportunity

- Up to 70% HIV-Syphilis Co-Infection in MSM
- Higher Prevalence of Syphilis (1.9MM) than HIV (1.5MM) in Pregnant Women
- Syphilis Screen & Confirm Eliminates Past Infections; thus overtreatment

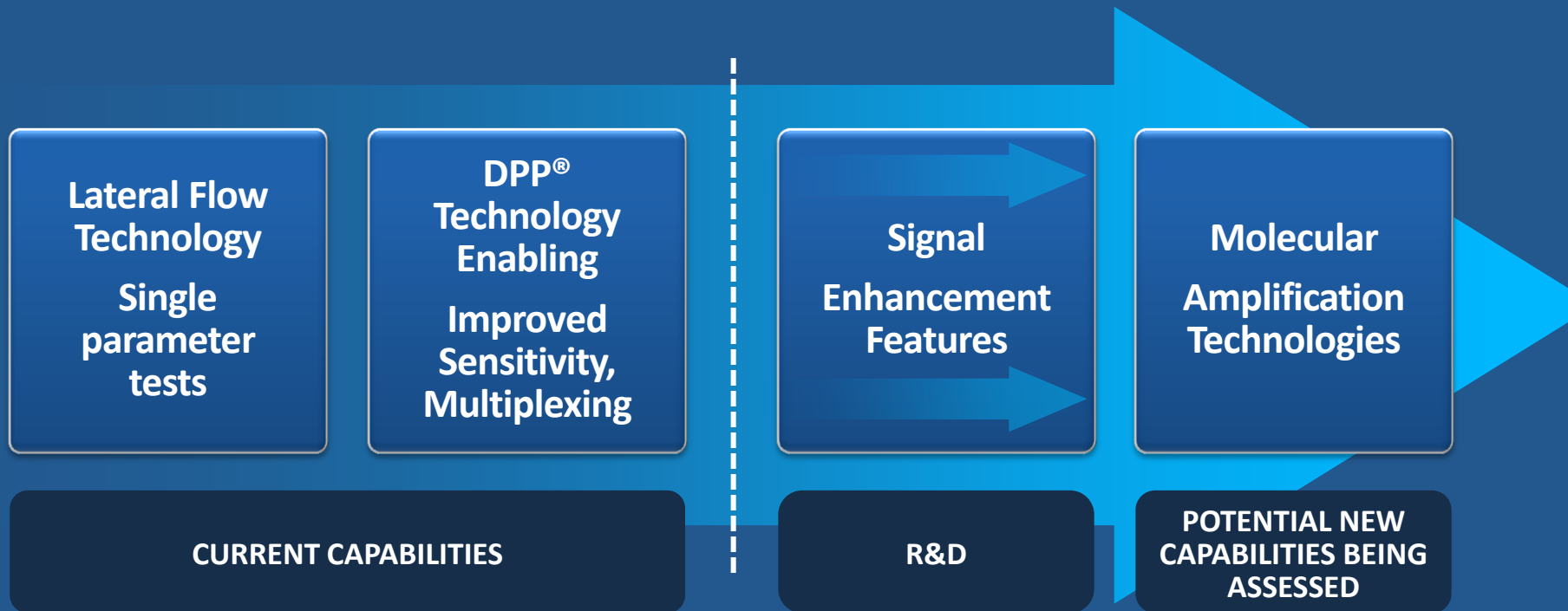
## HCV POCT – Emerging Market Opportunity

- 4MM in US Infected 75% Unaware
- Recent Revised CDC & USPSTF Recommendations for All Baby Boomers
- New Therapeutics



# POCTs - A Growing \$8B Global Market

## Long-term Trend Toward Molecular Levels of Detection



# Chembio's Lateral Flow Rapid HIV Tests Marketed World-Wide

- Total \$13.5MM 2012 Revenues
- In U.S. Sold Exclusively through Alere (Clearview®)
  - \$7.8MM 2012
  - Possibility to Sell Direct
- International Sales - Chembio Branded Through Multiple Channels:
  - E.g., PEPFAR, Global Fund UNICEF, etc.
  - \$5.7MM 2012
  - Record 2H Anticipated Based on \$5.3MM Order Received in Q2



Chembio SURE CHECK® HIV 1/2  
Alere Clearview Complete® HIV 1/2

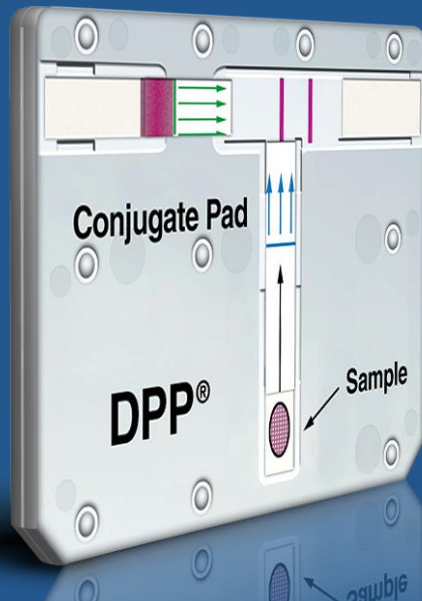


Chembio HIV 1/2 STAT-PAK®  
Alere Clearview HIV 1/2 STAT-PAK®

# Chembio's DPP® Patented Point-of-Care Technology

- Proprietary Platform Technology that Uniquely Enables Multiplexing for Higher Value Tests
- Increases Sensitivity as Compared with Lateral Flow Technology
- Validated with Numerous Partners, Regulatory Agencies

## Mechanism



## Result

Screening Test



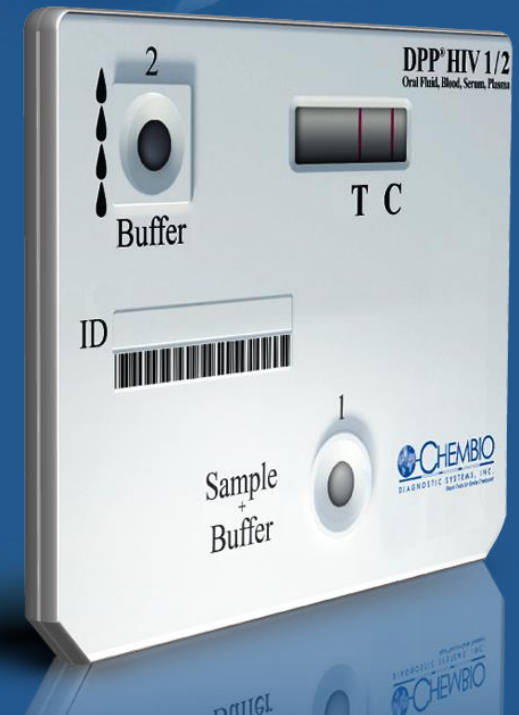
Confirmatory/Multiplex Test



# Chembio DPP® HIV 1/2 Assay FDA-Approved Dec. '12

## CLIA Waiver expected Q1 2014

- No Alternative to Current ~\$35MM Oral Fluid Product
- Superior blood matrix performance over top 4 market share products in early detection study
- Superior Oral Fluid sensitivity v. Market Leader in only head-to-head study
- User friendly, safe and efficient SampleTainer™ Sample Collection System
- Separate and Reagent Free Oral Fluid Collection Device



# Chembio DPP® Sales in Brazil

## Expanding Relationships and Sales Opportunities

### Five DPP® Products with Brazilian MOH Supplier

- \$10.1MM 2012 Revenues
- ~\$6MM Forecast 2013

### New Collaboration with LabTest Brazil

- Leading Brazilian IVD Company
- Addressing Private & Public Markets in Brazil
- Potential Additional Markets, Contract Manufacturing
- Assembly & Distribution - DPP® Co-branded
- 2013 Plan = Initial Products Registrations

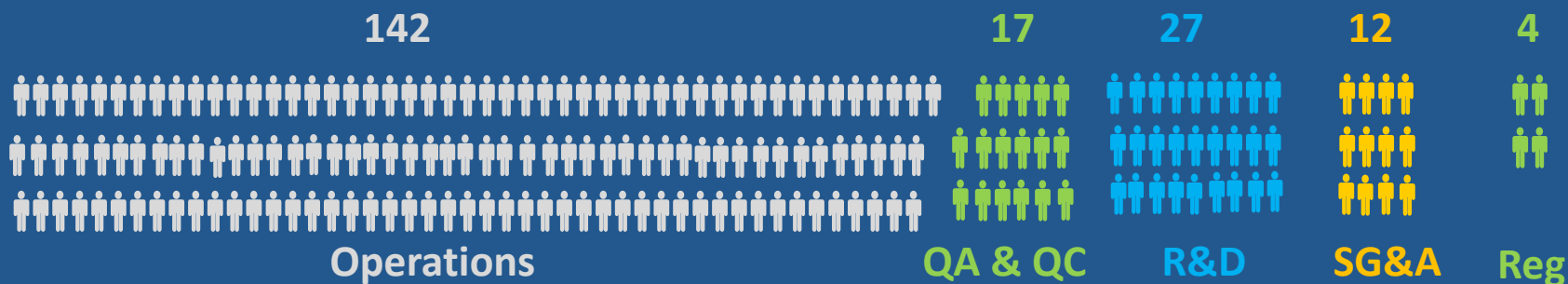
# Chembio's DPP® HIV-Syphilis and Syphilis Screen & Confirm Tests

- Large Global Market Opportunities for Pre-Natal and MSM Screening
  - HIV-Syphilis Comb. Leverages Global PMTCT Funding
  - Syphilis Screen & Confirm - Unique POC Solution Eliminates Previously Treated Cases
  - USAID and WHO Evaluations in Process
  - INDRE (Mexico) Data @100% Sensitivity & Specificity
- Anticipated FDA Approvals in Q4 2014 - CLIA waiver Q1 2015
  - Recent Meeting with FDA Extending Review Period Due to Change of HIV-Syphilis Product to PMA (v. 510K)
  - Significant Potential International Sales



# Organization & Facility

- FDA- and USDA-Approved Development & Manufacturing Facility
- All Company Operations in 30,600 Sq. Ft. Leased Facility in Medford, NY



**TOTAL EMPLOYMENT: Approximately 200**

# Chembio's Business Strategy for Growth:

- Establish commercial capabilities to increase revenue and maximize profits
- Develop, license or acquire POCT products/technologies that add value
- Expand manufacturing capabilities to supply our customers

# Priorities & Areas of Focus: Growth

## Commercial Operations

- Invest in Sales & Marketing to promote DPP technology globally
  - Deploy sales & technical resources in key regional areas

## Technology Investment

- New Product Launch (DPP HIV/SYP, SYP S&C)
- Develop New Technologies (HIV 4G, HCV) that address healthcare concerns



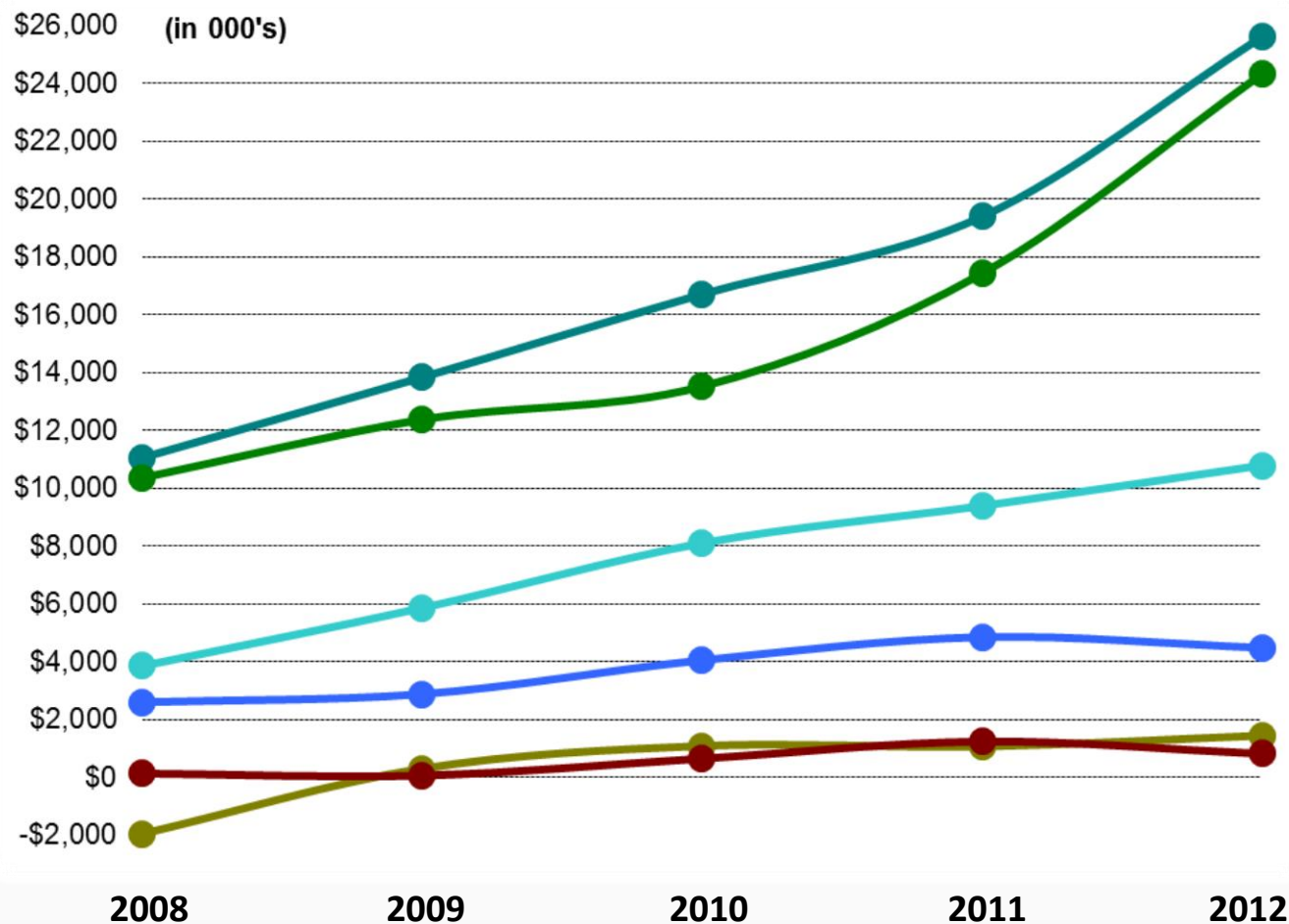
# Priorities & Areas of Focus: Operations

## Manufacturing Operations

- Process Excellence Program (Lean / Six Sigma)
- Engineering & Automation
- Targeted Cost Savings
  - Productivity / Labor Efficiencies
  - Scrap (10% improvement from FY12)



# Selected Financial Data FY2008 –2012



**2012**

**Total Revenue**  
\$25,611

**Product Revenue**  
\$24,327

**Gross Margin**  
\$10,790

**R&D Expense\***  
\$4,486

**Net Income before Taxes**  
\$1,450

**Clinical Trial Expense**  
\$820

# FY2011-2012 - Selected Financial Results

in (000's)	Year Ended Dec 31, 2012		Year Ended Dec 31, 2011	
Net Product Revenues	\$ 24,327		\$ 17,422	
Non-Product Revenues	1,283		1,966	
TOTAL REVENUES	25,610		19,388	
GROSS MARGIN	10,790	42%	9,390	48%
OPERATING COSTS:				
Research and development exp.	4,486	18%	4,878	25%
Selling, general and administrative exp.	4,852	19%	3,424	18%
	9,338		8,302	
INCOME FROM OPERATIONS	1,452		1,088	
OTHER INCOME (EXPENSES):	(2)		(12)	
NET INCOME-Before Taxes	1,450	6%	1,076	6%
Income tax (benefit) provision	509		(5,133)	
NET INCOME	\$ 941	4%	\$ 6,209	32%

2012 U.S. Lateral Flow HIV Sales	\$ 7.8 MM
2012 Ex-U.S. Lateral Flow HIV Sales	\$ 5.7 MM
2012 Brazil DPP Sales	\$10.1 MM



# Six Months Ended June 2012 & 2013

## Selected Financial Results

in (000's)	6 mo June 30, 2013		6 mo June 30, 2012	
Net Product Revenues	\$ 11,375		\$ 12,174	
Non-Product Revenues	697		563	
<b>TOTAL REVENUES</b>	<b>12,072</b>		<b>12,737</b>	
<b>GROSS MARGIN</b>	<b>4,975</b>	<b>41%</b>	<b>5,903</b>	<b>46%</b>
<b>OPERATING COSTS:</b>				
Research and development exp.	2,546	21%	2,358	19%
Selling, general and administrative exp.	2,322	19%	2,313	18%
	4,868		4,671	
<b>INCOME FROM OPERATIONS</b>	<b>107</b>		<b>1,232</b>	
<b>OTHER INCOME (EXPENSES):</b>	<b>9</b>		<b>(1)</b>	
<b>NET INCOME-Before Taxes</b>	<b>116</b>	<b>1%</b>	<b>1,231</b>	<b>10%</b>
Income tax (benefit) provision	40		489	
<b>NET INCOME</b>	<b>\$ 76</b>	<b>1%</b>	<b>\$ 742</b>	<b>6%</b>

**Anticipate Record Third Quarter and Second Half 2013 Revenues**

# Current Financial Position and Share Information

(\$ in 000s)	June'13 Unaudited	Dec.'12
Cash	\$8,645	\$2,952
Total Assets	\$23,542	\$17,335
Total Liabilities	\$3,929	\$3,460
Shareholder Equity	\$19,613	\$13,875

## *Share Information as of September 20, 2013*

Ticker Symbol (NASDAQ)	CEMI
Outstanding Shares	9.32 million
Fully Diluted Shares	9.99 million
Share Price	\$3.83
Market Capitalization	\$38.26 million

# Leadership

Executive	Previous Experience	Joined
<b>Lawrence Siebert, J.D.</b> Chairman & CEO	1981-1991, Partner, Stanwich Partners, Inc.; 1992-2002 Siebert Associates LLC, Manager; Siebert Capital Corp. , President	2002
<b>Richard Larkin, CPA</b> Chief Financial Officer	2000-2003 CFO of Visual Technology Group; 1987-2000 CFO of Protex International Corp.	2003
<b>Sharon Klugewicz, M.S.</b> Chief Operating Officer	20+ Years at Pall Corporation, most recently as Sr. VP - Scientific & Laboratory Services	2012
<b>Javan Esfandiari, M.S.</b> SVP Research & Development	1993-1997, R&D Director On-Site Biotech; 1997-2000, Co-Founder of Sinovus Biotech AB (Sweden), which was acquired by Chembio in 2000	2000

# Anticipated Milestones - 2013-2014

- Record Revenues in Q3 & Second Half of 2013
- Oral Fluid HIV Test CLIA Waiver & Launch
  - Establishing Chembio-branded U.S. Public Health Commercial Organization for Pipeline of Complementary Products
- Expanding International Revenues for Lateral Flow and DPP® Products
- 2014 FDA Submission & Approval of DPP HIV-Syphilis Test
- New Distribution, Contract Development & OEM Deals
- Increased Production Capacity
- Pursue Acquisitions or Licenses of Complementary Products/Technologies

# Growth Through Global Sales and Partnerships

- Global Health Markets
  - PEPFAR
  - Global Fund
- US Market
  - FDA Approved Lateral Flow Blood Tests
  - FDA Approved DPP® Oral Fluid HIV Test
  - Syphilis Products – Launch 2H 2014
- OEM Partnerships
  - FIOCRUZ
  - LabTest
- Funded Research Collaborations
  - CDC, DOD, NIH
- Hepatitis-C and HIV Fourth Generation Tests

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