

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 30, 2018 (May 30, 2018)



CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of Incorporation)

**0-30379**

(Commission File Number)

**88-0425691**

(IRS Employer Identification Number)

**3661 Horseblock Road**

**Medford, NY 11763**

(Address of principal executive offices)

**631-924-1135**

(Registrant's Telephone Number)

**N/A**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**ITEM 7.01. REGULATION FD DISCLOSURE.**

On May 30, 2018, the Company posted a PowerPoint Presentation to its website titled “Corporate Presentation May 2018”. A copy of the presentation is provided herewith as Exhibit 99.1.

**ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS**

Exhibits.

99.1 Presentation, dated May 30, 2018, titled “Corporate Presentation May 2018”.

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

May 30, 2018

Chembio Diagnostics, Inc.

By: /s/ John J. Sperzel III  
John J. Sperzel III  
Chief Executive Officer

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## EXHIBIT INDEX

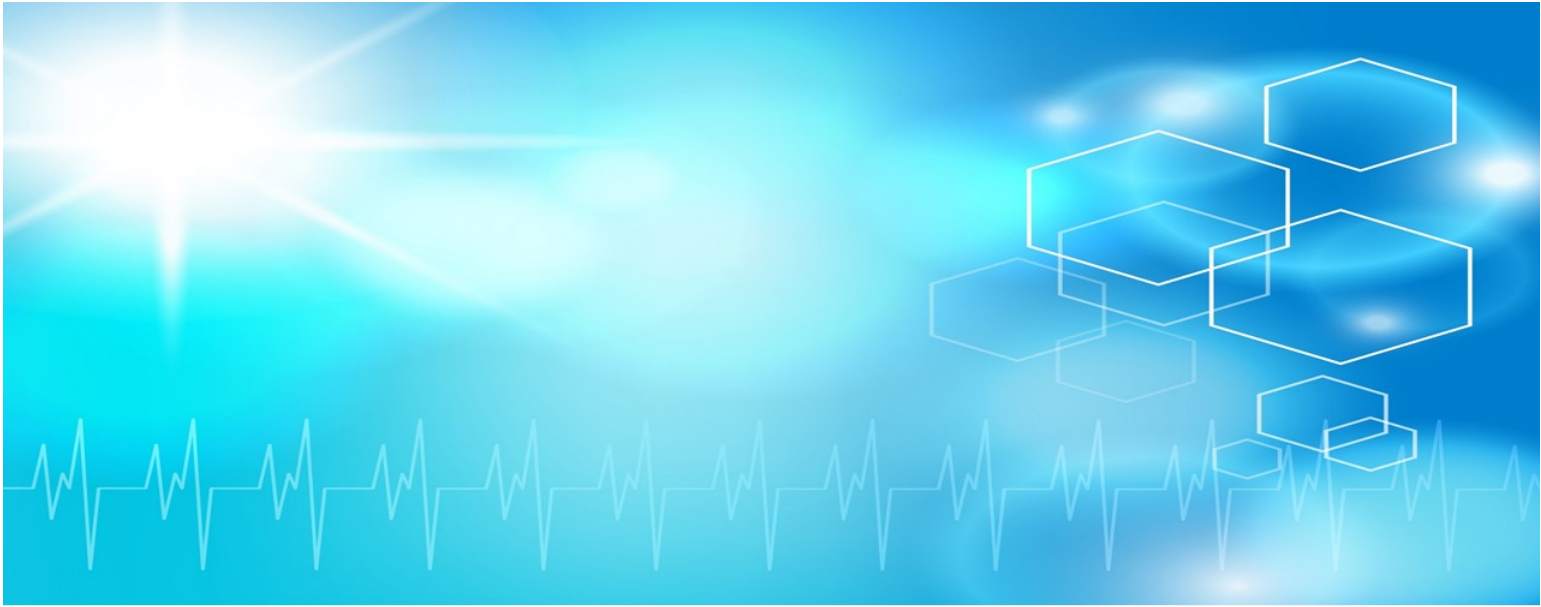
Exhibit  
Number

Description

[99.1](#)

Presentation, dated May 30, 2018, titled “Corporate Presentation May 2018”.

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# Corporate Presentation

May 2018



# Safe Harbor Statement

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.

## Our Vision

To reduce the incidence of disease globally

## Our Mission

To develop and commercialize rapid, easy-to-use, and reliable point-of-care tests that improve diagnosis and monitoring of disease

# Patented DPP® Technology Platform

Offers uniqueness and broad global market application

- Easy to use
- Fingerstick blood / oral fluid
- Results in 15 minutes
- Highly sensitive and specific
- Multiplexing capabilities
- Quantitative Results



99.8%  
Sensitivity<sup>1</sup>

100%  
Specificity<sup>1</sup>



# Strategic Focus

Executing on our key building blocks

## EXPANDING...

Our core sexually transmitted disease (STD) business

## BUILDING...

A broad tropical and fever disease portfolio

## LEVERAGING...

Our DPP® technology and scientific expertise via collaborations

## PREPARING...

For additional growth with enhanced manufacturing capability

# Expanding our Core STD Business

Multiple organic growth drivers are moving the business



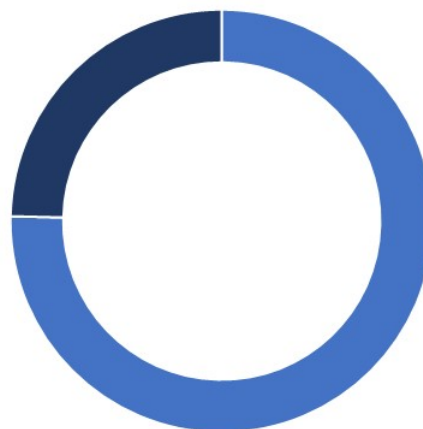
# Sexually Transmitted Disease Market

HIV and Syphilis affect ~50 million globally

## IMPORTANT GEOGRAPHIES

- U.S. – FDA approved, CLIA Waived
- Africa – WHO prequalified
- Europe – CE marked
- Brazil – ANVISA approved
- Mexico – COFEPRIS approved

■ 36.7M living with HIV ■ 12M Syphilis infections/year

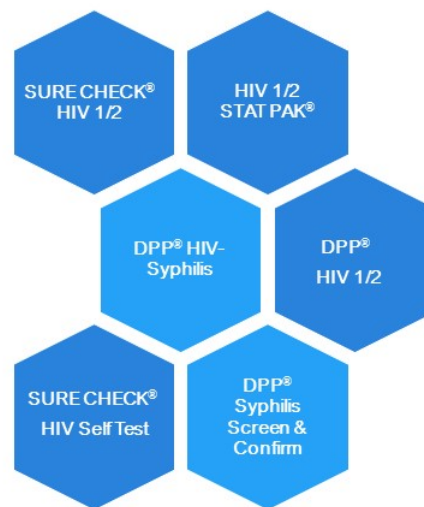


# Addressing HIV-Syphilis Co-infection

A highly differentiated approach

## KEY ADVANTAGES

- Easy to use
  - 2.5– µL15 blood sample
- Rapid results
  - 15-20 minute test time
- Reliable performance
  - Sensitive
  - Specific



# Building Tropical & Fever Disease Portfolio

Key advantages include sensitivity, specificity and multiplexing

## Single Tests



## Multiplex Tests



# Tropical and Fever Disease Market

Established markets and channels present significant opportunity

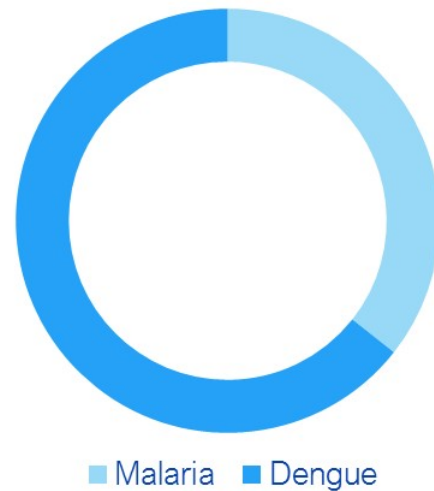
## Opportunities in Established Markets

- Malaria: 216M annual infections
- Dengue: 390M annual infections

## Emerging Markets









- Zika
- Chikungunya
- Ebola
- Lassa
- Marburg
- Leptospirosis
- Burkholderia
- Rickettsia

~600M annual infections



# Tropical and Fever Disease

R&D funding from World-Leading Organizations: \$7.3MM ('15-'17)

	DPP® Malaria Assay
	DPP® Dengue Assay
   	DPP® Zika Assay DPP® Zika/Dengue/Chikungunya Assay
THE PAUL G. ALLEN FAMILY FOUNDATION	DPP® Fever Panel Assay - Africa
 Because diagnosis matters	DPP® Fever Panel Assay - Asia
	DPP® Ebola Assay DPP® Malaria/Ebola Assay

# Technology Collaborations




Why are global leaders choosing Chembio to solve their challenges?

- Deep scientific expertise with a proven technology platform
  - Sensitive and specific
  - Multiplexing capabilities
  - Quantitative results
- Successful track record developing DPP® tests with diverse collaborators
  - Global commercial companies
  - Governments
  - Non-governmental organizations
- Extensive experience achieving key regulatory approvals
  - U.S. FDA, WHO PQ, CE mark, ANVISA, COFEPRIS



# Technology Collaborations

Ongoing collaborations provide significant growth potential

 AstraZeneca	DPP® “Undisclosed Biomarker” Assay
 lumiraDx	Point-of-care infectious disease portfolio
<b>Undisclosed Partner</b>	DPP® Cancer Assay
<i>Perseus Science Group LLC</i>	DPP® Concussion Assay
 USDA	DPP® Bovine TB Assay

# Technology Collaborations

What opportunities do our technology collaborations provide?

- Expansion into new markets
  - Cancer Diagnostics
  - Concussion / Traumatic Brain Injury
  - Veterinary
- Broadening application from POC diagnostics to companion diagnostics
  - Drugs
  - Vaccines
- Cost-effective development funded by collaborators

Note: all technology collaboration projects are under development

# Preparing For Additional Growth

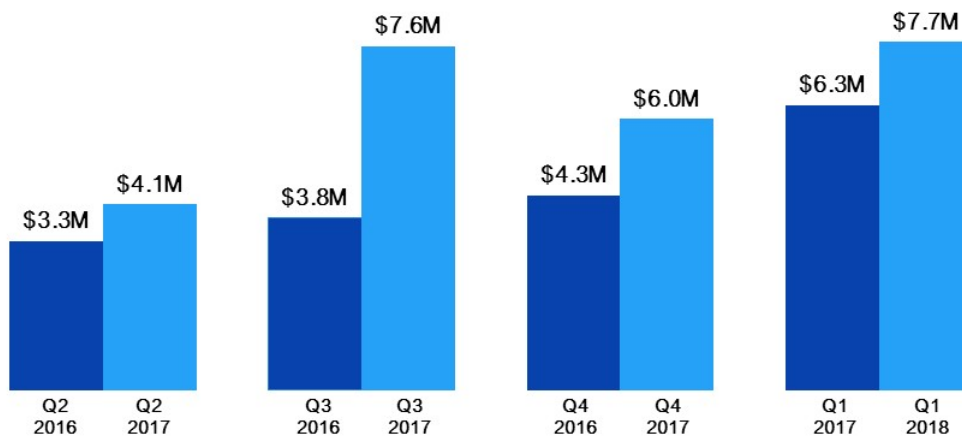
## Product, People, Process

- Building the product portfolio
- Strengthening the talent (Leadership, Board, Organization)
- Expanding manufacturing capacity (U.S. and Malaysia)

# Financial Highlights

Revenue Growth 38% LTM: \$18.4M (Q2 '17) to \$25.4M (Q1 '18)

Revenue (millions)



\$12.5M cash and equivalents as of 3/31/2018

LTM: Last twelve months ended Q2'17 vs. LTM Q1'18



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# 2018 Milestones and Next Steps

## Driving new revenues

- Complete DPP® Malaria Assay development → file registrations
- Complete DPP® biomarker (AstraZeneca) development → file registrations
- Submit DPP® Zika 510(k) with U.S. FDA → launch in the U.S. market
- File DPP® Dengue registrations → launch in APAC and LATAM markets
- Complete DPP® Cancer development → file registrations

# Investment Highlights

- Superior DPP® technology platform with broad application
- Growing pipeline of products and markets
- Nimble global organization prepared to scale operationally

