

# RAPID Tests for EARLIER Treatment

DPP\*HIV1/2

TC



January 2012

### **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 to obtain regulatory approval in a timely manner, as well as the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forwardlooking 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.



# **Chembio Overview**

- Develops, Manufactures, Licenses and Markets Rapid Point-of-Care (POC) Diagnostic Tests
  - In-licensed Lateral Flow technologies & Chembio's Patented Dual Path Platform (DPP<sup>®</sup>)
  - Branded, Private Label, and Licensing Strategies Anticipated to Result in Continued Organic Growth

# Profitable 2009-2010 and through 9/30/2011

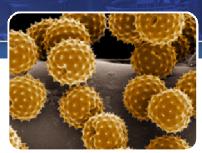
- 38% Product Revenue Growth through 9/30/2011 v. 9/30/2010
- Continued Strong Revenue Growth Anticipated in 2012, primar from new products approved in Brazil
- Fully Integrated Facility in Medford, NY
  - FDA PMA (CBER) & USDA Approved; ISO 13.485 Certified
  - ~28,000 Square Feet; 140 Employees





# **POCTs - A Growing Global Market**

- \$7B Global Point-of-Care Test (POCT) Market within \$40B In-Vitro Diagnostics Market
- POCTs for Sexually Transmitted Diseases (STDs) & Blood Pathogens
  - Public/Global Health Programs
  - OTC HIV
- Other POCT Markets
  - Veterinary (Vector-borne, Companion Equine, Production, Specialty)
  - Screening Programs





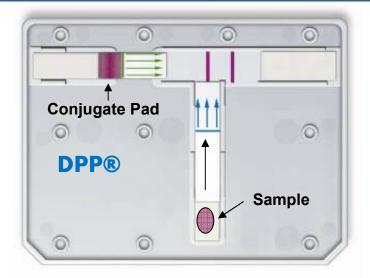


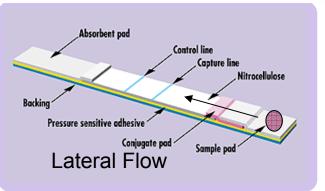




## DUAL PATH PLATFORM (DPP<sup>®</sup>) – Improved Accuracy and Multiplexing vs. Lateral Flow Technologies

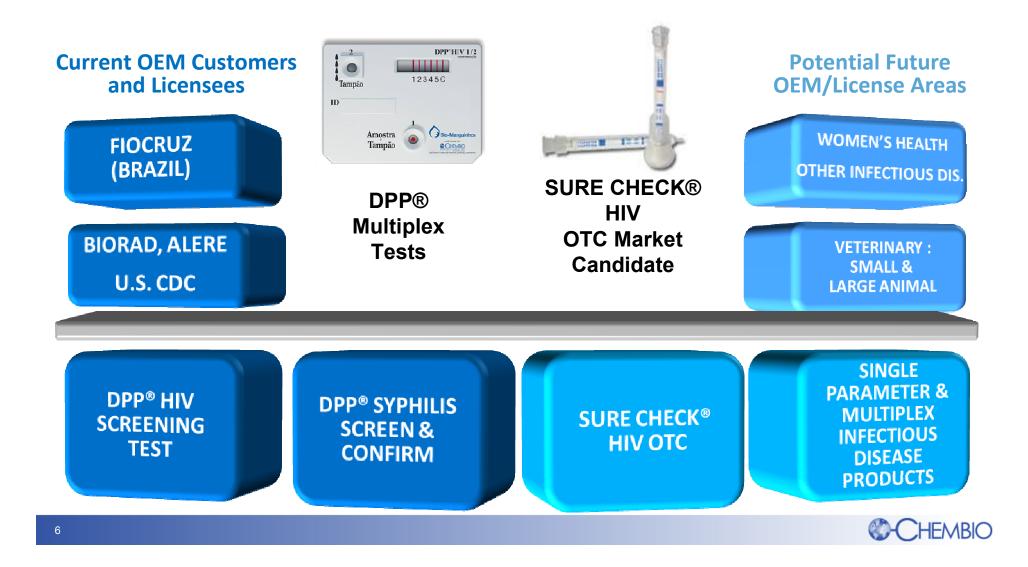
- Patented Platform Technology with a Multitude of Potential Diagnostic Applications
  - Foundational DPP Patent issued in U.S.;
    Additional patents issued or pending in U.S. & many foreign jurisdictions
- Independent Sample Path and Direct Binding
  - Improves Performance (Sensitivity and Specificity)
  - Enar 2 2 Tampão 12345C DPP'HIV1/2 12345C DPP'HIV1/2 12345C DPP'BIV1/2 DPP'HIV1/2 DPP'BIV1/2 DPP'BIV1







### Our Branded Products Will Support and be Complemented By our OEM and Licensed Products



# **Chembio's FDA Approved Rapid HIV Tests**

Marketed By Alere in U.S. and Chembio Distributors ex-U.S. for Professional Use

- Estimated 20% or more of the 1.1MM HIV+ individuals in U.S. are not aware of their status
- Products sold in US professional market by Alere Inc. (NYSE:ALR) as Clearview<sup>®</sup> brand
  - 10-Year exclusive agreement through Sept. 2016 Based on ASP sharing
  - 9 Month YTD Sales: \$5.39 Million, a 52% increase v. comparable 2010 period
- Ex-US under Chembio Brands (STAT-PAK® & SURE CHECK®)
- Chembio Pursuing OTC Approval for Sure Check



# FDA Approved Rapid HIV Tests and Chembio's DPP HIV Test that is Pending Regulatory Approval

	Clearview Complete	Clearview STAT PAK	DPP HIV Screen	OraQuick	Uni-Gold
		ather part		June 1	
Manufacturer	Chembio	Chembio	Chembio	Orasure Technologies, Bethlehem PA	Trinity Biotech, Dublin Ireland
Current or Planned Distribution	Private Label for Alere Direct & Distribution	Private Label for Alere Direct & Distribution	Direct & Distributors	Direct sales force	Direct sales force & distributors
FDA Approval Date	2006	2006	Clinical trials 90% Completed	2003	2003
Technology	Lateral Flow	Lateral Flow	Dual Path Platform (DPP <sup>®</sup> )	Lateral Flow	Lateral Flow
Est. US Market Shr.	8%	12%	N/A	65%	15%
FDA Sensitivity	99.7%	99.7%	TBD	99.3%OF/99.6% WB	100%
FDA Specificity	99.9%	99.9%	TBD	99.8%OF/100% WB	99.7%
Features					
Sample Types	All Blood Matrices	All Blood Matrices	Blood & Oral Fluid Claims being pursued	Oral Fluid and all blood matrices except serum	All Blood Matrices
True IgG Control	Υ	Y	Υ	Υ	Ν
Sample Size (in microliters)	<5	<5	<5	<5	40
HIV-2	Υ	Y	Υ	Υ	Ν



# Pipeline: Chembio-Branded Products Anticipated Timelines – US Market

CLINICAL TRI	ALS/REGULATORY SUBMISSIONS	REGULATORY APPROVAL OR CLEARANCE/COMMERCIAL SALES							
Product	2011	2012	Est. Current/Potential U.S. Market Size						
DPP <sup>®</sup> HIV Screen	Clinical Trials 90%+ Complete; PMA Module I submitted and responded. PMA Module II submitted October.	Respond to Module II & Complete Clinical Trials. Submit Module III. FDA Approval, CLIA waiver, US Market Launch 1H 2013	\$70MM/\$150MM US POCT Market Developed into 7MM Unit Market since 2003						
DPP <sup>®</sup> Syphilis Screen & Confirm	CE Marking Granted October Establishing EU Distribution. Clinical Trials Commenced for US FDA 510(K) Submission	Launch in EU Complete clinical trials in US & Submit 510(K) to FDA for Clearance & US Market Launch 1H 2013	NA/\$70MM 69MM Syphilis tests performed in US; 50MM Clinical; Assumes 20% convert to POCT						
Sure Check <sup>®</sup> HIV OTC	Product Already Approved for Professional Use which is Pre- requisite	Complete Pre-IDE Requirements and Begin Phase II Clinical Trials	NA/\$150MM Assumes 5MM unit market @ \$30/OTC unit						



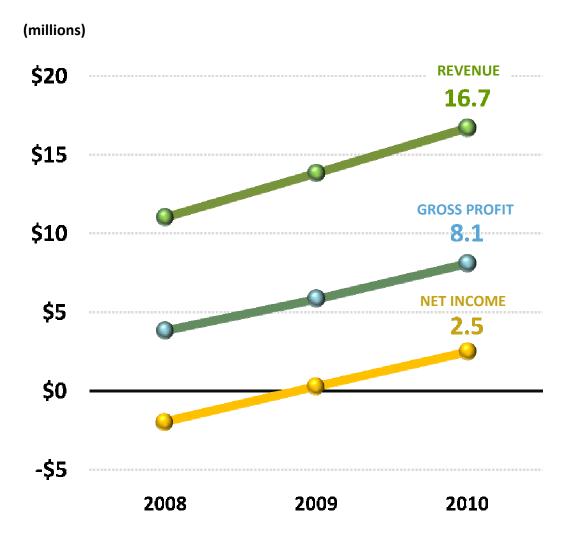
### **Pipeline: OEM Contracts with FIOCRUZ Brazil** Anticipate Minimum of \$9MM in full year 2012 Revenues vs. \$2.6MM through 9/30/2011 YTD

Contract	2010	2011	2012			
	Approved	Commercial Sales	Commercial Sales			
DPP® HIV Screening	Commercial Sales	Commercial Sales				
DPP® HIV Confirmatory	Approved	Commercial Sales	Commercial Sales			
DPP® Syphilis Treponemal		Approved Q1 '11	Commercial Sales			
	Agreement Signed	Commercial Sales				
DPP® Syphilis	December 2010		Submission			
Treponemal/ Non-Treponemal			Approval			
DPP® Canine	Submitted	Approved Q1'11	Commorcial Salas			
Leishmaniasis	Submitted	Commercial Sales	Commercial Sales			
DPP® Leptospirosis		Submitted Q2' 2011	Commercial Sales			
		Approved Q3'11				



# Financial Summary - FY2008-2010 Results

- Record Revenues and Earnings
- Improving Gross Margins
- Operating Cash Flow Strengthened Balance Sheet
- \$1.5MM QTDP Grant in 2010 credited to R&D Expense
- \$.3MM 2010 Expense related to possible Strategic Transaction





# 2010 Full Year and Nine Month 2010 & 2011 Selected Financial Results

	September 30, 2011-YTD		September 30, 2010-YTD		December 31, 2010	
Net Product Revenues	\$11,516,325		\$8,337,133		\$13,516,359	I
Non-Product Revenues	1,655,294		2,700,728		3,188,344	
TOTAL REVENUES	13,171,619		11,037,861		16,704,703	
GROSS MARGIN	6,647,353	50%	5,609,841	51%	8,100,699	48%
OPERATING COSTS:						
Research and development expenses	3,697,309	28%	2,822,455	26%	2,586,308	15%
Selling, general and administrative expense	2,412,867	18%	2,143,715	19%	2,940,721	18%
	6,110,176		4,966,170		5,527,029	
INCOME FROM OPERATIONS	537,177		643,671		2,573,670	
OTHER INCOME (EXPENSES):	(9,030)		(11,103)		(60,326)	
NET INCOME	528,147	4%	632,568	6%	2,513,344	15%

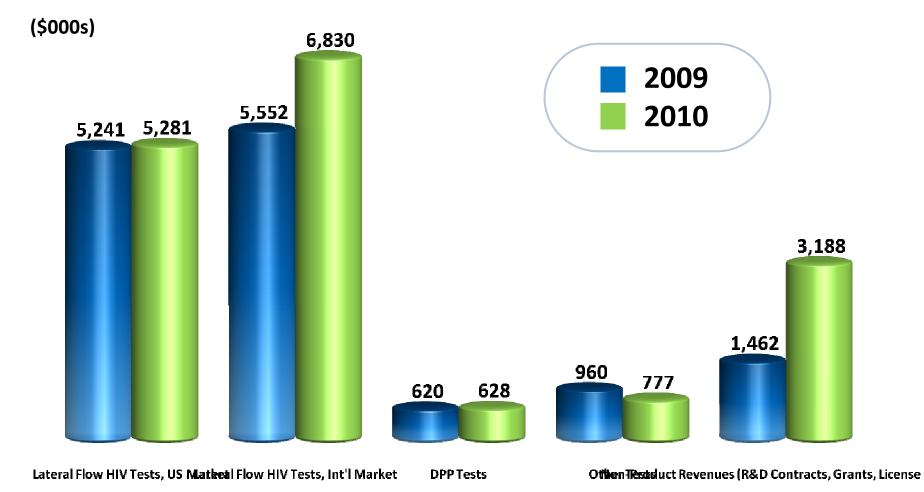


# Three Months September 2010 & 2011 Selected Financial Results

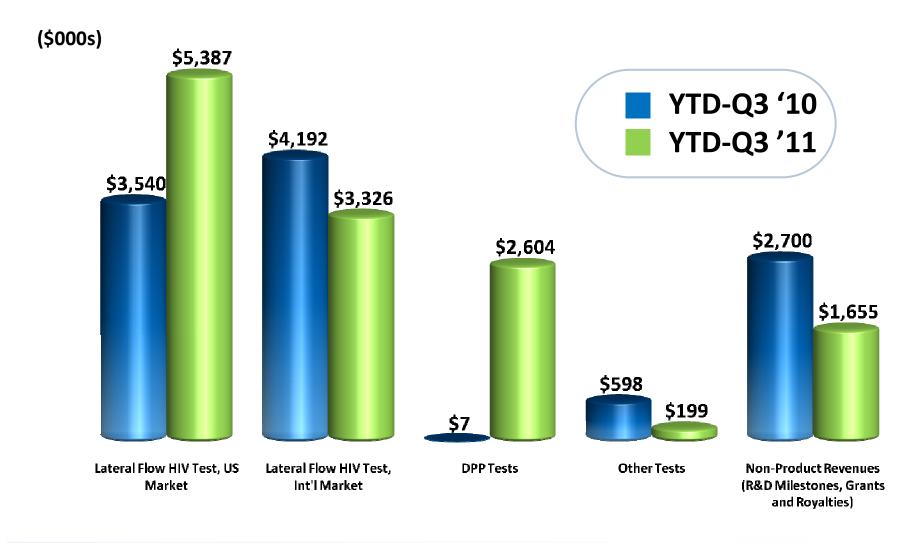
	3 MOS Sept 30, 2011	3 MOS Sept 30, 2010
Net Product Revenues	\$5,526,883	\$3,786,572
Non-Product Revenues	394,904	718,431
TOTAL REVENUES	5,921,787	4,505,003
GROSS MARGIN	2,670,733 45%	<b>2,208,501</b> 49%
OPERATING COSTS:		
Research and development expenses	<b>1,242,295</b> <sup>21%</sup>	5 <b>1,230,100</b> 27%
Selling, general and administrative expense	<b>949,237</b> 16%	801,854 18%
	2,191,532	2,031,954
INCOME FROM OPERATIONS	479,201	176,547
OTHER INCOME (EXPENSES):	(3,596)	(8,571)
NET INCOME	475,605 8%	167,976 4%



# **Revenue Growth by Category: 2009 vs. 2010**



### **Revenue Growth by Category: YTD-Q3-2011 vs.** YTD-Q3-2010





# **Selected Balance Sheet Data**

(\$ in millions)	Sept'11	Dec. '10	Dec. '09
Cash	\$ 3,045	\$ 2,136	\$ 1,068
Accounts Receivable	2,658	3,946	1,776
Inventories	2,588	1,349	1,556
Total Current Assets	8,480	7,637	4,667
Net Fixed Assets	849	813	580
Other Assets	770	636	1,068
Total Assets	\$ 10,099	\$ 9,086	\$ 6,315
Total Current Liabilities	3,199	3,076	3,173
Total Liabilities	3,345	3,277	3,227
Total Equity	6,754	5,809	3,088
Total Liabilities & Stockholders' Equity	\$ 10,099	\$ 9,086	\$ 6,315



# **Anticipated Milestones 2012-13**

#### Clinical & Regulatory Programs for Branded Products

#### •DPP<sup>®</sup> HIV Oral Fluid Test

- Completion of Clinical Trials
- Submit Module III for DPP®HIV PMA
- Receive FDA PMA Approval and CLIA waiver

#### •Syphilis Screen & Confirm

- Completion of Clinical Trials
- Submit to FDA for 510(K) Clearance
- Receive Clearance

#### •Sure Check<sup>®</sup> HIV OTC Pre-IDE

- Commence & Complete Phase II Clinical Trials

#### **Product Revenues & Operating Results**

- Full Year of New Products Launched in Brazil through FIOCRUZ
- Launch of DPP<sup>®</sup> HIV & Syphilis Tests in Global & US Markets
- Continued US Lateral Flow HIV Test Market Share Gains
- Potential New International Market Opportunities for Unique DPP<sup>®</sup> Products

#### Potential New Products & Marketing Agreements

•Developments Related to Potential New Branded and/or OEM Products & Related Strategic Collaborations

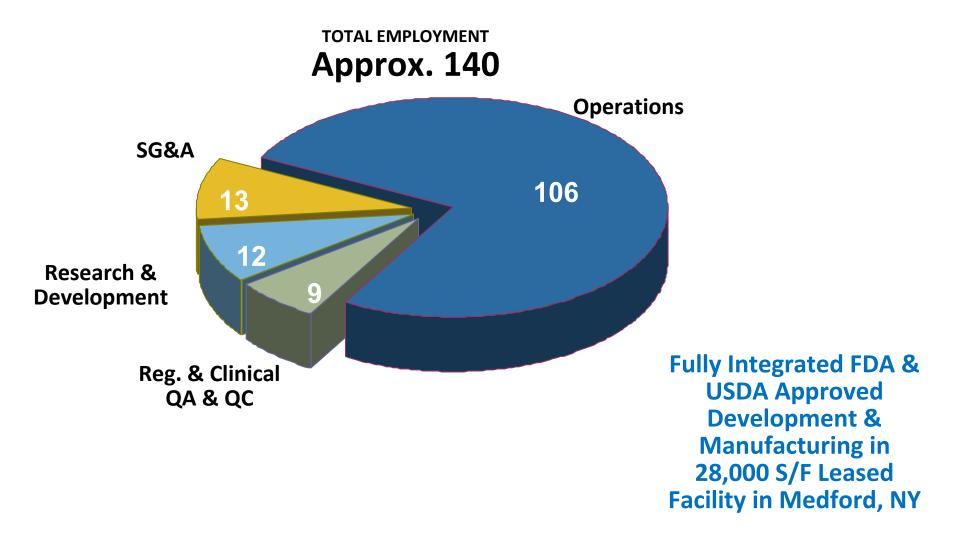
# Leadership

Executive		Joined Company*
Lawrence Siebert	Chairman & CEO	2002
Richard Larkin	CFO	2003
Javan Esfandiari	SVP R&D	2000
Tom Ippolito	VP Regulatory, Clinical, QA/QC	2005
Rick Bruce	VP Operations	2000

Independent Directors	Joined Board
Gary Meller, MD, MBA	2005
Kathy Davis, MBA	2007
Barbara DeBuono, MD, MPH	2011
Peter Kissinger, Ph.D	2011

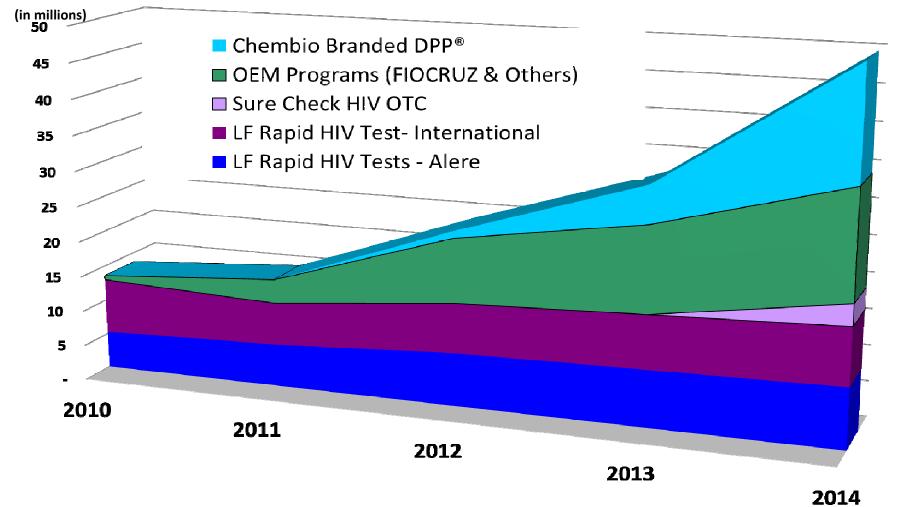


# **Organization & Facility**





# **Potential Impact of OEM & Branded Products on Revenue\***



\*This portrays one scenario of the potential impact of new products. It is based on a number of assumptions, including but not limited to regulatory approvals, market demand, market share, sales and marketing, and pricing, of which there can be no assurance



## **CEMI Selected Share Data**

(in millions except per share data)

Ticker Symbol (OTC:QB)	CEMI
Price 12/30/11	\$0.42
52 Week High	\$0.580
52 Week Low	\$0.210
Outstanding Shares (MM)	63.3
Market Capitalization (MM)	\$26.6
Fully Diluted (FD) Shares (MM)	69.6
Management Holding (MM)-FD	12.3
Average Daily Volume (3 Mos)	31,000

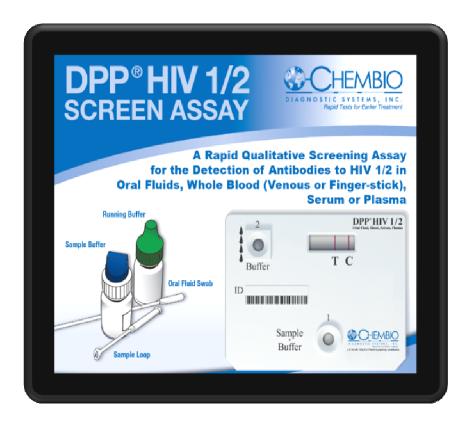
<b>Options and Warrants</b>	Amt.	Avg. Ex. Price
<b>Options</b> (4.64MM held by mgmt. & board)	6.18	\$0.213
Warrants (Expire by 2/15/12)	0.07	\$0.810
<b>Total Options &amp; Warrants</b>	6.25	\$0.220





# DPP<sup>®</sup> HIV Screening Assay For Use with Oral Fluid or Blood Samples

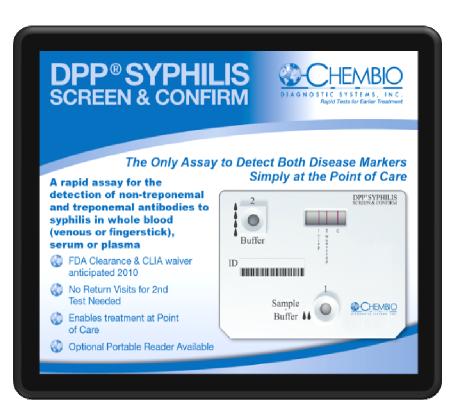
- Submitted PMA Module I in Q2 2011
- Submitted PMA Module II October 2011 US
- Clinical Trials Being Completed for Submissions of Module III in Q1 2012
- Anticipated FDA PMA Approval, CLIA waiver in 2012
- Market Launch in Q4 or early 2013





# **DPP® Syphilis Screen & Confirm**

- First POCT in US for Syphilis
- All Pregnant Women Tested for Syphilis
- Current Laboratory Tests Inadequate
- Enables Confirmation & Treatment At POC
- CE Marked October 2011, International Distribution being Established
- US 510(K) Clinical Trials 2012
- Anticipate FDA Clearance 2013





# **SURE CHECK® HIV OTC**

Pre-IDE Studies 2011, Q1-2012 with "Phase II" Clinical Trials Beginning Thereafter

- Patented All-In-One Barrel Device
- Increasing Market Acceptance in Professional Market (Clearview Complete by Alere)
- IDE, Clinical Trials 2012-13
- Anticipated FDA Approval 2014



# **Comparative Selected Operating Results** 2005-2010

	Dec-10		Dec-09			Dec-08	_		Dec-07			Dec-06	_		Dec-05
REVENUES:	Det-10		Dec-05			Dec-08			Dec-07			Dec-00			Dec-05
Net sales	\$ 13,516,359		\$ 12,372,493		\$	10,355,768		\$	8,764,877		\$	6,294,012		\$	3,359,532
Research grant income	3,188,344		1,461,755			693,803			466,071			208,468			581,198
TOTAL REVENUES	16,704,703		13,834,248			11,049,571			9,230,948			6,502,480			3,940,730
Cost of sales	8,604,004		7,973,843			7,197,850			6,435,239			4,894,208			2,996,082
GROSS PROFIT	8,100,699	48%	5,860,405	42%		3,851,721	35%		2,795,709	30%		1,608,272	25%		944,648
OVERHEAD COSTS:															
Research and development expenses	2,586,308	15%	2,883,696	21%		2,605,343	24%		1,906,653	21%		1,401,472	22%		1,364,898
Selling, general and administrative expenses	2,940,721	18%	2,659,382	19%		3,317,046	30%		3,765,220	41%		4,786,993	74%		2,877,737
	5,527,029		5,543,078			5,922,389			5,671,873			6,188,465			4,242,635
INCOME (LOSS) FROM OPERATIONS	2,573,670		317,327			(2,070,668)			(2,876,164)			(4,580,193)			(3,297,987)
OTHER INCOME (EXPENSES):															
Other income (expense)	(3,923)		(6,696)			95,812			120,862			(57,464)			21,867
Interest income	4,147		9,032			34,403			145,289			29,532			39,803
Interest expense	(14,727)		(10,603)			(8,317)			(16,879)			(386,895)			(15,683)
	(14,503)		(8,267)			121,898			249,272			(414,827)			45,987
INCOME (LOSS) BEFORE INCOME TAXES	2,559,167		309,060			(1,948,770)			(2,626,892)			(4,995,020)			(3,252,000)
Income taxes	45,823		-			-			-			-			-
NET INCOME (LOSS)	2,513,344	15%	309,060	2%		(1,948,770)	-18%		(2,626,892)	-28%		(4,995,020)	-77%		(3,252,000)
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ 2,513,344	15%	\$ 309,060	2%	\$	(1,948,770)	-18%	\$	(8,272,202)	-90%	\$	(8,205,066)	-126%	\$	(6,769,022)
Basic income (loss) per share	\$ 0.04		\$ 0.00		\$	(0.03)		\$	(0.57)		\$	(0.80)		\$	(0.88)
					~	(0.00)		\$	(0.57)		~	(		+	(0.00)
Diluted income (loss) per share	\$ 0.04		 \$ 0.00		\$	(0.03)		Ş	(0.57)		\$	(0.80)		\$	(0.88)
Diluted income (loss) per share Weighted average number of shares outstanding, basic	\$ <b>0.04</b> 62,102,861		<b>\$ 0.00</b> 61,946,435		Ş	( <b>0.03</b> ) 61,266,954		Ş	(0.57)		Ş	<b>(0.80)</b> 10,293,168		Ş	7,705,782





# RAPID Tests for EARLIER Treatment

DPP\*HIV1/2

TC

### Thank You www.chembio.com OTC-QB: CEMI

#### **Investor Presentation**

January 2012