



NASDAQ: CEMI



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

Investor Presentation

November 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 – Direct and Through Partnerships
  - \$8B Global Market with Current Pipeline Addressing \$650MM
- Four Consecutive Years of Profitability & Revenue Growth
  - Revenues and Net Income through Q3'13 up 22% and 75%, respectively
- Patented DPP® - A Platform POCT Technology
  - Uniquely Enables Multiplexing for Higher Value Tests & Increased Sensitivity
  - DPP® Oral Fluid HIV Test – FDA-Approved - CLIA waiver pending
  - DPP® HIV-Syphilis Test (USAID approved; Anticipate FDA PMA Submission in Q4 2014 )
- Pipeline of DPP® POCT Products
  - DPP® Syphilis Screen & Confirm Test
  - DPP® HCV Ab & HIV Ag-Ab Test

# 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

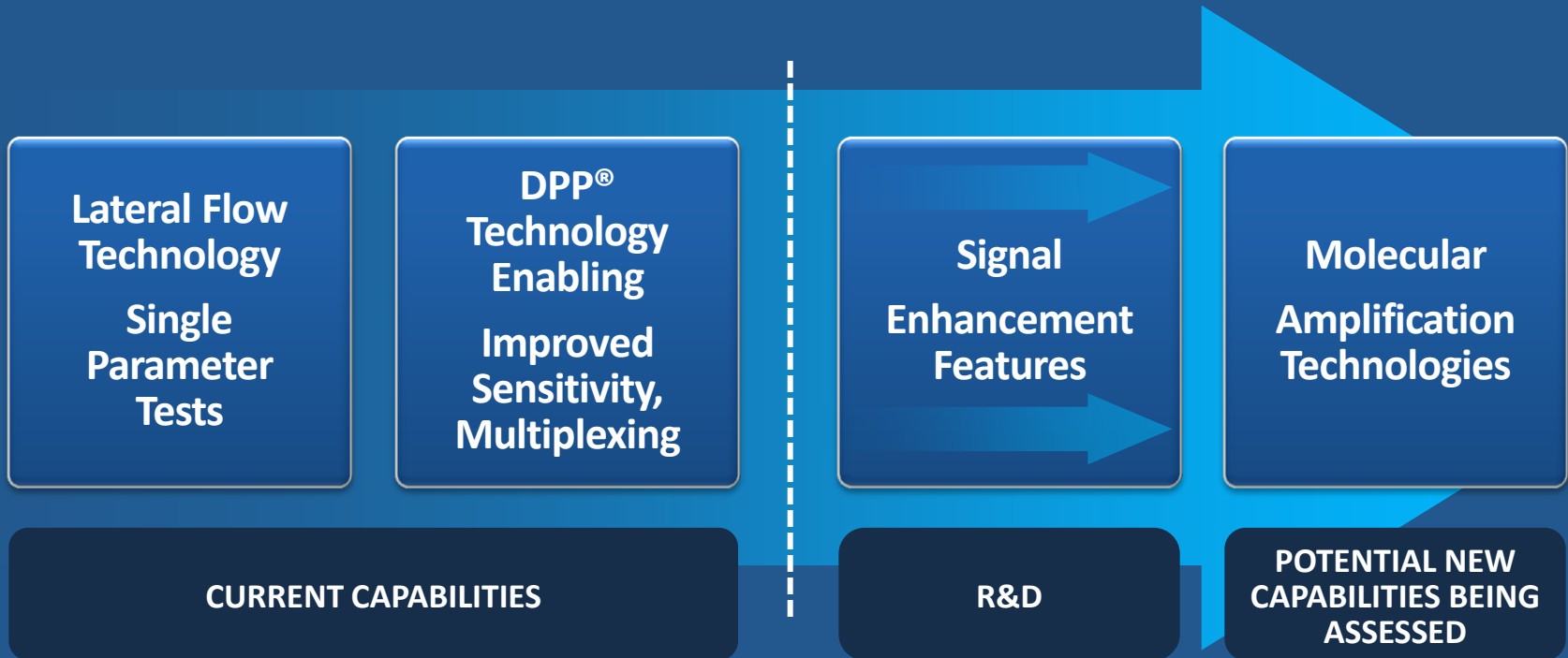
- Procurements primarily funded by PEPFAR, Global Fund, and WHO
- Sales channel ; NGO-direct & through distributors (11% FY12 revenue)
- Commercial resource deployment

## SOUTH/CENTRAL AMERICA

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

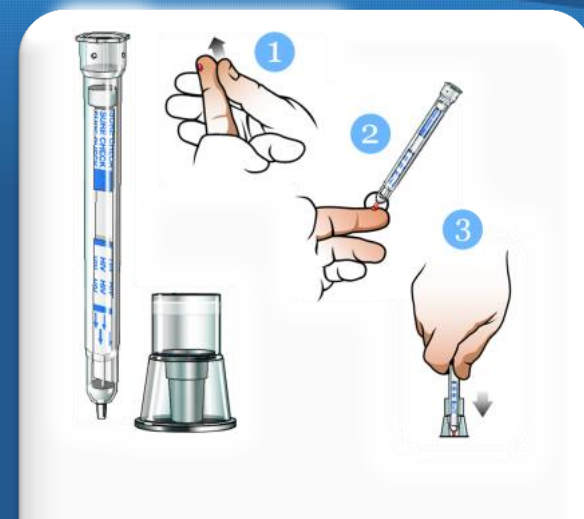
# POCTs - A Growing \$8B Global Market

## Long-term Trend Toward Molecular Levels of Detection



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

- Total \$13.5MM FY 2012
  - 76% YTD Increase Through Q3YTD vs. Comparable 2012 Period to \$9.1MM
- In U.S. Market Sold Exclusively through Alere
  - \$7.8MM in FY 2012
  - 22% YTD Increase Through Q3YTD vs. Comparable 2012 Period to \$7.1 MM
  - Possibility to Sell Direct in 2014
- International Market Sold Through Multiple Channels
  - \$5.7MM in 2012
  - 172% YTD Increase Through Q3YTD vs. Comparable 2012 Period to \$9.1MM YTD



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

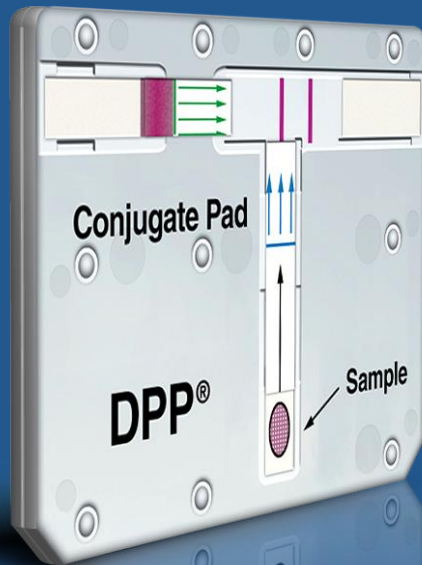


Chembio HIV 1/2 STAT-PAK®  
Alere Clearview HIV 1/2 STAT-PAK®

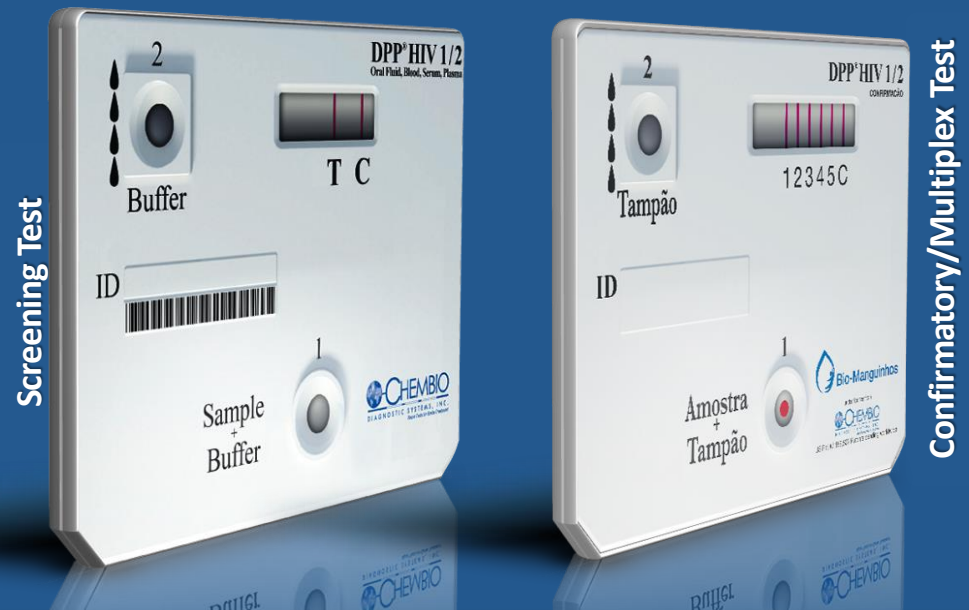
# Chembio's DPP® Patented Point-of-Care Test Technology - POCTs for Early Detection & Improved Health

- 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
- New DPP® Patents Issued in 2013

Mechanism



Result





# 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

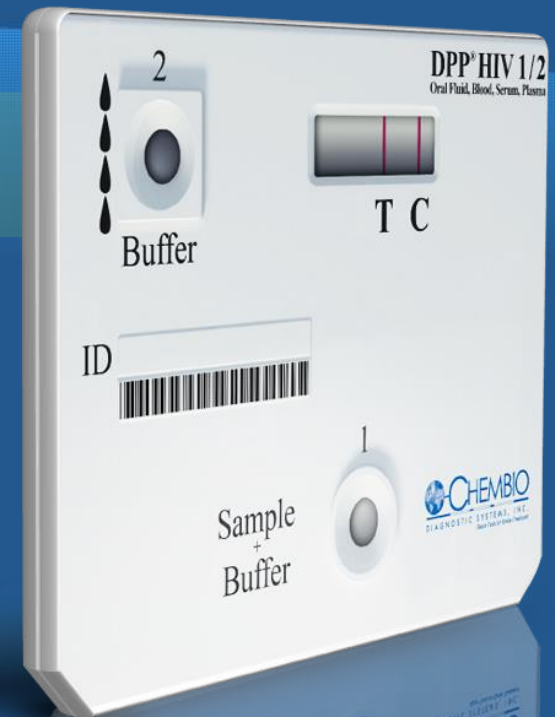
## Established, Growing Markets

### U.S.

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

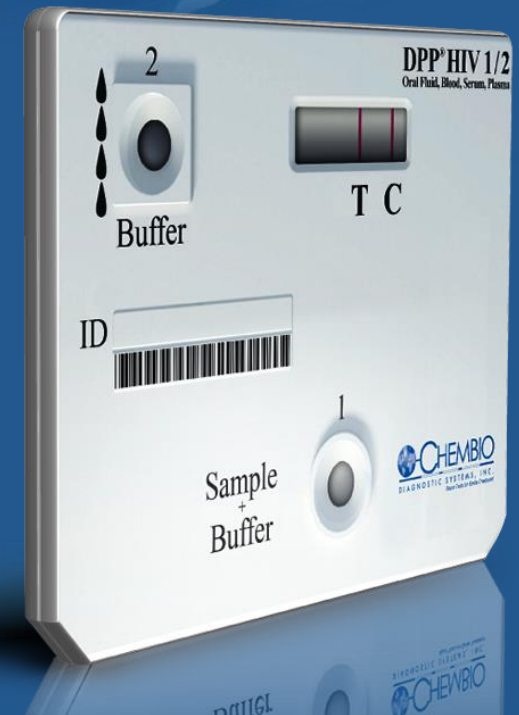
### International

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



# Chembio DPP<sup>®</sup> HIV 1/2 Assay FDA-Approved Dec. '12 CLIA Waiver Expected Q1 2014

- Build on Established Position/Performance of Our FDA Lateral Flow Products with Only 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<sup>™</sup> Sample Collection System
- Separate and Reagent-Free Oral Fluid Collection Device



## *Additional POCT Products in Pipeline*

# **DPP<sup>®</sup> HIV-Syphilis and Syphilis Screen & Confirm Tests**

- **DPP<sup>®</sup> HIV-Syphilis POCT**
  - Large Global Market Opportunities for Pre-Natal and MSM Screening; Up to 70% HIV-Syphilis Co-Infection in MSM
  - Higher Prevalence of Syphilis (1.9MM) than HIV (1.5MM) in Pregnant Women
  - International & US Regulatory Approval and Commercialization Efforts Underway
    - First Such Test to be USAID-approved
    - Anticipate FDA PMA Submission in Q4 2014
- **DPP<sup>®</sup> Syphilis Screen & Confirm POCT**
  - Eliminates Past Infections, thereby Overtreatment
  - CE Marked
  - Being Re-Validated with Good Progress in Q3 & Q4TD

# 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 &  
Improve  
Manufacturing  
Capabilities to  
Supply Our  
Customers

# Commercial Strategy: Top Line Growth (Sales)

**Build a Sales & Marketing Organization to Increase Our Revenue and Maximize Profits**

**Tactic  
#1**

**Move up Value Stream in US Diagnostics Market  
“USA Direct” for Certain Products**

**Tactic  
#2**

**Future Growth –  
New Markets and  
New Applications**

**Tactic  
#3**

**Maximize  
Opportunities in  
Developing World  
Markets**

# Commercial Strategy: Top Line Growth (Sales)

Tactic  
#1

Move up Value  
Stream in US  
Diagnostics  
Market “USA  
Direct” for Certain  
Products

## US Launch Project Plan in Place

Director of Sales & Director of Marketing  
Candidates Finalized

Engaged with Distribution Partners

Ongoing Discussion and Planning around Alere  
Options

- Anticipating Proposal from Alere
- Ongoing Assessment/Readiness for Alternative Scenarios & Options

# Commercial Strategy: Top Line Growth (Sales)

## Future Growth – New Markets & New Applications



- CE Marked Products – New Market Opportunities in EU
- International OEM – e.g. FIOCRUZ, Labtest Brazil, Other Potential OEM Agreements in Other Regions
- Niche Market Channels with HIV Oral Fluid Test



# Commercial Strategy: Top Line Growth (Sales)

Maximize Opportunities in Developing World Markets



- Significant Opportunities for Products in Global Health Programs in Africa and South America
  - Pursue Selection for National Testing Algorithms
  - Established Sales Director in Africa in Q3 , Other Regions Under Review

# 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

# Additional Priorities & Areas of Focus: Technology

## Technology Investment

- New Product Launch (DPP HIV/SYP, SYP S&C)
- Develop New Technologies (HIV 4G, HCV) that Address Healthcare Concerns
- Identify Additional Technologies to License/Acquire that will Complement our Commercial Strategy



# Additional Priorities & Areas of Focus: Operations

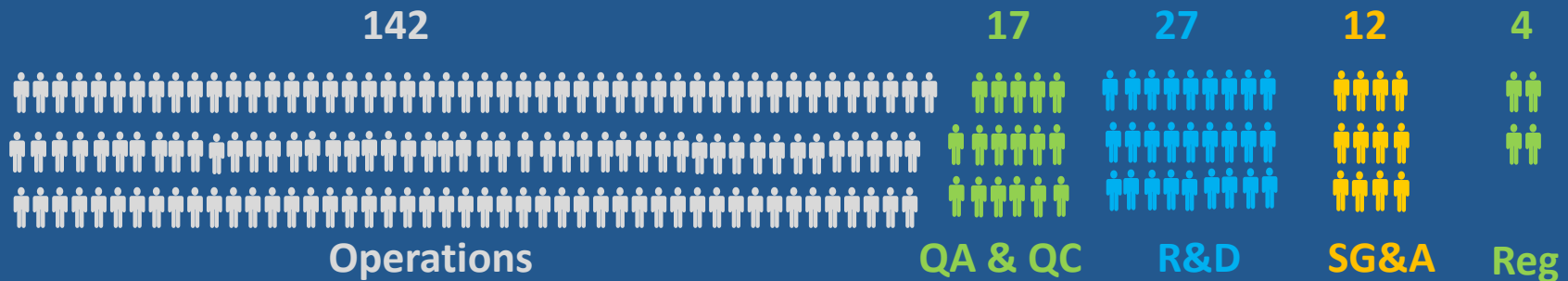
## Manufacturing Operations

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



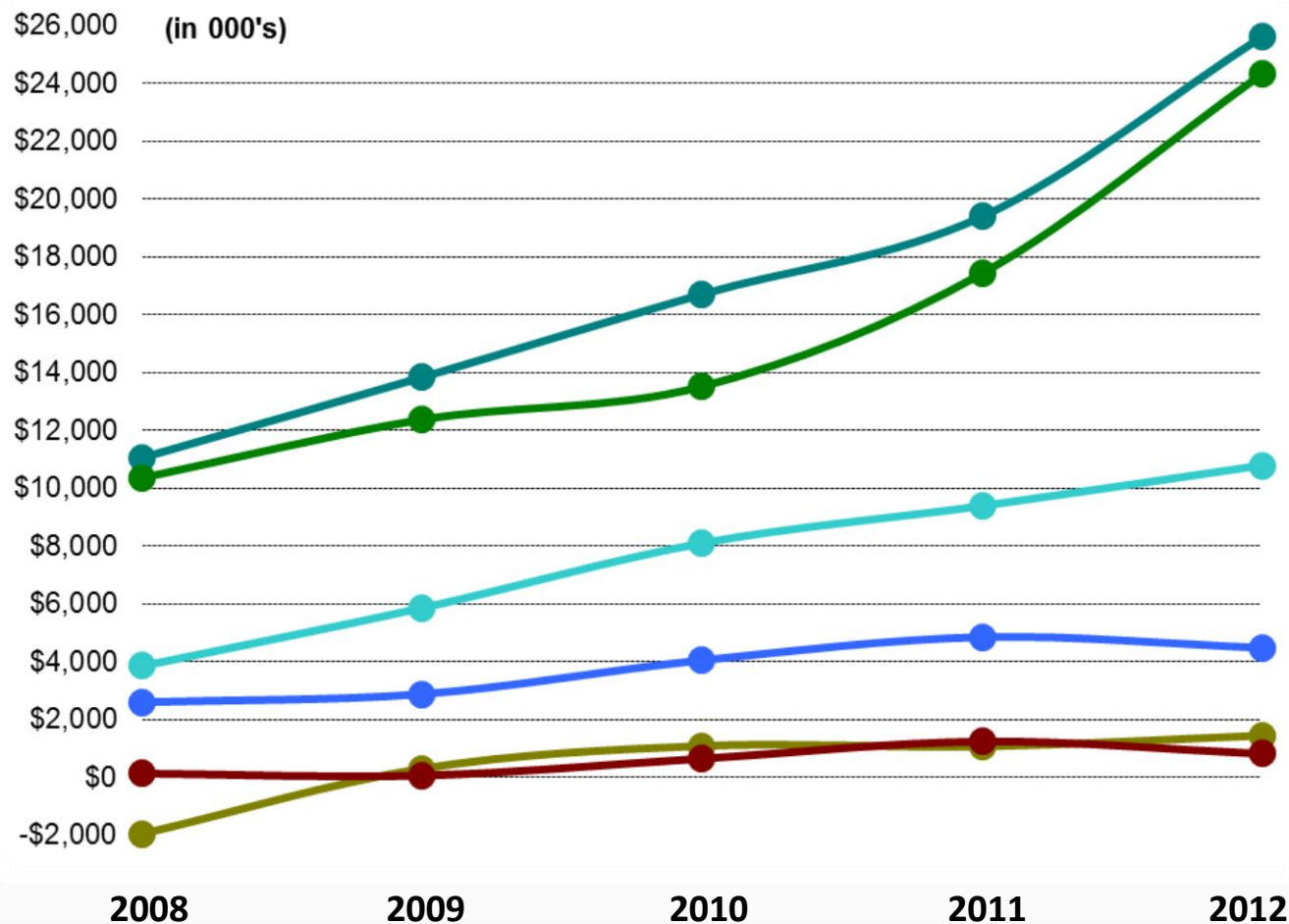
# Organization & Facility

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



**TOTAL EMPLOYMENT: Approximately 200**

# Selected Financial Data FY2008 –2012



**2012**

**Total Revenue**  
\$25,611

**Product Revenue**  
\$24,327

**Gross Profit**  
\$10,790

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

**Pre-Tax Income**  
\$1,451

**Clinical Trial Expense**  
\$1,451

# FY2010-2012 - Selected Financial Results

For The Years Ended (in 000's)	Dec 31, 2012		Dec 31, 2011		Dec 31, 2010	
Net Product Revenues	\$	24,327	\$	17,422	\$	13,516
Non-Product Revenues		1,283		1,966		3,188
<b>TOTAL REVENUES</b>		<b>25,610</b>		<b>19,388</b>		<b>16,704</b>
<b>GROSS MARGIN</b>		<b>10,790 42%</b>		<b>9,390 48%</b>		<b>8,101 48%</b>
<b>OPERATING COSTS:</b>						
Research and development exp.		4,486 18%		4,878 25%		2,586 15%
Selling, general and administrative exp		4,852 19%		3,424 18%		2,941 18%
		9,338		8,302		5,527
<b>INCOME FROM OPERATIONS</b>		<b>1,452</b>		<b>1,088</b>		<b>2,574</b>
NET INCOME-Before Taxes		1,450 6%		1,076 6%		2,559 15%
Income tax (benefit) provision		509		(5,133)		46
<b>NET INCOME</b>	\$	<b>941 4%</b>	\$	<b>6,209 32%</b>	\$	<b>2,513 15%</b>
Diluted earnings (loss) per share	\$	0.11	\$	0.73	\$	0.29
Weighted avg shs outstanding-diluted		8,614,944		8,556,284		8,865,114

**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**

# Third Quarter 2012-2013

## Selected Financial Results

Third Quarter Ended (in 000's)	Sept. 30, 2013		Sept. 30, 2012			
Net Product Revenues	\$	9,045	\$	4,745		
Non-Product Revenues		573		262		
<b>TOTAL REVENUES</b>		<b>9,618</b>		<b>5,007</b>		
<b>GROSS MARGIN</b>		<b>4,056</b>	<b>42%</b>	<b>1,729</b>	<b>35%</b>	
<b>OPERATING COSTS:</b>						
Research and development exp.		1,602	17%	1,006	20%	
Selling, general and administrative exp		1,380	14%	1,208	24%	
		2,982		2,214		
<b>INCOME FROM OPERATIONS</b>		<b>1,074</b>		<b>(485)</b>		
NET INCOME-Before Taxes		1,076	11%	(486)	-10%	
Income tax (benefit) provision		359		(194)		
<b>NET INCOME</b>	\$	<b>717</b>	<b>7%</b>	\$	<b>(292)</b>	<b>-6%</b>
Diluted earnings (loss) per share	\$	0.07		\$	(0.04)	
Weighted avg shs outstanding-diluted		9,824,019		8,001,472		

***2013 - Increased Lateral Flow Revenues –  
Offset by Reduced Brazil DPP Revenues***



# Nine Month 2012-2013 Selected Financial Results

<b>Nine Months Ended (in 000's)</b>	<b>Sept. 30, 2013</b>		<b>Sept. 30, 2012</b>	
Net Product Revenues	\$	20,420	\$	16,919
Non-Product Revenues		1,269		825
<b>TOTAL REVENUES</b>		<b>21,689</b>		<b>17,744</b>
<b>GROSS MARGIN</b>		<b>9,031 42%</b>		<b>7,632 43%</b>
<b>OPERATING COSTS:</b>				
Research and development exp.		4,148 19%		3,364 19%
Selling, general and administrative exp.		3,702 17%		3,521 20%
		7,850		6,885
<b>INCOME FROM OPERATIONS</b>		<b>1,181</b>		<b>747</b>
NET INCOME-Before Taxes		1,192 5%		745 4%
Income tax (benefit) provision		399		295
<b>NET INCOME</b>	\$	<b>793 4%</b>	\$	<b>450 3%</b>
Diluted earnings (loss) per share	\$	0.08	\$	0.05
Weighted avg shs outstanding-diluted		9,433,152		8,616,917

***2013 - Increased Lateral Flow Revenues –  
Offset by Reduced Brazil DPP Revenues***

# CEMI Selected Share & Balance Sheet Data

\$6MM Common Stock Public Offering Closed on April 3, 2013

1.2MM Shares @ \$5.00 per share, \$5.450MM Net Proceeds

*in millions except per share and daily volume data*

<b>Ticker Symbol (NASDAQ)</b>	<b>CEMI</b>
<b>Price 10/31/13</b>	<b>\$3.72</b>
<b>52-Week High</b>	<b>\$5.80</b>
<b>52-Week Low</b>	<b>\$3.00</b>
<b>Outstanding Shares</b>	<b>9.32</b>
<b>Market Capitalization</b>	<b>\$34.69</b>
<b>Fully Diluted Shares</b>	<b>9.99</b>
<b>Managements Holdings</b>	<b>1.55</b>
<b>Avg. Daily Volume (3 mos. to 10/31/13)</b>	<b>40,000</b>
<b>Average Daily Volume (Oct. 2013)</b>	<b>30,000</b>

<b>Options – Mgmt. &amp; Board</b>	<b>Total</b>	<b>Avg. Ex. Price</b>
<b>533K</b>	<b>669K</b>	<b>\$2.70</b>

<b>(\$ in 000s)</b>	<b>Sept.'13 Unaudited</b>	<b>Dec.'12</b>
<b>Cash</b>	<b>\$8,046</b>	<b>\$2,952</b>
<b>Total Current Assets</b>	<b>18,007</b>	<b>4,821</b>
<b>Total Assets</b>	<b>24,326</b>	<b>17,335</b>
<b>Total Current Liabilities</b>	<b>3,935</b>	<b>3,378</b>
<b>Total Liabilities</b>	<b>3,935</b>	<b>3,460</b>
<b>Stockholders' Equity</b>	<b>20,391</b>	<b>13,875</b>
<b>Total Liabilities &amp; Stockholders' Equity</b>	<b>24,326</b>	<b>17,335</b>

# 2012 & 2013 Milestones Achieved

## Product Development/Regulatory

- Received FDA PMA Approval of DPP Oral Fluid HIV Test – CLIA Waiver Pending
- Received CE Mark for Sure Check HIV 1/2 Assay
- USAID Approval of HV-Syphilis Test

## Corporate/Operations

- Strengthened Management Team
- Poised for Fifth Straight Year of Sales Growth and Profitability with Strong Gains in Domestic and International Segments
- Strengthened Balance Sheet with Common Stock Issuance, Establishing Institutional Shareholder Base
- Increased Production Capacity to Meet Sales Growth

## Commercialization

- Entered International Assembly & Distribution Agreement w/Labtest of Brazil
- Initial International Registrations for HIV-Syphilis ; Receiving Initial Orders

# Anticipated Milestones - 2013-2014

## Product Development/Regulatory

- Oral Fluid HIV Test CLIA Waiver & Launch
- FDA Submission & Approval of DPP<sup>®</sup> HIV-Syphilis Test

## Corporate/Operations

- Increase Production Capacity
- Pursue Acquisitions or Licenses of Complementary Products/Technologies
- Announcement of New CEO

## Commercialization

- Implement US and International Commercial Strategy, Expand Market and Sales Opportunities
- Expand International Revenues for Lateral Flow and DPP<sup>®</sup> Products
- New Distribution, Contract Development & OEM Deals

# Leadership - Executive Team

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
<b>Thomas Ippolito</b> VP Regulatory & Clinical Affairs	25 years experience in the development of vaccines, therapeutics and IVDs working with several major pharmaceutical, vaccine and diagnostic companies	2005
<b>Michael Steele</b> VP Sales Marketing & Bus. Dev.	20-years of business development and strategy execution at life sciences companies Sera Care Life Sciences, Serologicals, Inc. and Corautus Genetics.	2012

# Leadership – Independent Directors

**Gary Meller, M.D., MBA – Director since 2005, Member of: Chairman Compensation Committee, Audit Committee and Nominating and Corporate Governance Committee**  
President of CommSense Inc., M.D. University of New Mexico School of Medicine, MBA Harvard Business School.

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**Katherine L. Davis – Director since 2007, Member of: Chairman Audit Committee, Compensation Committee and Chairman Nominating and Corporate Governance Committee**  
Owner of Davis Design Group LLC; MBA Harvard Business School, Bachelors of Science in Mechanical Engineering from the Massachusetts Institute of Technology.

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**Peter Kissinger Ph.D. –Director since 2011, Member of: Audit Committee**  
Professor of Chemistry and Associate Department Head at Purdue University; B.S. in Chemistry from Union College, Schenectady, N.Y., and a Ph.D. in Analytical Chemistry from the University of North Carolina in Chapel Hill.

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**Barbara DeBuono M.D., M.P.H. – Director since 2011, Member of: Compensation Committee, Chairman of Special Sub-Committee for CEO Search**  
Senior Vice President for Market Development at TREO Solutions ; B.A. from the University of Rochester, M.D. from the University of Rochester School of Medicine, and Masters in Public Health (M.P.H.) from Harvard University School of Public Health.

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