CHEMBIO DIAGNOSTICS, INC.
Form 8-K
October 22, 2018

UNITED STATES
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): October 17, 2018

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	0-30379	88-0425691
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

3661 Horseblock Road, Medford, New York 11763
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (631) 924-1135

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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 1.01 Entry into a Material Definitive Agreement

Proposed Acquisition of opTricon GmbH

On October 17, 2018, we entered into a share purchase agreement pursuant to which we agreed to acquire all of the outstanding shares of opTricon GmbH, or opTricon, for a purchase price of $5.5 million in cash. We refer to the share purchase agreement as the Purchase Agreement and to the transaction as the Proposed Acquisition. The Proposed Acquisition is scheduled to close on October 31, 2018, subject to standard closing conditions. The Purchase Agreement contains customary representations and warranties from us and from opTricon. Of the purchase price to be paid at closing, $100,000 will be held in escrow for a purchase price adjustment based on the working capital of opTricon and $750,000 will be held in escrow to satisfy certain claims that we may make against the sellers in accordance with the terms of the Purchase Agreement.

opTricon, based in Berlin, Germany, is a developer and manufacturer of handheld analyzers for rapid diagnostic tests. Since 2015 we and opTricon have been parties to an agreement under which we have collaborated in developing our DPP Micro Reader, a handheld, battery-operated analyzer that uses an innovative image sensor to provide, when combined with our DPP tests, a quantitative interpretation of diagnostic results. We intend that opTricon will become a Chembio Center-of-Excellence for optical technology and will serve as our European headquarters. As part of its ongoing business, opTricon will continue to develop and manufacture hand-held analyzers for original equipment manufacturers that do not compete with us. The DPP Micro Reader is included in most of our new product development initiatives and regulatory approvals and submissions. If we complete the Proposed Acquisition, we will secure global commercial rights to opTricon’s offerings and technology and we will be able to produce DPP Micro Readers at a reduced cost, thereby enabling us to promote DPP tests and DPP Micro Readers more actively across global markets.

We cannot assure you that the Proposed Acquisition will close on the scheduled date or at all, or that we will achieve the intended benefits from the Proposed Acquisition.

Item 2.02 Results of Operations and Financial Condition

Third Quarter 2018 Revenue

We preliminarily estimate that revenue for the third quarter of 2018 will be in the range of $9.2 million to $9.4 million, an increase of 21.3% to 23.9% from revenue of $7.6 million in the third quarter of 2017.

The range for revenue for the third quarter of 2018 represents a preliminary estimate because our financial closing procedures for the quarter remain to be performed and other developments may arise by the time the financial results for the quarter are completed. As a result, there is a possibility that revenue will not be within the range we currently estimate. This information is provided by and is the responsibility of management. Our independent registered public accounting firm has not audited, reviewed, compiled or performed any procedures with respect to this information and, accordingly, does not express an opinion or any other form of assurance on it.

Item 8.01 Other Events

Grant of Equity Awards

On October 8, 2018, the compensation committee of the board of directors made awards of restricted stock and restricted stock units under our 2014 Stock Incentive Plan to our four current non-employee directors and our six current executive officers, for an aggregate of 261,657 shares of common stock. Of the shares of common stock awarded, (a) 7,772 shares of restricted stock were awarded to each of Katherine L. Davis, Gail S. Page, Mary Lake

Polan and John G. Potthoff, who comprise our non-employee directors; (b) shares of restricted stock were awarded to executive officers as follows: Javan Esfandiari; 38,860; Neil A. Goldman, 31,088; David Gyorke, 20,725; Sharon Klugewicz, 20,725; and John J. Sperzel III, 98,446; and (c) restricted stock units covering 20,725 shares of common stock were awarded to executive officer Robert Passas. Awards to non-employee directors vest based on continued service for one year after grant, and awards to key employees vest in three annual installments.

The awards were made in connection with the compensation committee's review of our executive and director compensation programs with its independent compensation consultant, Pearl Meyer & Partners, LLC, and are intended to continue to (a) improve alignment of interests of our directors and executive officers with our long-term stockholders, taking into account our history of limited and occasional equity compensation awards, and (b) facilitate our retention of key leaders to better ensure a stable management team focused on long-term growth goals. The compensation committee's review of our executive compensation programs is an ongoing process and additional changes to those programs may be made in the future.

Purchase Commitment from Bio-Manguinhos

On September 4, 2018, we received a $10.5 million commitment from Bio-Manguinhos to purchase test components and intermediate product for the production of DPP HIV and DPP Leishmania assays in Brazil and their subsequent supply to Brazil's Ministry of Health. We expect to supply these items during 2019. Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation (also known as Fiocruz), is responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet the demands of Brazil's national public health system. We have a long-standing relationship with Bio-Manguinhos, supplying multiple products for point-of-care detection of HIV and other infectious diseases.

Updated Summary of Our Business

Chembio Diagnostics, Inc. is a leading provider of point-of-care diagnostic products for the detection and diagnosis of infectious diseases. We have been expanding our product portfolio based upon our proprietary DPP technology platform, which uses a small drop of blood from the fingertip to provide high-quality, cost-effective diagnostic results in approximately 15 minutes. We seek to build additional revenue streams by entering into strategic collaborations with leading global healthcare companies in order to leverage the DPP platform.

Compared with traditional lateral flow technology, the DPP technology platform provides enhanced sensitivity and specificity, advanced multiplexing capabilities, and, when used with the DPP Micro Reader, quantitative results. Our DPP HIV test provides sensitivity of 99.8% and specificity of 100%, and has been approved by the U.S. Food and Drug Administration, or FDA, and approved as a waived test under the Clinical Laboratory Improvement Amendments of 1988.

We are pursuing four corporate priorities, aimed at executing on our key building blocks to drive growth and operating efficiency:
- expand our core point-of-care infectious disease business;
- leverage our patented DPP technology and scientific expertise through collaborations;
- broaden our sales channels worldwide; and
- automate our U.S. manufacturing operations to increase capacity and margin.

Industry

The DPP technology platform addresses the lateral flow test market, which includes infectious diseases, cardiac markers, cholesterol and lipids, pregnancy and fertility, and drugs of abuse. Based on our review of third-party reports and other information, we estimate that the market for lateral flow tests will increase from $5.5 billion in 2017 to $8.2 billion in 2022, representing a compound annual growth rate of 8.2%.

Infectious disease tests constitute the largest, and fastest growing, segment of the lateral flow test market. We currently are targeting lateral flow test solutions for three areas of infectious diseases: sexually transmitted disease, mosquito-borne disease and hepatitis. The market for lateral flow infectious disease tests is being driven by the high prevalence of infectious diseases globally, an increase in the geriatric population, growing demand for rapid test results, and advancements in multiplexing. Based on our review of third-party reports and other information, we estimate that the market for lateral flow infectious disease tests will increase from $1.4 billion in 2017 to $2.3 billion in 2022, representing a compound annual growth rate of 10.7%.

Products

Our point-of-care infectious disease portfolio is comprised of multiple commercial products, each serving unique customer requirements. The key advantages of our products include:

·only a tiny drop of blood from the fingertip is required;
·reliable test results are provided in approximately 15 minutes; and
·based on our advanced multiplexing, results for more than one disease can be obtained from a single test.

We have obtained U.S. and, directly or through our partners, selected international regulatory approvals for infectious disease tests as follows:

PRODUCT (ASSAY)	U.S.	INTERNATIONAL
DPP HIV 1/2		
DPP HIV-Syphilis		
DPP Syphilis Screen & Confirm		
DPP Zika		
DPP Leishmaniasis		
STAT-PAK HIV 1/2		
STAT-PAK Chagas		
SURE CHECK HIV 1/2		
SURE CHECK HIV 1/2 Self Test		

Organic growth in our core infectious disease business is being driven by:

- growth in the overall market for lateral flow infectious disease tests, which we estimate will increase at an compound annual growth rate of 10.7% through 2022 (see "—Industry" above);
- our increased market penetration in existing markets and channels, including in the United States, Brazil, Africa and Europe;
- our registration of existing and new products in unchartered countries and regions, such as Latin America and Southeast Asia;
- our entry into new market segments, such as international HIV Self-Testing; and
- advances in our product pipeline in sexually transmitted disease and fever and tropical disease, with key products including a multiplex test for HIV and syphilis in the U.S. market and tests for chikungunya, dengue, malaria and Zika.

We market and sell both individual and multiplex tests for sexually transmitted infectious diseases, such as HIV and syphilis. HIV and syphilis continue to be major global public health issues. According to World Health Organization estimates:

- HIV has claimed more than 35 million lives, including 940,000 in 2017. Approximately 36.9 million were living with HIV at the end of 2017, and 1.8 million were newly infected during 2017.
- There were 18.0 million prevalent cases of syphilis as of 2012, and 5.6 million new infections were estimated to occur annually.
- Elimination of mother-to-child transmission, or MTCT, of both HIV and syphilis is a global health priority. In 2013, 1.9 million pregnant women were infected with syphilis worldwide. Congenital syphilis contributes significantly to infant mortality, accounting for 305,000 annual perinatal deaths worldwide in 2013. Globally, more than 1.4 million pregnant women were infected with HIV as of 2015, and MTCT of HIV is estimated to have resulted in over 150,000 infant cases in 2015.

We are seeking to address the global concerns related to HIV and syphilis co-infection through the development of a novel, multiplex test for both HIV and syphilis. We have developed a DPP HIV-Syphilis multiplex test and received regulatory approvals covering a number of international markets, including Brazil, Europe, Malaysia and Mexico. In the United States we have completed a clinical trial and filed a Pre-Market Approval Application with the FDA, which is in the review process. We believe we are well-positioned to be the first company to introduce a multiplex rapid test for HIV and syphilis.

We also market and sell tests for selected fever and tropical diseases, such as Chagas, leishmaniasis and Zika. The market for lateral flow testing for tropical and fever disease includes established markets for disease such as dengue and malaria, which the World Health Organization estimates together account for more than 600 million infections worldwide annually. There are also a number of emerging markets for lateral flow tests for diseases such as burkholderia, chikungunya, ebola, lassa, leptospirosis, Marburg, rickettsia and Zika. We are developing tests, using the DPP platform, to detect all of the aforementioned tropical and fever diseases, as stand-alone or multiplex assays.

Since 2015 we have received over $9 million of funding from some of the world's leading health organizations, which has helped us accelerate the expansion of our pipeline of infectious disease tests. Our collaborators have included Bill & Melinda Gates Foundation, The Paul G. Allen Family Foundation, Oswaldo Cruz Foundation (Fiocruz) and FIND, as well as U.S. government agencies such as Centers for Disease Control and Biomedical Advanced Research and Development Authority (U.S. Department of Health and Human Services). Many of the tests in our infectious disease pipeline are approaching commercialization, and several have received initial regulatory approvals:

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification &Validation	Phase IV Clinical/ Regulatory	Phase V Commercial Launch
DPP HIV-Syphilis (US)	Self-funded				Submitted FDA Q1 2018	
DPP Dengue (International)	Fiocruz				Submitted ANVISA[1] Q3 2018	
DPP Dengue NS1 (International)	Fiocruz			Ongoing		
DPP Zika (US/International)	Fiocruz					Received FDA EUA[2], ANVISA, CE mark
DPP Chikungunya (International)	Fiocruz					Received ANVISA, Malaysia
DPP Dengue-Zika-Chik (International)	Fiocruz				Submitted ANVISA Q3 2018	Received Malaysia
DPP Malaria (International)	Bill & Melinda Gates Foundation			Ongoing		
DPP Ebola (US, International)	Centers for Disease Control				Submitted FDA EUA Q1 2018	
DPP Fever Panel (Africa)	The Paul G. Allen Family Foundation				Field Testing: Africa, South America	
DPP Fever Panel (Asia)	FIND		Ongoing			

1 Agência Nacional de Vigilância Sanitária (Brazil)
2 Emergency Use Authorization

Collaborations

We are building additional revenue streams by leveraging our patented DPP technology and scientific expertise through collaborations. Leading global healthcare organizations have chosen to collaborate with us based on our deep scientific expertise with our proven DPP technology platform and capabilities, our successful record of developing DPP tests with a diverse set of collaborators including global commercial companies, governments and non-governmental organizations, and our extensive experience in obtaining regulatory approvals in the United States (FDA), Brazil (ANVISA), the European Union (CE mark) and Mexico (COFEPRIS), as well as from the World

Health Organization (Prequalification, or PQ).

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification & Validation	Phase IV Clinical/ Regulatory	Phase V Commercial Launch
DPP Undisclosed Biomarker	AstraZeneca			Ongoing		
DPP Cancer	Undisclosed			Ongoing		
Infectious Disease Portfolio	lumiraDx	Initiated Q3 2018				
DPP Concussion	Perseus Science		Ongoing			
DPP Bovine Tuberculosis	USDA		Ongoing			
DPP Hepatitis C Ab	FIND		Ongoing			
DPP Hepatitis C Ag	FIND	Initiated Q3 2018				

By leveraging our DPP technology platform, we are creating opportunities to expand into new markets such as cancer diagnostics, concussion and traumatic brain injury, and veterinary and we are broadening the application of our technology from point-of-care diagnostics to include companion diagnostics. Research and development costs related to the collaborations are fully funded by our collaborators.

Sales Channels

Our products are sold globally, both directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies and consumers. Historically, we marketed and sold our products only into a handful of countries and regions. In recent years we have hired a small number of sales executives to begin building our own channels in key markets such as the United States, Europe, Latin America, Africa and Southeast Asia. With sales growth as an underlying objective, we are focused on increasing sales in existing geographies, expanding sales into new geographies, and broadening sales coverage in key markets.

Automation of U.S. Manufacturing

We are automating our U.S. manufacturing processes and expanding our manufacturing capacity. In late June 2018, we received delivery of our first automated line of manufacturing equipment, which we expect will commence production during the fourth quarter of 2018. This automated manufacturing line will be used for DPP test production and will allow assembly of various configurations of DPP tests on the line. The automated line will have an annual capacity of between five and ten million tests, depending on the test configuration, and will use vision-guided, robotic operation to improve inspection and quality control. As we transition from total manual to automated assembly, we believe the reduced variable costs can help drive product margin improvement.

Executive Officers and Key Employees

Our executive officers and key employees, and their ages and positions as of October 10, 2018, are set forth below:

Name	Age	Position
Executive officers:		
John J. Sperzel III	55	Chief Executive Officer
Neil A. Goldman	51	Chief Financial Officer; Executive Vice President
Javan Esfandiari	52	Chief Scientific & Technology Officer; Executive Vice President
Sharon Klugewicz	50	Senior Vice President; Chief Quality and Regulatory Officer
Robert Passas	64	Senior Vice President; Chief Commercial Officer
David Gyorke	59	Senior Vice President; Chief Operations Officer
Key employees:		
Tom Ippolito	55	Vice President of Regulatory Affairs, Quality Assurance and Quality Control
Paul Lambotte	66	Vice President of Research & Development
Christine Rousseau	51	Vice President of Corporate Development

Executive Officers

John J. Sperzel (55), Chief Executive Officer and Director. Mr. Sperzel was appointed Chief Executive Officer of Chembio Diagnostics, Inc. and a member of our Board in March 2014. Prior to joining Chembio Diagnostics, Inc., Mr. Sperzel, was the President and CEO of International Technidyne Corporation (ITC) from September 2011 to December 2013. Mr. Sperzel served as President at Axis-Shield from September 2004 to September 2011. He also has held senior leadership positions at Bayer Diagnostics (Siemens Dx), Instrumentation Laboratory, and Boehringer Mannheim Diagnostics (Roche Dx). Mr. Sperzel graduated from Plymouth State College in New Hampshire, with a Bachelor of Science in Business Administration/Management. He currently serves on the board of directors of Diadexus, Inc., the common stock of which is registered under the Securities Exchange Act of 1934, and as an advisor to the board of the Diagnostic Marketing Association, and was the president of the board of that Association in 2007. Mr. Sperzel's knowledge of, and experience in, the point-of-care diagnostics industry, together with his knowledge and experience as CEO of Chembio Diagnostics, Inc. make him an excellent candidate for continuing to serve on the Board.

Neil A. Goldman (51), Chief Financial Officer; Executive Vice President. Mr. Goldman joined Chembio Diagnostics, Inc. in December 2017 as Chief Financial Officer and Executive Vice President. Mr. Goldman previously worked at J.S. Held LLC, a private equity-sponsored national consulting firm to insurance carriers and law firms. At J.S. Held, Mr. Goldman served as Executive Vice President - Corporate Development and CFO from 2015 to 2017, during which time he successfully completed six acquisitions and drove significant sales and EBITDA growth. From 2005 to 2015, Mr. Goldman held senior level positions at Unwired Technology LLC and then Delphi Corp., now Aptiv plc (NYSE: APTV), following Delphi's acquisition of Unwired in 2014. Mr. Goldman's positions at Unwired included Executive Vice President-Corporate Development and CFO, and Senior Vice President-Chief Operating & Financial Officer. At Delphi, Mr. Goldman served as Global Finance Director for the Delphi Data Connectivity division. Prior to Unwired, Mr. Goldman served as CFO of EPPCO Enterprises from 2003 to 2005 and worked from 1989 to 2002 at Ernst & Young and Cap Gemini Ernst & Young following the latter's acquisition of Ernst & Young's consulting business. At Ernst & Young, Mr. Goldman was an auditor, primarily of Fortune 500 companies, and advanced into regional and national management consulting provisions. Mr. Goldman received a B.S. in Business-Accountancy from Miami University, Oxford, OH. Mr. Goldman is a Certified Public Accountant, licensed in the State of Ohio.

Javan Esfandiari (52), Chief Science And Technology Officer; Executive Vice President. Mr. Esfandiari joined Chembio Diagnostics, Inc. in 2000. Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where

he served as Director of Research and Development concerning lateral flow technology until Chembio Diagnostics, Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was working in collaboration with Sinovus Biotech AB on development of veterinary lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden. He has published articles in various veterinary journals and has co-authored articles on tuberculosis serology with Dr. Lyashchenko.

Sharon Klugewicz (50), Senior Vice President; Chief Quality and Regulatory Officer. Prior to joining Chembio Diagnostics, Inc. in September 2012, Ms. Klugewicz, served as Senior Vice President, Scientific & Laboratory Services at Pall Corporation (NYSE:PLL), a world leader in filtration, separation and purification technologies. Prior to that, Ms. Klugewicz held a number of positions at Pall Corporation over her 20-year tenure there, including in the Pall Life Sciences Division, in Marketing Product Management, and Field Technical Services, which included a position as Senior Vice President, Global Quality Operations. Ms. Klugewicz holds an M.S. in Biochemistry from Adelphi University and a B.S. in Neurobiology from Stony Brook University.

Robert Passas Ph.D. (64), Senior Vice President; Chief Commercial Officer. Dr. Passas joined Chembio Diagnostics, Inc. in October 2016 and serves as President EMEA and APAC Regions. Prior to joining the Company, from 2011 to 2016, Dr. Passas was a member of the Board and the Group Commercial Director, responsible for worldwide marketing, international sales, and technical and customer support at The Binding Site Group Ltd., Birmingham, U.K.. Previously, he was employed at each of Trinity Biotech plc (as Executive VP for global sales and marketing), Quidel Corporation, and Abbot Diabetes Care. Dr. Passas received a Ph.D. in analytical chemistry and a B.S. in medical biochemistry from the University of Surrey.

David Gyorke (59), Senior Vice President; Chief Operations Officer. Mr. Gyorke joined Chembio Diagnostics, Inc. in January 2017. Mr. Gyorke has responsibility for Manufacturing and Operations for the Company's Medord, NY and Kuala Lumpur, Malaysia manufacturing facilities. Prior to joining Chembio Diagnostics, Inc., Mr. Gyorke held VP of Operations positions at the following start-up companies: Nanomix from 2011 to 2016, an electro-chemistry-based IVD POC system; NeoVista from 2008 to 2011, an ophthalmic brachytherapy surgical device; and Farallon Medical from 2004 to 2008, a PT-time POC system (acquired by Coagusense). Prior to that he served as VP of Operations for Cholestech from 1999 to 2003, an IVD POC system, and held Technical Management positions at Boston Scientific-Target from 1993 to 1999. He received his Bachelors of Engineering (Industrial) at California Polytechnic State University.

Key Employees

Tom Ippolito (55), Vice President of Regulatory Affairs, QA and QC. Mr. Ippolito joined Chembio Diagnostics, Inc. in June 2005, and serves as Vice President, Regulatory Affairs. Prior to joining Chembio Diagnostics, Inc., Mr. Ippolito served as Vice President, Regulatory and Quality at Biospecifics Technologies. He previously held a number of positions with United Biomedical, Biospecifics, Merck, Rhone Merieux, Organon Teknika, Analytab Products Inc., and Olympus. Mr. Ippolito holds the position of Course Director of the Fundamentals of Bioscience Program at the State University of Stony Brook and is the instructor for clinical development and regulatory affairs.

Paul Lambotte Ph.D. (66), Vice President of Research & Development. Dr. Lambotte joined Chembio Diagnostics, Inc. in December 2014, and serves as Vice President of Product Development. Prior to joining Chembio Diagnostics, Inc., from 2012 to 2014, Dr. Lambotte was President of PLC Inc., a point-of-care product development consulting company. He previously served as Chief Science Officer at Axxin Pty Ltd from 2009 to 2012, held positions of VP of R&D and Business Development at Quidel Corporation from 2000 to 2009, and before that held a number of positions at Beckman Coulter and Hybritech Inc. Dr. Lambotte is the inventor of several patents in the field of rapid, point-of-care diagnostic products. He received a Master in Biochemistry and a PhD in Protein Biochemistry from the University of Mons, Belgium, and did post-doctoral work at the Ludwig Institute for Cancer research in Brussels, Belgium.

Christine Rousseau Ph.D. (51), Vice President of Corporate Development. Dr. Rousseau joined Chembio Diagnostics, Inc. in July 2018, and serves as Vice President of Corporate Development. Prior to joining Chembio Diagnostics, Inc., Dr. Rousseau spent nine years at the Bill & Melinda Gates Foundation as a Senior Program Officer in Global Health, Integrated Technology Solutions Product Development from 2013 to 2017 and Program Officer in Global Health, HIV Diagnostics from 2008 to 2013. Before that, Dr. Rousseau spent ten years as a research scientist and faculty

member at the University of Washington, with emphasis in the areas of HIV and HCV. Earlier in her career, she was a Senior Fellow at the Fred Hutchinson Cancer Research Center and HIV Director & Founding Board Member of the Sustainable Sciences Institute. Dr. Rousseau received a Ph.D. in Molecular and Cell Biology from University of California Berkeley, a M.S. in Epidemiology from the University of Washington, and a B.S. in Molecular Genetics from Ohio State University.

FORWARD-LOOKING STATEMENTS AND STATISTICAL DATA

Special Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements represent plans, estimates, objectives, goals, guidelines, expectations, intentions, projections and statements of our beliefs concerning future events, business plans, objectives, expected operating results and the assumptions upon which those statements are based. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and are typically identified with words such as “may,” “could,” “should,” “will,” “would,” “believe,” “anticipate,” “estimate,” “expect,” “intend,” “plan,” or wo of similar meaning. We caution that the forward-looking statements are based largely on our expectations and are subject to a number of known and unknown risks and uncertainties that are subject to change based on factors which are, in many instances, beyond our control. Actual results, performance or achievements could differ materially from those contemplated, expressed, or implied by the forward-looking statements.

The following factors, among others, could cause our financial performance to differ materially from that expressed in such forward-looking statements:

- our ability to obtain or maintain necessary regulatory approvals for some of our products;
- the timely development of competitive new products and services, and the acceptance of those products and services by new and existing customers;
- the lack of availability of alternative third-party suppliers for certain important product components;
- the timely development of competitive new products and services, and the acceptance of these products and services by new and existing customers;
- the willingness of users to substitute competitors’ products and services for our products and services;
- new developments in health treatments or new non-diagnostic products that reduce or eliminate the demand for our products;
- changes in consumer spending and savings habits;
- the strength of the U.S. economy in general and the strength of the local economies in which we operate;
- geopolitical conditions, including acts or threats of terrorism, actions taken by the United States or other governments in response to acts or threats of terrorism and/or military conflicts, which could impact business and economic conditions in the United States and abroad;
- the effects of, and changes in, trade, monetary and fiscal policies and laws, including interest rate policies;
- inflation, interest rate, market and monetary fluctuations;
- availability of resources for introduction and marketing of our products;
- technological changes;

- our ability to attract and retain key employees;
- continued funding of, and our ability to participate in, large testing programs in the United States and worldwide;
- uncertainty as to our future profitability;
- the impact of changes in financial services policies, laws and regulations, including those concerning taxes, banking, securities and insurance, and the application thereof by regulatory bodies;
- the effect of acquisitions we may make, including the failure to achieve expected revenue growth or expense savings;
- the growth and profitability of non-interest or fee income being less than expected; and
- unanticipated regulatory or judicial proceedings.

Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should read this Current Report on Form 8-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Industry and Market Data

This prospectus supplement contains estimates, projections and other data concerning our industry, our business, and the markets for our products. Where expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by World Health Organization. We also include data that we have compiled, obtained, identified or otherwise derived from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. Other than World Health Organization, we do not expressly refer to the sources from which this data is derived. While we are not aware of any misstatements regarding any third-party data presented in, or underlying or supporting data presented in, this prospectus supplement, information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
10.1	Lease Agreement, dated February 15, 2017, between Horseblock Associates and Chembio Diagnostics, Inc. with respect to office space for units located at 3661 Horseblock Road, Medford, New York, as amended
10.2	Lease Agreement, dated February 4, 2013, between Sherwood Corporate Center LLC and Chembio Diagnostics, Inc. with respect to office and warehouse space at 91-1A Colin Drive, Holbrook, New York, as amended on September 19, 2017
10.3+	Chembio Diagnostics, Inc. Annual Incentive Bonus Plan (2017)
10.4+	Offer Letter from Chembio Diagnostics, Inc. to Robert Passas, dated October 19, 2016

+Indicates management contract or compensatory plan.

SIGNATURE

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

CHEMBIO DIAGNOSTICS, INC.

Dated: October 22, 2018 By: /s/ John J. Sperzel III
John J. Sperzel III
Chief Executive Officer and President