



NASDAQ: CEMI



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

Investor Presentation

March 2014



# 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 Segment
- Five Consecutive Years of Profitability & Revenue Growth
  - 2013 Revenues and Product Gross Margin Increased by 15% and 8% respectively vs. 2012
- Patented DPP<sup>®</sup> - A Platform POCT Technology
  - Uniquely Enables Multiplexing for Higher Value Tests & Increased Sensitivity
  - DPP<sup>®</sup> Oral Fluid HIV Test – FDA-Approved - CLIA waiver pending
  - DPP<sup>®</sup> HIV-Syphilis Test – Strong outlook for international sales in 2014
- Pipeline of DPP<sup>®</sup> POCT Products
  - DPP<sup>®</sup> 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 (30% FY13 revenue)
- DPP® HIV PMA approval (Dec'12) / CLIA pending
- Funded Research Collaborations with CDC, DOD, NIH (6% FY13)

## EU

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

## ASIA

Feb. 2014 License, Distribution, Tech. Transfer and Contract Manufacturing Agreements

## SOUTH/CENTRAL AMERICA

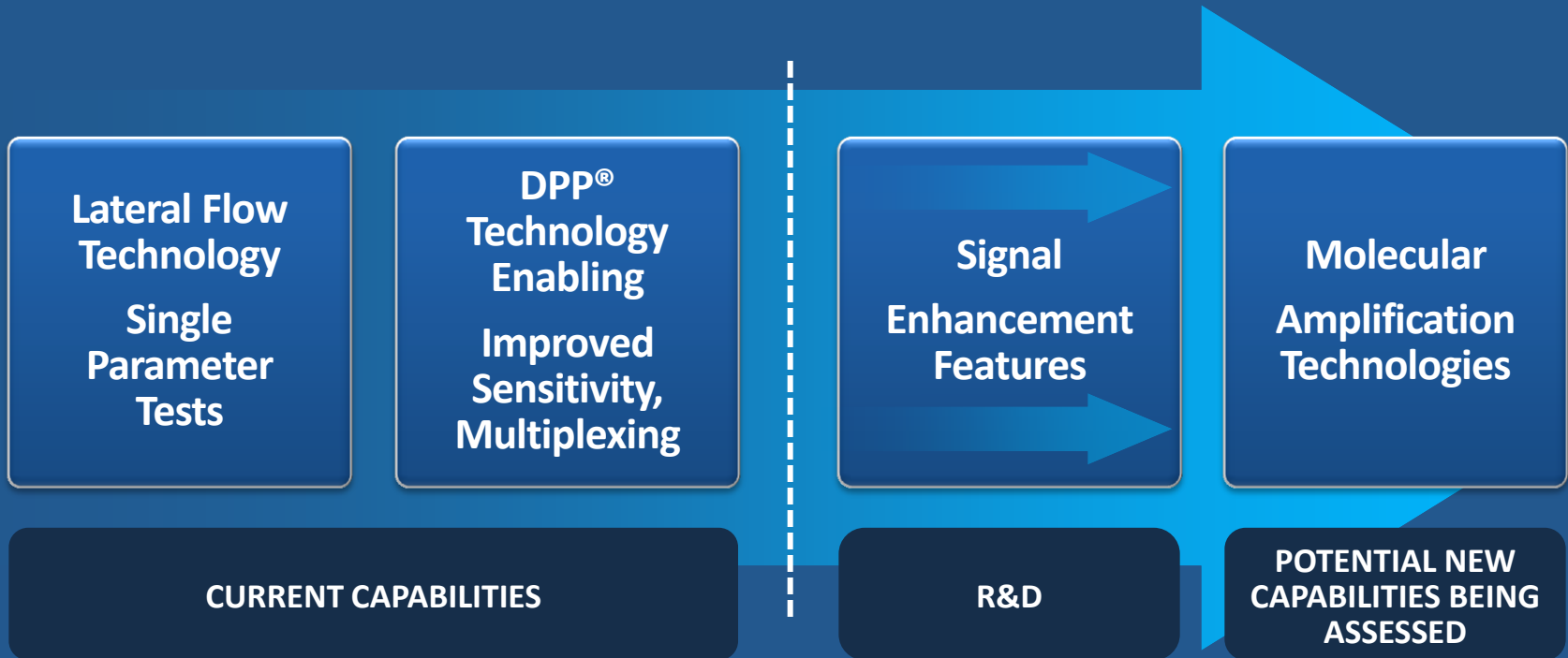
- Strong OEM Partnerships (FIOCRUZ, Labtest); Branded products sold to NGOs, private distributors (45% FY13)

## AFRICA

- Procurements primarily funded by PEPFAR, Global Fund, and WHO
- Sales channel ; NGO-direct & through distributors (14% FY13 revenue)
- Commercial resource deployment

# 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 \$20.2MM FY 2013
  - 50% Increase vs. FY2012
  - 5-8.5% Royalties Ending Feb. 2015
- In U.S. Market Sold Exclusively through Alere
  - \$8.9MM in FY 2013
  - 14% Increase vs. FY2012
  - Possibility to Sell Direct in 2014
- International Market Sold Through Multiple Channels
  - \$11.8MM in FY2013
  - 84.5% Increase vs. FY2012



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

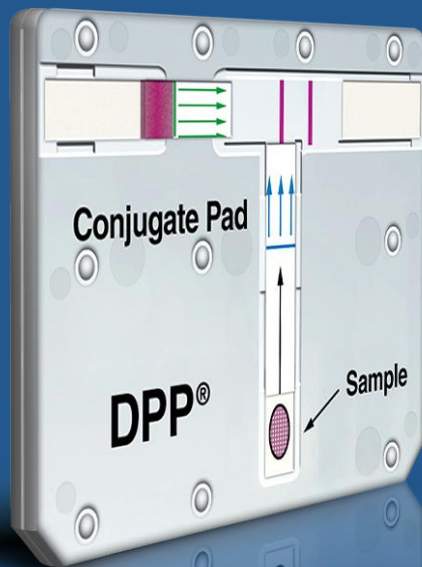


Chembio HIV 1/2 STAT-PAK®  
Alere Clearview HIV 1/2 STAT-PAK®

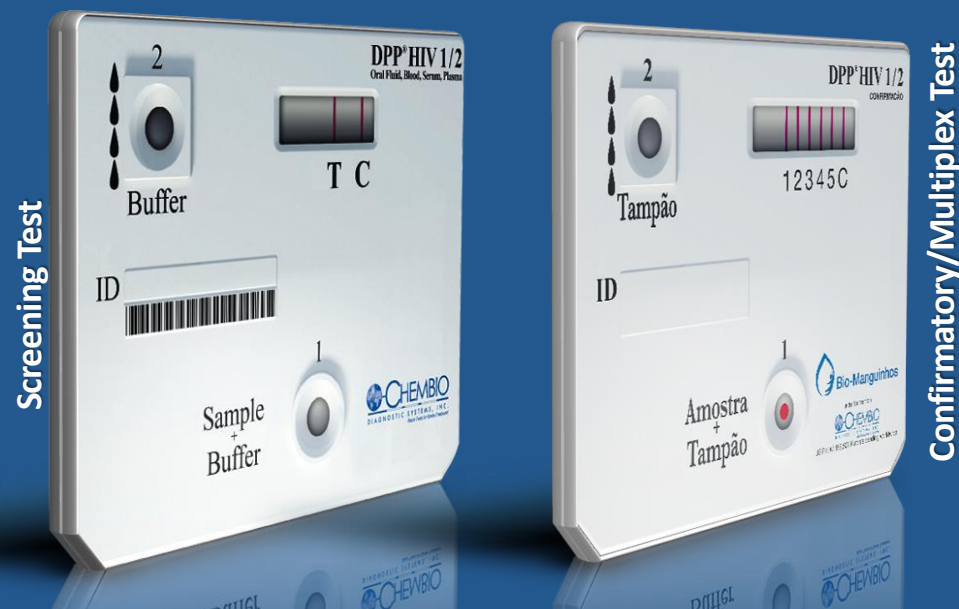
# Chembio's Dual Path Platform (DPP®) Patented Point-of-Care Test Technology

- 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
- New DPP® Patents Issued in 2013

Mechanism



Result





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

Chembio Pipeline POCT	Total Estimated Market Opportunity	Targeted Launch
HIV POCT - U.S.	\$75 MM	\$8.9MM Product Sales 2013 ; New Oral Fluid Product Launch 2014
HIV-Syphilis - U.S.	\$75 MM	2015
Hepatitis C POCT – U.S.	\$100 MM	2016
Combined Estimated Market for Above – ex-U.S.	\$400 MM	\$27.5MM Product Sales in FY2013 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

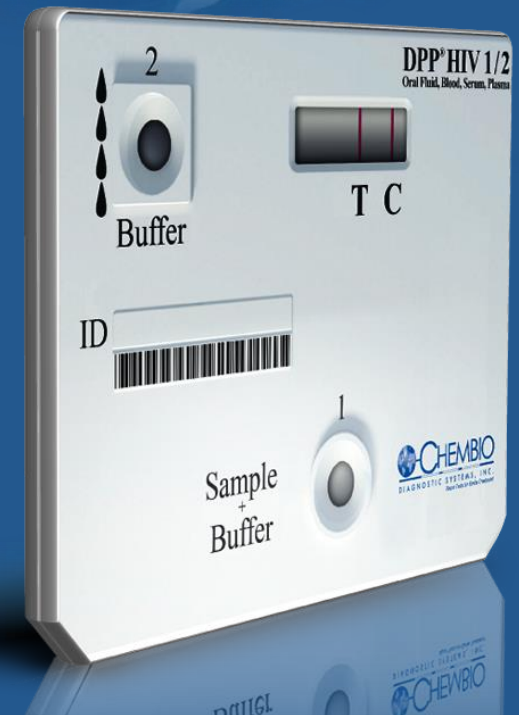
- 2.5 MM New Infections Worldwide in 2012
- Designation in PEPFAR & Other Donor-Funded Countries' Testing Protocols



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

CLIA Waiver Application Filed with FDA , November 2013  
Anticipated Launch in 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



# DPP<sup>®</sup> HIV-Syphilis Multiplex Assay

- Large Global Market Opportunities for Pre-Natal and MSM Screening
- Higher Prevalence of Syphilis (1.9MM) than HIV (1.5MM) in Pregnant Women
- International & US Regulatory Approval and Commercialization Efforts Underway
- Up to 70% HIV-Syphilis Co-Infection in MSM
  - First Such Test to be USAID-approved
  - Strong Start and Outlook 2014
  - Anticipate FDA PMA Submission in 2014

# OEM & License Agreements

## Expanding Relationships and Sales Opportunities

### Oswaldo Cruz Foundation

- Five DPP® Products , ~\$6MM 2013 revenues
- Brazilian MOH Supplier

### Collaboration with LabTest Brazil

- Assembly & Distribution - DPP® Co-branded
- 2014 Plan = Initial Products Registrations

### Agreement with RVR Malaysia

- License, Distribution, Tech. Transfer and Contract Manufacturing

### Bio-Rad Laboratories

- Exclusive Licensee for DPP® HIV Confirmatory Application
- CE Marked 2013, FDA Pending

# 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**



# Additional Priorities & Areas of Focus: Technology

## Technology Investment

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



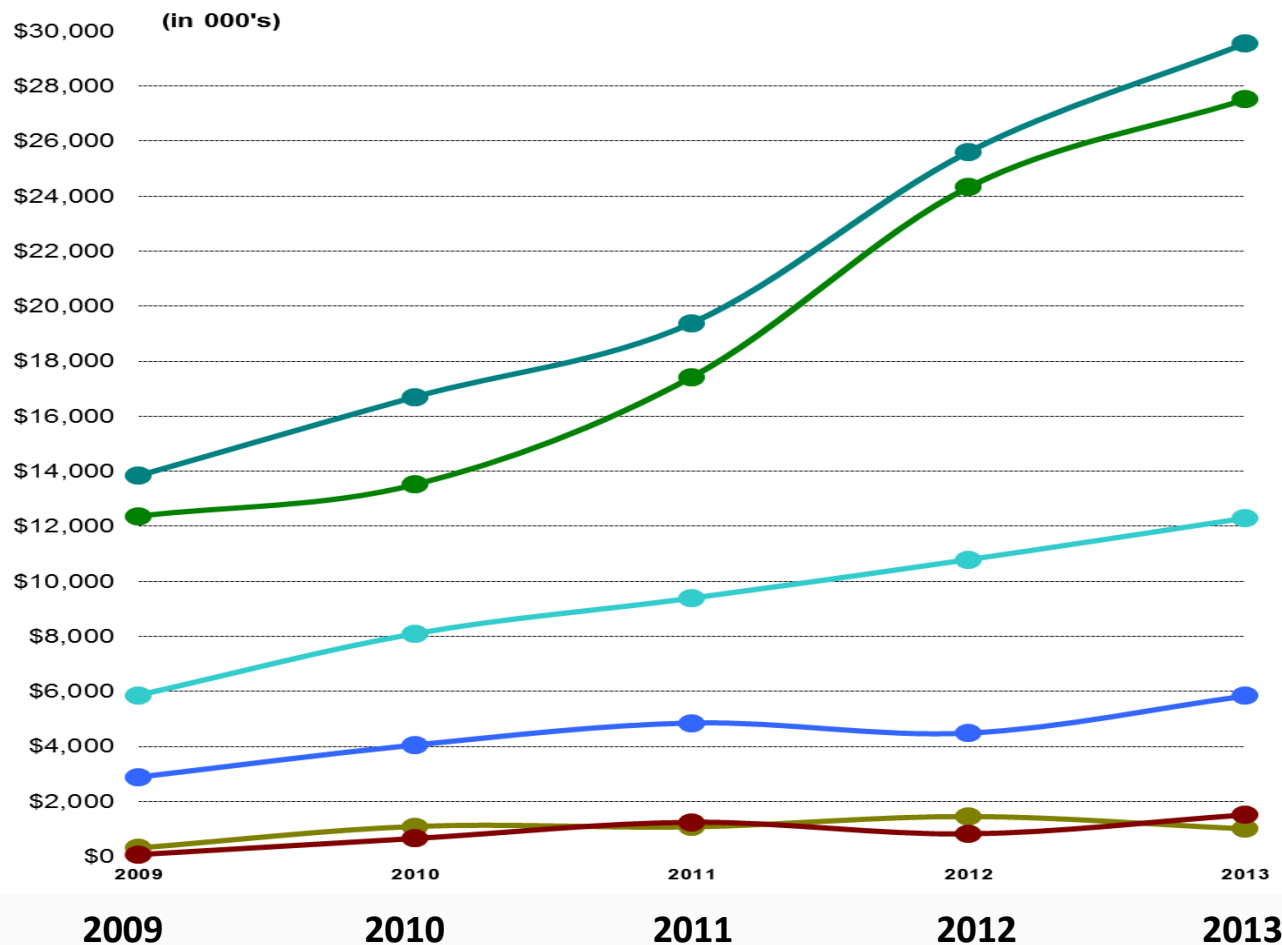
# Organization & Facility

- 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 FY2009 –2013



**2013**

**Total Revenue**  
\$29,550

**Product Revenue**  
\$27,516

**Gross Profit**  
\$12,300

**R&D Expense\***  
\$5,834

**Pre-Tax Income**  
\$530,800

**Clinical Trial Expense**  
\$1,515

# FY2011-2013 - Selected Financial Results

For The Years Ended (in 000's)	Dec 31, 2013		Dec 31, 2012		Dec 31, 2011	
Net Product Revenues	\$	27,516	\$	24,327	\$	17,422
Non-Product Revenues		2,034		1,283		1,966
<b>TOTAL REVENUES</b>		<b>29,550</b>		<b>25,610</b>		<b>19,388</b>
<b>GROSS MARGIN</b>		<b>12,300</b>	<b>42%</b>	<b>10,790</b>	<b>42%</b>	<b>9,390</b>
<b>OPERATING COSTS:</b>						
Research and development exp.		5,834	20%	4,486	18%	4,878
Selling, general and administrative exp.		5,461	18%	4,852	19%	3,424
		11,295		9,338		8,302
<b>INCOME FROM OPERATIONS</b>		<b>1,005</b>		<b>1,452</b>		<b>1,088</b>
Income tax (benefit) provision		487		509		(5,133)
<b>NET INCOME</b>	\$	<b>531</b>	<b>2%</b>	\$ <b>941</b>	<b>4%</b>	\$ <b>6,209</b>
Diluted earnings (loss) per share	\$	0.06		\$ 0.11		\$ 0.73
Weighted avg shs outstanding-diluted		8,994,080		8,614,944		8,556,284

# 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 02/28/14</b>	<b>\$3.80</b>
<b>52-Week High</b>	<b>\$5.70</b>
<b>52-Week Low</b>	<b>\$2.98</b>
<b>Outstanding Shares</b>	<b>9.32</b>
<b>Market Capitalization</b>	<b>\$35.43</b>
<b>Fully Diluted Shares</b>	<b>9.99</b>
<b>Managements Holdings</b>	<b>1.51</b>
<b>Avg. Daily Volume (3 mos. to 2/28/14)</b>	<b>47,000</b>

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

<b>(\$ in 000s)</b>	<b>Dec.'13</b>	<b>Dec.'12</b>
<b>Cash</b>	<b>\$9,650</b>	<b>\$2,952</b>
<b>Total Current Assets</b>	<b>18,531</b>	<b>4,821</b>
<b>Total Assets</b>	<b>24,487</b>	<b>17,335</b>
<b>Total Current Liabilities</b>	<b>4,310</b>	<b>3,378</b>
<b>Total Liabilities</b>	<b>4,310</b>	<b>3,460</b>
<b>Stockholders' Equity</b>	<b>20,177</b>	<b>13,875</b>
<b>Total Liabilities &amp; Stockholders' Equity</b>	<b>24,487</b>	<b>17,335</b>

# 2013 2014YTD Milestones Achieved

## Product Development/Regulatory

- Received FDA PMA Approval of DPP Oral Fluid HIV Test
- Substantially Completed CLIA waiver studies
- Received CE Mark for Sure Check HIV 1/2 Assay
- USAID Approval, Initial Sales of HV-Syphilis Test

## Corporate/Operations

- Achieved 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
- Established Distribution, License , Tech. Transfer, Contract Manufacturer in Asia
- Initial International Registrations for HIV-Syphilis ; Receiving Significant Initial Orders



# Anticipated Milestones - 2014

## Product Development/Regulatory

- Oral Fluid HIV Test CLIA Waiver & Launch
- CE Marks for HIV 1/2 STAT-PAK<sup>®</sup>, DPP<sup>®</sup> HIV & HIV-Syphilis Products
- International Sales Growth of DPP<sup>®</sup> HIV-Syphilis Test
- 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 & 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

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