

# **Corporate Presentation**

January 2023



## Safe Harbor Statement

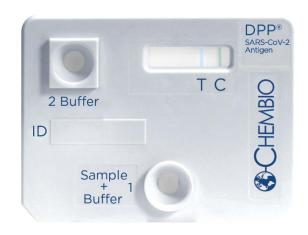
Statements contained in this presentation that are not historical facts may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the intent, belief or current expectations of Chembio and its management with respect to the further development of its products. Such statements, which are only expectations, 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 forward-looking statements due to a number of important factors, including, but not limited to the following, any of which could be exacerbated even further by the continuing COVID-19 outbreak in the United States and globally: the ability of Chembio to maintain existing, and timely obtain additional, regulatory approvals, particularly for its proposed diagnostic tests; Chembio's dependence upon, and limited experience with, new or forthcoming diagnostic tests; the highly competitive and rapidly developing market for testing solutions in our areas of focus, which includes a number of competing companies with strong relationships with current and potential customers, including governmental authorities, and with significantly greater financial and other resources that are available to Chembio; and the risks of doing business with foreign governmental entities, including geopolitical, international and other challenges as well as potential material adverse effects of tariffs and other changes in U.S. trade policy. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and its subsequent Quarterly Reports on Form 10-Q, particularly under the heading "Risk Factors".

DPP, STAT-PAK, STAT-VIEW and SURE CHECK are Chembio's registered trademarks. For convenience, these trademarks appear in this presentation without

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We deliver high-quality diagnostic tests that provide results in approximately 15 minutes using fingertip blood, nasal swabs and other sample types









## Investment Highlights

Broad technology portfolio including proprietary dual path platform ("DPP") technology with expanding portfolio of point-of-care and over-the-counter ("OTC") diagnostic applications

Scaled commercial team and sales channels to penetrate high growth markets

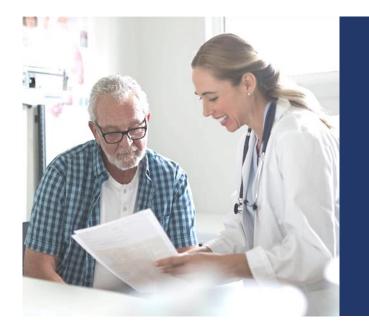
Current and pipeline products focused on anticipated higher-value testing applications and markets to drive average sales prices

Investments in automation and contract manufacturing intended to lower cost of product revenue

Profit improvement initiatives focused on lowering manufacturing and infrastructure costs as well as strategic review of non-core business assets



### Point-of-Care Testing: an expanding solution for the evolving healthcare system



Delivers rapid results while patients are on site

Enables immediate triage and treatment decisions

Reduces costs and improves outcomes in the modern, decentralized healthcare system



# **Chembio Snapshot**

Chembio Develops and Commercializes High-quality Point-of-Care and OTC Diagnostic Tests for the Rapid Detection and Diagnosis of Infectious Diseases That Provide Results in Approximately 15 Minutes Using Fingertip Blood, Nasal Swabs and Other Sample Types

#### **3 Rapid HIV Tests in the U.S.**<sup>1</sup>

HIV 1/2 STAT-PAK Assay SURE CHECK HIV 1/2 Assay DPP HIV 1/2 Assay



23

Issued U.S.

Patents

**211** Employees Worldwide<sup>2</sup> **80+** Distribution Partners

#### **3 Core Product Technologies**



#### Pre-2020

Broad portfolio of infectious disease products was focused principally on sexually transmitted disease and fever & tropical disease in high volume low margin markets

### 2020 – 2021

Shifted substantially all resources to **leverage the DPP technology platform** to address the acute & escalating need for diagnostic testing for **COVID-19** 

#### 2022 & On

Exciting future framed around **extracting value** from DPP technology for anticipated highervalue point-of-care assays in developed markets, SURE CHECK platform for developing OTC markets, and executing the Global Competitiveness Program (GCP)



# Global Competitiveness Program | 6 Key Drivers

Designed to Accelerate the Company's Path to Profitability



Shift focus from low-margin government contracts to higher margin point-of-care and OTC business



Focus on products with recurring revenues in growth markets



Lower manufacturing costs through leveraging the company's prior investments in automation



Conduct strategic review of non-core businesses and assets



Expand test portfolio with additional DPP tests targeting SARS, Respiratory, HIV/Syphilis, Syphilis and Lyme



Reduce infrastructure costs





# Chembio and Market Tailwinds Enable Long-Term Growth

### Chembio

Participation in large, high-growth markets

Product portfolio leverages unique technology platforms – (DPP, SURE CHECK, STAT-PAK & in-licensed) to deliver value in premium verticals

Hybrid commercial approach utilizing direct and distribution channels to maximize footprint across end markets

Manufacturing automation driving capacity expansion and improved efficiency

### Market

Decentralized healthcare delivery

Self-testing

Workforce shortages





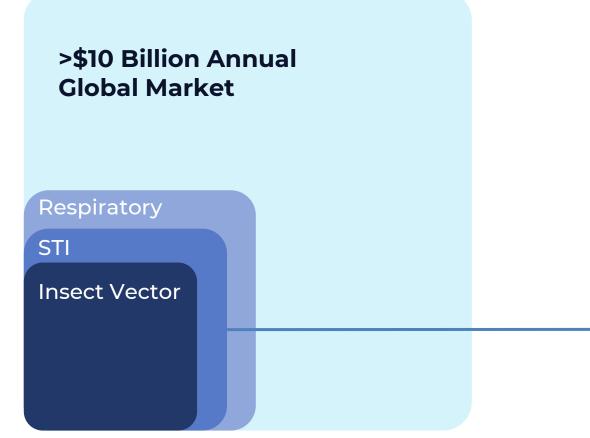
# Proliferation of Point-of-Care Diagnostics

Pursuing Global OTC Opportunity – delivering tests to patients



# Point-of-Care Diagnostics Market

Large and growing opportunity



### Participating in fast growing segments



(Not to scale, relative sizing)

Data does not include the impact of COVID

Source: "Influenza Testing Products Market" Page 52 & Page 57, Global Point of Care Diagnostics Market to 2019, The Insight Partners. Aug 2019

https://www.cdc.gov/mmwr/volumes/68/wr/mm6824a3.htm#:~:text=Virus%20Surveillance&text=During%20September%2030%2C%202018%E2%80%93May,5.0%25)%20for%20influenza%20B. https://idhjournal.com/article/S2468-0451(19)30018-5/fulltext https://www.frontiersin.org/articles/10.3389/fped.2019.00322/full

CHEMBIO D I A G N O S T I C S, I N C.

## Chembio Addresses Unmet Stakeholder Needs

- ✓ Accurate results
- Complete diagnostic information: advanced multiplexing, objective, numerical data
- ✓ Removes capital cost barrier







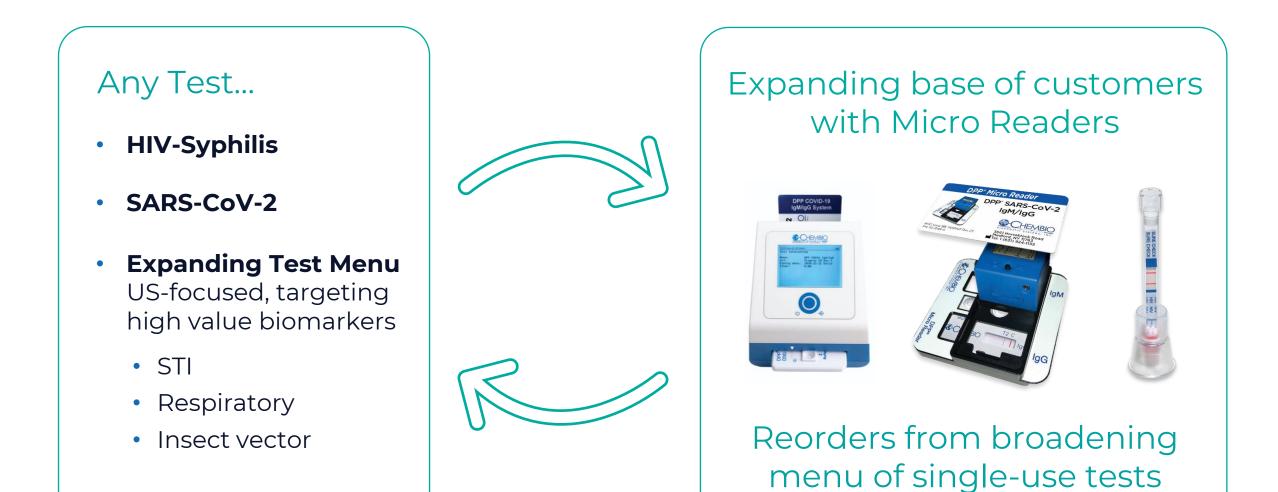
X Inconsistent results

### X Difficult to interpret results

X Significant capital outlay



# Reader and Tests Enable Recurring Revenue Model





# Patented DPP Technology Platform

### Features

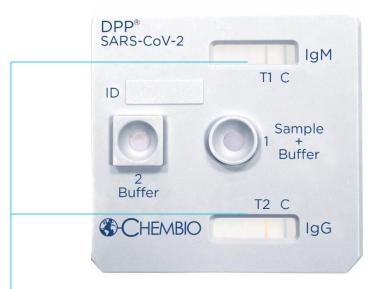
Simple – Easy to use

- $\overline{(2)}$
- Fast Results in ~15 minutes

Reliable – FDA approved, CLIA waived<sup>1</sup>

### Uniqueness

- Enhanced sensitivity and specificity
- Advanced multiplexing capabilities
- Numerical results with DPP Micro Reader within 15 seconds







# SURE CHECK Self-Testing Platform

### Features

Or Novel Design | All-in-one sample collection and test device

Convenient | Self-contained unit including safety materials<sup>1</sup>

Trusted & Proven | Over 13M self-tests used professionally

### Overview

- Chembio's SURE CHECK HIV 1/2 Assay is an FDA-approved, CLIA-waived<sup>2</sup> rapid point-of-care test that detects antibodies to HIV-1 and HIV-2
- World's smallest sample size: 2.5 µl
- Self Testing/OTC product in over 40,000 international pharmacies
- Menu expansion opportunities



**SURE CHECK HIV Self-Test** Penetrating OTC (pharmacy and eCommerce) markets in Brazil and Europe, pursuing U.S.



# STAT-PAK Technology Platform

### Features

Chembio's HIV 1/2 STAT-PAK Assay is the only HIV test that exceeds WHO performance thresholds<sup>1</sup>

Innovative Design | Small sample volume of 5-10 μl

Easy to Use | Test in 3 simple steps

HIV 1/2
STAT-PAK
Assay

Chagas STAT-PAK

Assay



### Overview

- Two main tests: (i) HIV 1/2 STAT-PAK Assay and (ii) Chagas STAT-PAK Assay
- Chagas Assay boasts 97.5% agreement to Enzyme-Linked Immunoassay<sup>2</sup>
- Minimal training required to use





## Proven Track Record of Global Product Approvals

### U.S.A.

DPP HIV-Syphilis System DPP HIV 1/2 SURE CHECK HIV 1/2 HIV 1/2 STAT-PAK DPP Zika IgM DPP Ebola Antigen (EUA) DPP Cervid TB DPP Elephant TB

### LATAM

DPP SARS-CoV-2 Antigen DPP COVID-19 IgM/IgG System DPP Respiratory Antigen Panel DPP HIV-1/2 Assay SURE CHECK HIV 1/2 Assay HIV 1/2 STAT-PAK Assay SURE CHECK HIV Self-Test Chagas STAT-PAK **DPP HIV-Syphilis System** DPP Syphilis Screen & Confirm Assay DPP Zika IgM/IgG System DPP ZCD IgM/IgG System DPP Dengue NS1 Antigen System DPP Dengue IgM/IgG System DPP Chikungunya System DPP Leishmaniasis Assay DPP Confirmatory Assay DPP Microreader



## EMEA & Asia

DPP SARS-CoV-2 Antigen DPP SARS CoV-2 IgM/IgG **DPP Respiratory Antigen Panel** STAT-VIEW HIV 1/2 Assay SURE CHECK HIV 1/2 Assay HIV 1/2 STAT-PAK Assay SURF CHECK HIV Self-Test DPP HIV 1 Assay **DPP HIV-Syphilis** DPP Syphilis Screen & Confirm Assay DPP Zika IgM/IgG System DPP ZCD IgM/IgG System **DPP Dengue Combo** Chagas STAT-PAK Assay DPP Microreader DPP Microreader II



<sup>1</sup> International includes approval from any single or combination of ANVISA, CE Mark, WHO, or others. Specific country registrations may be required.

## Development Criteria & Go-to-Market Strategy

### Focus on higher margin business in growing markets

- Rapid diagnosis impacts patient treatment and outcomes
- 2 Existing diagnostics underserve clinical needs due to performance or availability
- **3** Regional, demographic or clinically unique opportunities

**Creating high value products** 

to leverage direct salesforce and distributor network





# **Expanding Test Portfolio**

### Tests provide unique solutions for growing markets

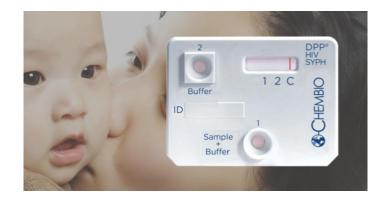
### SURE CHECK

- Recent OTC launches in Europe, UK & Brazil and pursuing U.S. OTC
- \$635 Million HIV point-of-care market<sup>1</sup>



#### CHEMBIO D I A G N O S T I C S, I N C.

### DPP HIV/Syphilis System



- The First & Only FDA approved CLIA-Waiver Pending HIV-Syphilis Rapid Test
- Opportunity to expand to nearly 250,000 CLIA-waived labs<sup>2</sup>

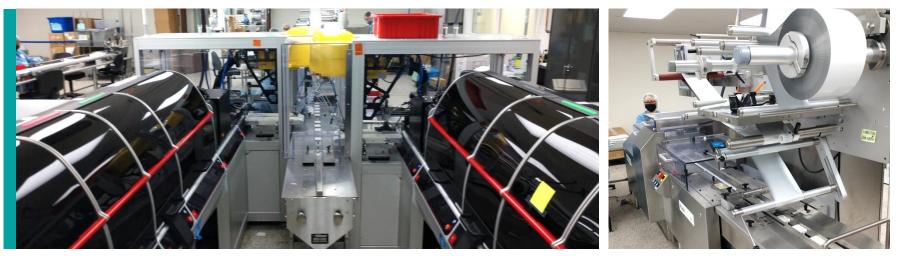
# Product Pipeline

Test	Feasibility	Regulatory 4Q2020–4Q2022	
		Pending	Approved
DPP HIV-Syphilis System		CLIA Waiver	FDA PMA
SURE CHECK HIV Self Test		US in development	WHO, CE, ANVISA, UK Southeast Asia
DPP SARS-CoV-2 Ag		FDA (EUA)	ANVISA, CE mark, SAPHRA
DPP SARS CoV-2 IgM/IgG			CE Mark
DPP Respiratory Antigen Panel			CE Mark, ANVISA
DPP SARS-CoV-2 Ag Self-Test		ANVISA, CE Mark	
DPP Syphilis TnT	Underway		
DPP Lyme IgM/IgG	Underway		



## **Operational Capabilities**

### **Enhanced Through Automation and Contract Manufacturing**



Fully-Automated Assembly & Packaging Lines



- **Flexible** Allows assembly of various configurations of tests on a single line
- >>>> Efficient Reduces variable manufacturing costs



Richard Eberly	President & CEO meridian BIOSCIENCE ZABbott
Larry Steenvoorden	EVP & CFO SIEMENS
Javan Esfandiari	EVP, Chief Technology Science Officer
Paul Angelico	EVP, Chief Operations Officer 🛛 🚾
Charles Caso	Sr. VP, Global Commercial Operations meridian BIOSCIENCE"
Tom Ippolito	VP, Quality & Regulatory Affairs
Stella Rivera	VP, Human Resources Wyeth Watson PALL



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