



NASDAQ: CEMI



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

Investor Presentation

May 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.

# Investment Summary



- Develops, Manufactures & Markets Point-of-Care Diagnostic Tests (POCTs) Using Company's Patented DPP® - A Platform POCT Technology
- >25% CAGR Revenue Growth FY2009-2012
- Products Sold Globally
- Partnered with Leading License & Distribution Partners in U.S. & South America
- Recent FDA Approval of Oral Fluid HIV Test
- Strong Pipeline of POCTs
- Experienced Management Team



# POCTs - A Growing Global Market

## Converting Lab Tests to POCT and Creating New Markets

In-Vitro Diagnostics Market

**\$45 Billion**

Global Point-of-Care Test Market

**\$10 Billion**

Lateral Flow  
Technology  
Single  
parameter  
tests

DPP®  
Technology  
Enabling  
Improved  
Sensitivity,  
Multiplexing

**CURRENT CAPABILITIES**

Signal  
Enhancement  
Features

**R&D**

Molecular  
Amplification  
Technologies

**POTENTIAL NEW  
CAPABILITIES  
BEING ASSESSED**

# Chembio's Pipeline - \$850MM Total Addressable Market

| Chembio Pipeline POCT                           | Total Market Opportunity | Targeted Launch   |
|---|--------------------------|---|
| US HIV (Oral Fluid, 4 <sup>th</sup> Generation) | \$ 75 MM                 | Q4-2013 (Oral Fluid), 2015 (4 <sup>th</sup> Generation) |
| US Syphilis-HIV                                 | \$ 75 MM                 | 2H -2014  |
| US HCV  | \$100 MM                 | 2015  |
| US OTC-HIV                                      | \$100 MM                 | 2015-2016   |
| US Veterinary (OEM)                             | \$100 MM                 | 2014  |
| International                                   | \$400 MM                 | 2013-2016   |
| Total   | \$850 MM                 | 2013-2016   |



# Chembio Diagnostics – Current Revenues & Markets

## 2012 - \$25.6MM Revenue Business, \$1.45MM Operating Income; Profitable Q1 2013

- ~50% of Revenue: Lateral Flow HIV Tests
  - 25% Share of \$75MM US Market
  - Participate in \$250 MM Ex-US Rapid HIV Professional Test Market
  - New HIV Self-Testing Market Opportunity
- ~40% of Revenue: Patented POCT Platform
  - Oral Fluid HIV Test FDA Approved 12/2012 & Five DPP® Products Approved and Successfully Launched in Brazil – 2011 -2012
  - Significant Developments for Single and Multiplex DPP® POCTs
- ~10% of Revenue: Other Products, Grants



# Anticipated Developments - 2013-2015

- Oral Fluid HIV Test CLIA Waiver & Launch
  - Direct Distribution in Public Health for Pipeline of Complementary Products
- Expanding International Revenues for Lateral Flow and DPP® Products
- FDA Submission & Approval of Two POCT Multiplex Syphilis Tests Based on DPP® Technology
- Development & FDA Approval of Multiplex Antigen/Antibody DPP® Tests for HIV and HCV
- FDA Approval of At-Home HIV Test
- Contract Development & OEM Partnerships – e.g., Veterinary, Tropical Diseases

# Chembio's Current POCT Market Opportunities

## HIV Rapid POCTS

- ~50,000 New Infections in US - 2012 ; 2.5 MM Worldwide
- Routine Testing USPSTF Recommendation
- CEMI Only Company with 3 FDA-Approved Tests
- CEMI Tests Designated in Selected International Protocols

## Syphilis Rapid POCTS – New Market Opportunity

- Up to 70% HIV-Syphilis Co-Infection in MSM
- All HIV+ Need be Tested for Syphilis & Vice Versa
- CEMI Has Two Unique POCTs – Anticipate 2014 Launch

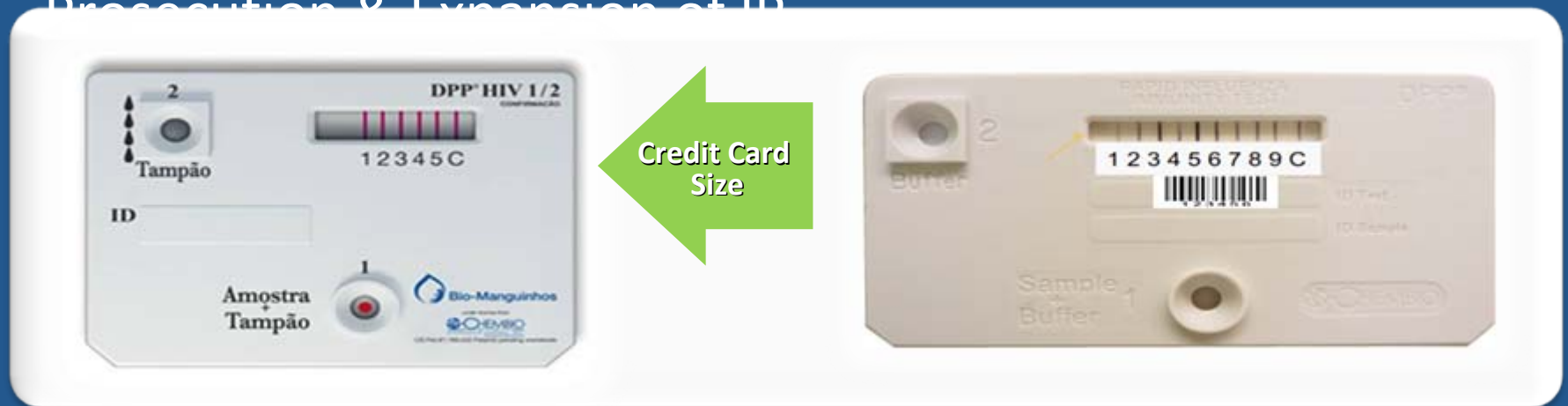
## Hepatitis-C Rapid POCT – New Market Opportunity

- 70MM U.S. Baby Boomer Screening Opportunity; New Therapeutics
- Product in Development



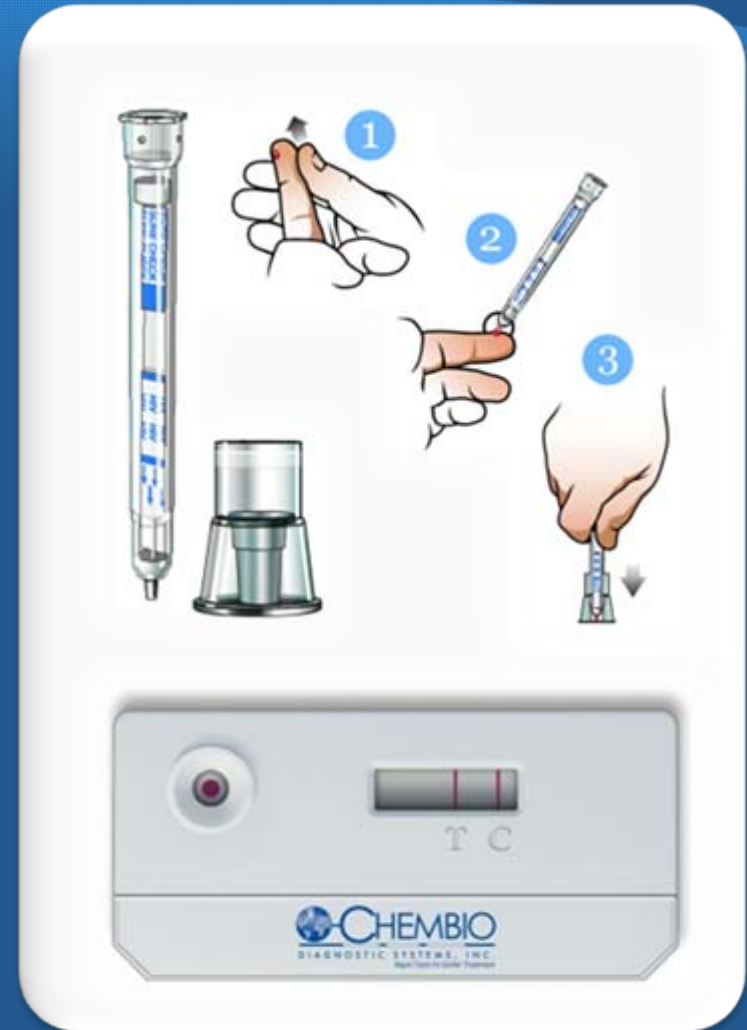
# DPP® - Chembio's Patented POCT Platform Technology

- 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
  - Bio-Rad Laboratories, Inc. CE Marked HIV Confirmatory Test, April 2013
- Patents Issued in US and Multiple Countries, Continuing Prosecution & Expansion of IP



# Two FDA-Approved Lateral Flow Rapid HIV Tests Sold Globally

- Utilize In-Licensed Lateral Flow Technology
- Large International Screening Programs (PEPFAR)
- Significant Potential New International Opportunities Pending
- In US Sold Exclusively through Alere (Clearview Brand)
  - 2012 Sales to Alere \$7.8MM
  - Q1 2013 Sales to Alere \$2.6MM



# DPP® HIV®1/2 Test for Use with Oral Fluid or Blood Samples

- First FDA-Approved Product on DPP® (Dec. 2012)
  - Center for Biologics Evaluation and Research (CBER) PMA Approved, CLIA Waiver Pending
- Improved Sensitivity vs. Market Leader\*
- Earlier Detection of Seroconverting Patients
- Proprietary SampleTainer™ Sample Collection System



# U.S. HIV Self-Testing “OTC” Opportunity

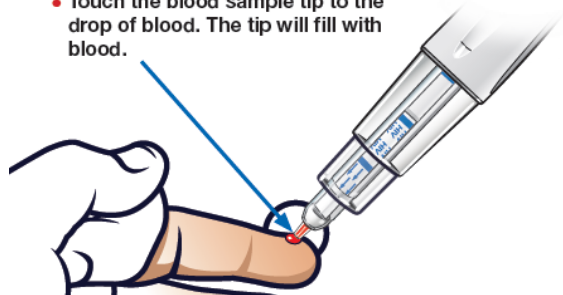
- Chembio Uniquely Positioned
- Assessing Market Size and Best Approach
- Filing IDE Early 2013 for Sure Check HIV
  - Pre-IDE Self-Testing Studies Show 100% Accuracy (n=300)



## SURE CHECK HIV HOME TEST



• Touch the blood sample tip to the drop of blood. The tip will fill with blood.



# Collaboration with FIOCRUZ in Brazil

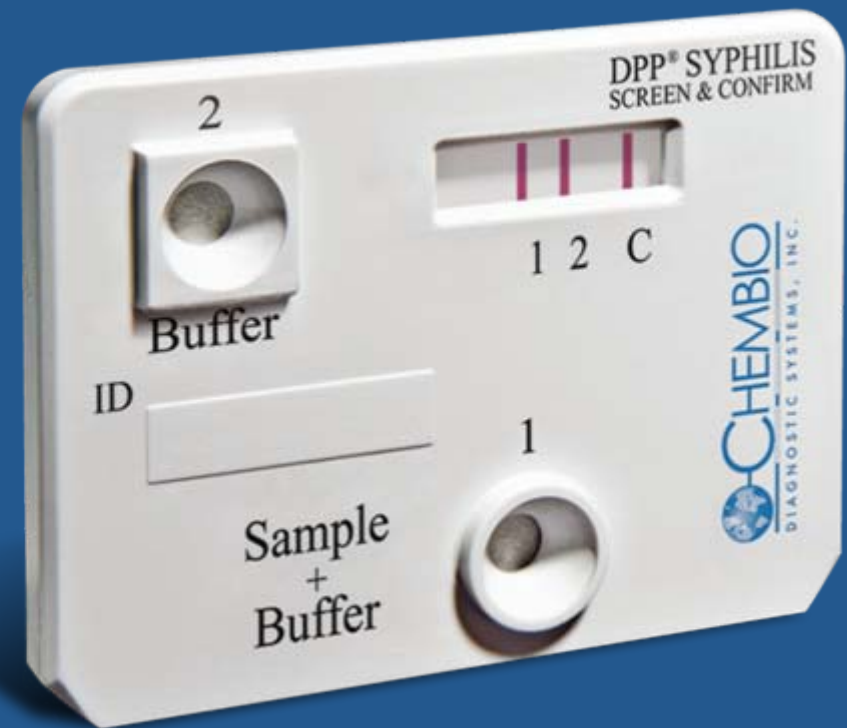
- First Commercial Success with DPP<sup>®</sup>
- Contracts with Supplier to Brazilian Federal Ministry of Health
- \$7MM of Potential Additional Purchases (~\$16MM Revenues 2011-Q1'13) for Five DPP<sup>®</sup> Products - may be exceeded
- Expect Tech Transfer & Conversion to License 2013-14
- Potential New Products & Partnerships in Brazil





# DPP® Syphilis Screen & Confirm & HIV-Syphilis Multiplex Tests

- Large Global Market Opportunity for Pre-Natal and MSM Screening
- Anticipated FDA Submissions in 2013, with 2014 Clearances
- Additional Products for Public Health Channel
- Leveraging DPP® Multiplexing Features



# Pipeline: Rapid Hepatitis C Point-of-Care Diagnostic

- Data Published in Journal of Clinical Virology showed good performance of Chembio's 1st Generation Prototype Assay
- Completed Feasibility to Establish Performance Comparable to Only POCT HCV Test – 2013 R&D to incorporate additional value-added features
- Recent CDC recommendations for testing on everyone born between 1945-1964
- Anticipated Timeline
  - Development & Clinical Trials – 2013-2014
  - US Market Launch Anticipated - 2015

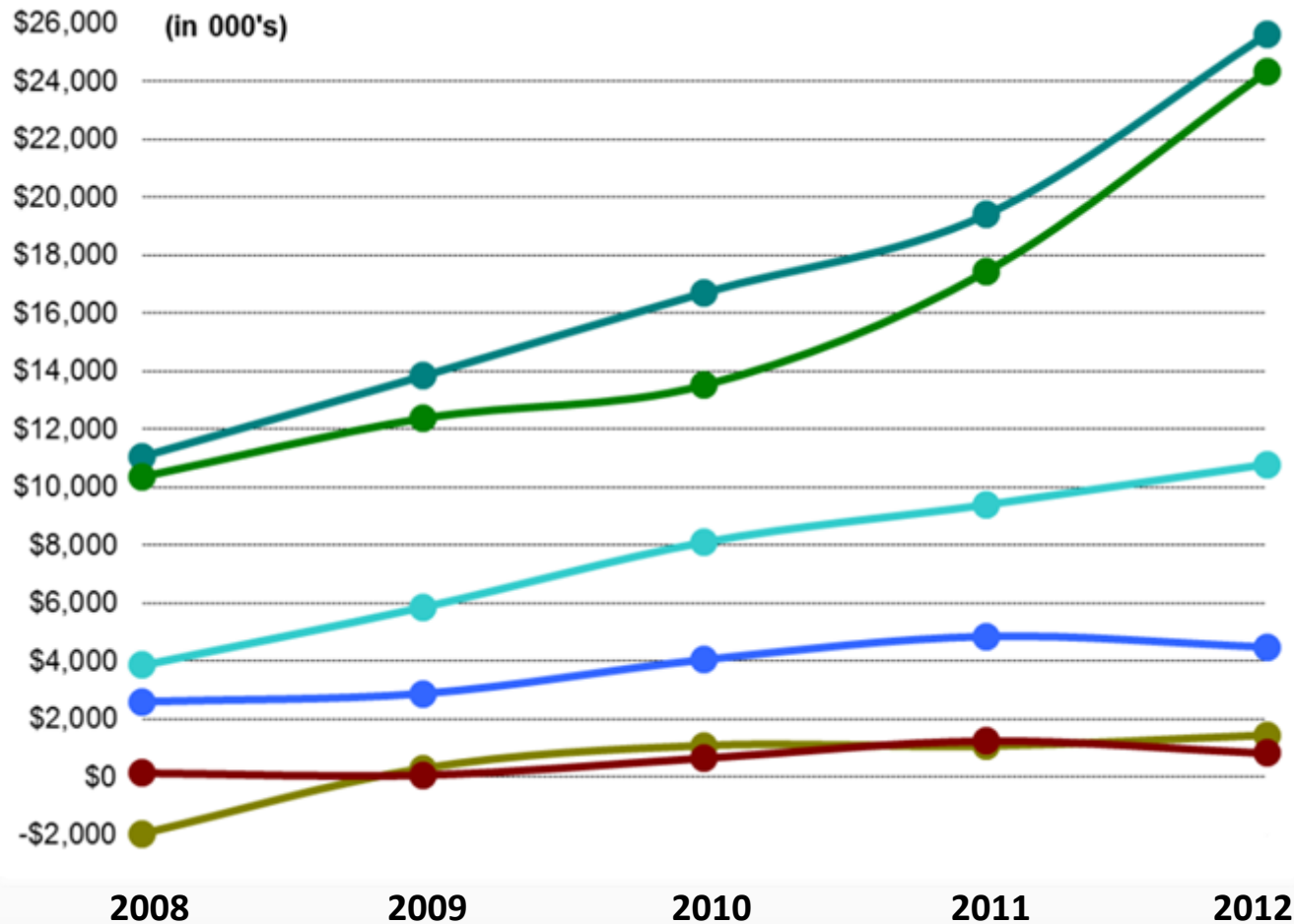






# Selected Financial Data FY2008 –2012

## Reporting Record Revenues Again for FY2012



**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**

# Strong Revenue & Operating Income Growth Q1 2013 and Years ended 2012 and 2011

| in (000's)                               | 3 Mos Ended<br>March 31, 2013 |              |            | 3 Mos Ended<br>March 31, 2012 |              |            | Year Ended<br>Dec 31, 2012 |               |            | Year Ended<br>Dec 31, 2011 |               |            |
|--|-------------------------------|--------------|------------|-------------------------------|--------------|------------|----------------------------|---------------|------------|----------------------------|---------------|------------|
| Net Product Revenues                     | \$                            | 6,313        |            | \$                            | 6,363        |            | \$                         | 24,327        |            | \$                         | 17,422        |            |
| Non-Product Revenues                     | \$                            | 365          |            | \$                            | 290          |            | \$                         | 1,283         |            | \$                         | 1,966         |            |
| <b>TOTAL REVENUES</b>                    | <b>\$</b>                     | <b>6,678</b> |            | <b>\$</b>                     | <b>6,653</b> |            | <b>\$</b>                  | <b>25,610</b> |            | <b>\$</b>                  | <b>19,388</b> |            |
| <b>GROSS MARGIN</b>                      | <b>\$</b>                     | <b>2,694</b> | <b>40%</b> | <b>\$</b>                     | <b>3,333</b> | <b>50%</b> | <b>\$</b>                  | <b>10,790</b> | <b>42%</b> | <b>\$</b>                  | <b>9,390</b>  | <b>48%</b> |
| <b>OPERATING COSTS:</b>                  |                               |              |            |                               |              |            |                            |               |            |                            |               |            |
| Research and development exp.            | \$                            | 1,045        | 16%        | \$                            | 1,379        | 21%        | \$                         | 4,486         | 18%        | \$                         | 4,878         | 25%        |
| Selling, general and administrative exp. | \$                            | 1,162        | 17%        | \$                            | 1,234        | 19%        | \$                         | 4,852         | 19%        | \$                         | 3,424         | 18%        |
|  | \$                            | 2,207        |            | \$                            | 2,613        |            | \$                         | 9,338         |            | \$                         | 8,302         |            |
| <b>INCOME FROM OPERATIONS</b>            | <b>\$</b>                     | <b>487</b>   |            | <b>\$</b>                     | <b>720</b>   |            | <b>\$</b>                  | <b>1,452</b>  |            | <b>\$</b>                  | <b>1,088</b>  |            |
| <b>OTHER INCOME (EXPENSES):</b>          | <b>\$</b>                     | <b>1</b>     |            | <b>\$</b>                     | <b>(1)</b>   |            | <b>\$</b>                  | <b>(2)</b>    |            | <b>\$</b>                  | <b>(12)</b>   |            |
| <b>NET INCOME-Before Taxes</b>           | <b>\$</b>                     | <b>488</b>   | <b>7%</b>  | <b>\$</b>                     | <b>719</b>   | <b>11%</b> | <b>\$</b>                  | <b>1,450</b>  | <b>6%</b>  | <b>\$</b>                  | <b>1,076</b>  | <b>6%</b>  |
| Income tax (benefit) provision           | \$                            | 171          |            | \$                            | 286          |            | \$                         | 509           |            | \$                         | (5,133)       |            |
| <b>NET INCOME</b>                        | <b>\$</b>                     | <b>317</b>   | <b>5%</b>  | <b>\$</b>                     | <b>433</b>   | <b>7%</b>  | <b>\$</b>                  | <b>941</b>    | <b>4%</b>  | <b>\$</b>                  | <b>6,209</b>  | <b>32%</b> |

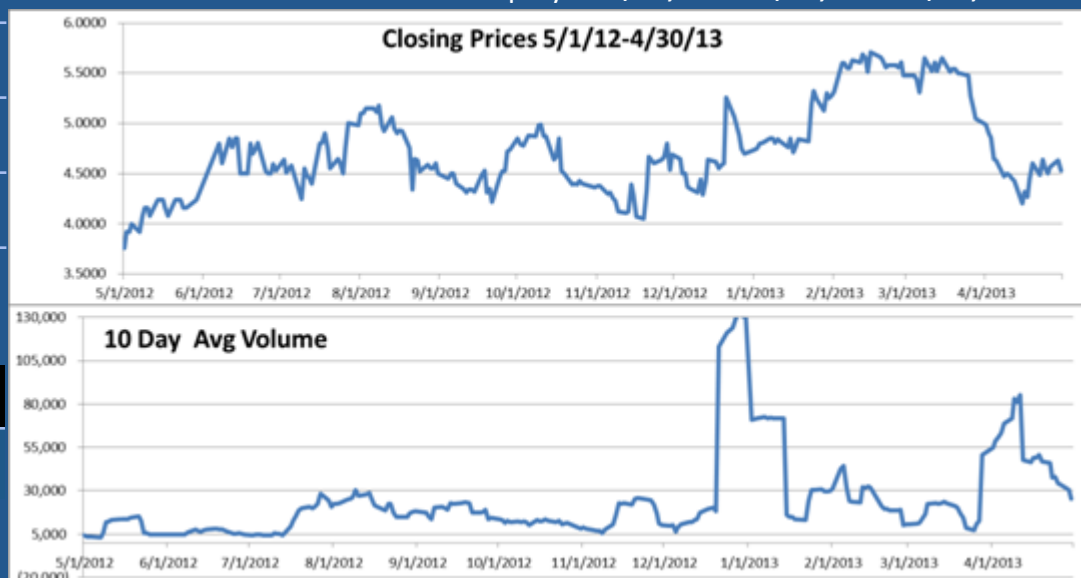
# CEMI Selected Share & Balance Sheet Data

*in millions except per share and daily volume data*

|                                       |                |
|---------------------------------------|----------------|
| Ticker Symbol (NASDAQ)                | <b>CEMI</b>    |
| Price 4/30/13                         | <b>\$4.53</b>  |
| 52-Week High                          | <b>\$5.80</b>  |
| 52-Week Low                           | <b>\$3.61</b>  |
| Outstanding Shares                    | <b>9.29</b>    |
| Market Capitalization                 | <b>\$42.07</b> |
| Fully Diluted Shares                  | <b>10.01</b>   |
| Managements Holdings                  | <b>1.62</b>    |
| Avg. Daily Volume (3 mos. to 4/30/13) | <b>32,000</b>  |
| Average Daily Volume (April 2013)     | <b>37,800</b>  |

| Options                    | Amt. | Avg. Ex. Price |
|----------------------------|------|----------------|
| 585K held by Mgmt. & Board | 725K | \$2.42         |

| (\$ in 000s)                             | Mar'13   | Dec'12   | Dec'11   |
|--|----------|----------|----------|
| Cash                                     | \$2,599  | \$2,952  | \$3,011  |
| Total Current Assets                     | 11,234   | 11,009   | 8,992    |
| Total Assets                             | \$17,473 | \$17,335 | \$15,486 |
| Total Current Liabilities                | 3,213    | 3,378    | 2,858    |
| Total Liabilities                        | 3,213    | 3,460    | 2,991    |
| Stockholders' Equity                     | 14,260   | 13,875   | 12,495   |
| Total Liabilities & Stockholders' Equity | \$17,473 | \$17,335 | \$15,486 |

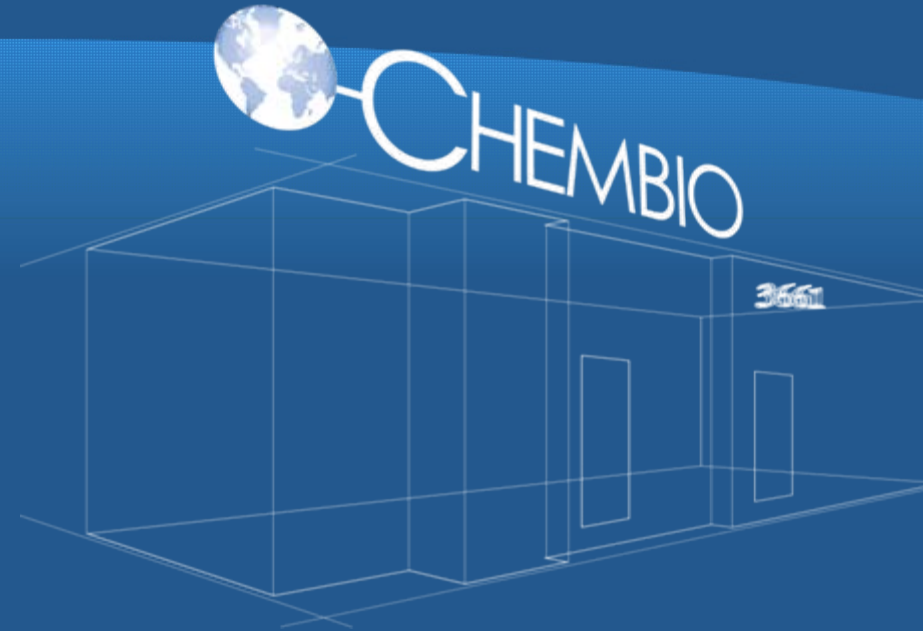


# Leadership

| Executive                |                                  | Joined Company |
|--------------------------|----------------------------------|----------------|
| Lawrence Siebert         | Chairman & CEO                   | 2002           |
| Richard Larkin           | CFO                              | 2003           |
| Javan Esfandiari         | SVP Research & Development       | 2000           |
| Tom Ippolito             | VP Regulatory & Clinical Affairs | 2005           |
| Sharon Klugewicz         | VP QA/QC & Technical Operations  | 2012           |
| Rick Bruce               | VP Operations                    | 2000           |
| Michael Steele           | VP Sales Marketing & Bus. Dev.   | 2012           |
| Independent Directors    |                                  | Joined Board   |
| Gary Meller, MD, MBA     |                                  | 2005           |
| Katherine Davis, MBA     |                                  | 2007           |
| Barbara DeBuono, MD, MPH |                                  | 2011           |
| Peter Kissinger, Ph.D    |                                  | 2011           |

# 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 171**

116

15

29

11



Operations

Reg. & Clinical QA & QC

R&D

SG&A

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