CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 18, 2019
UNITED STATES
Securities and Exchange Commission
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018
or

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from_____ to _____.

Commission File No. 0-30379

CHEMBIO DIAGNOSTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	88-0425691
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3661 Horseblock Road, Medford, NY	11763
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.01 par value	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes __ No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes __ No X

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No__

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes X No __

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ] Accelerated filer [X]
Non-accelerated filer [ ] Smaller reporting company [X]
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 [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes __ No X

As of the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates was $154,594,062.

As of March 1, 2019, the registrant had 17,166,459 shares of common stock outstanding.

Documents Incorporated By Reference
Portions of the registrant's proxy statement for its 2019 annual meeting of stockholders are incorporated by reference in Part III of this report.

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Unless the context requires otherwise, the words “our,” “our company,” “us,” “we” and similar terms refer to Chembio Diagnostics, Inc. and its consolidated subsidiaries.

DPP, SAMPLETAINER, STAT-PAK, STAT-VIEW and SURE CHECK are our registered trademarks. For convenience, these trademarks appear in this prospectus supplement without ® symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks. This report also includes trademarks and service marks owned by other organizations.

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

This report contains statements reflecting our views about our future performance that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are generally identified through the inclusion of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “objective,” “outlook,” “plan,” “potential,” “project,” “seek,” “should,” “stra “would” or variations of such words or similar expressions. All statements addressing our future operating performance, and statements addressing events and developments that we expect or anticipate will occur in the future, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based upon currently available information, operating plans, and projections about future events and trends.

This report 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, or WHO. 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 WHO, we do not expressly refer to the sources from which this data is derived.

Forward-looking statements and statistical estimates inherently involve risks and uncertainties that could cause actual results to differ materially from those predicted or expressed in this report. These risks and uncertainties include those described below in “Item 1A. Risk Factors.” Investors are cautioned not to place undue reliance on any forward-looking statements or statistical estimates, which speak only as of the date they are made. We undertake no obligation to update any forward-looking statement or statistical estimate, whether as a result of new information, future events or otherwise.

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PART I

ITEM 1. BUSINESS

Overview

We are 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 Dual Path Platform, which we refer to as the 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 technology collaborations with leading global healthcare companies 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 test for human immunodeficiency virus, or HIV, provides sensitivity of 99.8% and specificity of 100%, and has been approved by the U.S. Food and Drug Administration, or FDA, and cleared as a waived test under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. On November 6, 2018, we completed our acquisition of opTricon GmbH, a Berlin-based developer and manufacturer of handheld analyzers for rapid diagnostic tests, which we believe will enable us to promote DPP tests and DPP Micro Readers more actively across global markets.

We are pursuing three corporate priorities, the key building blocks to drive growth and operating efficiency: (1) expand our commercialization; (2) advance our research and development pipeline; and (3) prepare for future growth.

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, which are performed with a tiny drop of blood from the fingertip and provide results in approximately 15 minutes, include:

- enhanced sensitivity and specificity;
- advanced multiplexing; and
- quantitative results, when used with DPP Micro Reader.

We have obtained U.S. FDA approvals and, directly or through our partners, 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 a 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, Latin America, Africa and Europe;
- our registration of existing and new products in unchartered countries and regions, such as selected countries in Latin America and Southeast Asia;
- our entry into new market segments, such as international HIV Self-Testing; and
- advances in our product pipeline in infectious disease with key products including a multiplex test for HIV and syphilis in the U.S. market and tests for dengue, zika and chikungunya.

We market and sell both stand-alone 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 WHO 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 DPP HIV-Syphilis 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 in the United States.

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

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, The Oswaldo Cruz Foundation or FIOCRUZ, and the Foundation for Innovative New Diagnostics or FIND, as well as U.S. government agencies such as Centers for

Disease Control, or CDC, and the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services or BARDA, and the U.S. Department of Agriculture, or USDA. 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-Chikungunya (International)	Fiocruz				Submitted ANVISA Q3 2018	Received Malaysia
DPP Malaria (International)	Bill & Melinda Gates Foundation			Ongoing		
DPP Ebola (US, International)	Centers for Disease Control				Received FDA EUA Q4 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 (Comisión Federal para la Protección contra Riesgos Sanitarios, or COFEPRIS) as well as from WHO (Prequalification, or PQ).

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification & Validation	Phase IV Clinical/ Regulatory	Phase V Commercial Launch
DPP Eosinophilic / Respiratory	AstraZeneca			Ongoing	Received CE mark Q4 2018	
DPP Cancer	Undisclosed LumiraDx			Ongoing		

Infectious Disease Portfolio		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 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. During 2018, we took delivery of our first automated manufacturing line. 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 manual to automated assembly, we believe the reduced variable costs will improve product gross margins.

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DPP Technology & Development

Our commercially available products employ either our patented DPP technology or traditional lateral flow technology. We believe products developed using our DPP technology can provide superior diagnostic performance compared with products that utilize traditional lateral flow technology.

We are executing our strategy to leverage DPP intellectual property, as well as our scientific and operational expertise, to create new collaborations where we will serve as an exclusive development and manufacturing partner. Examples of such collaborations include the following:

- In January 2015, we entered into an agreement with the Concussion Science Group (CSG) Division of Perseus Science Group LLC to develop a point-of-care diagnostic test for traumatic brain injury, including sports-related concussions, utilizing both our DPP and optical analyzer technologies.
- In October 2017, we signed a development agreement with AstraZeneca for the development of a quantitative point-of-care test for eosinophilic respiratory disease, utilizing both our DPP and optical analyzer technologies.
- In April 2018, we entered into a collaboration agreement with LumiraDx to develop new point-of-care diagnostic tests for infectious diseases. Under terms of the agreement, we receive funding from LumiraDx, subject to satisfying certain milestones, to develop certain new point-of-care infectious disease tests. Following the regulatory approval and commercialization of tests in accordance with this agreement, Chembio will both sell reagents to, and receive royalty payments from, LumiraDx on sales of all products developed through this collaboration.
- In November 2018, we acquired opTricon (Berlin, Germany), a leading developer of handheld optical analyzers rapid diagnostic tests. See “Management’s Discussion & Analysis of Financial Condition and Results of Operations—Recent Developments.”

Competition

Many of our competitors are significantly larger and have greater financial, research, manufacturing, and marketing resources. Important competitive factors include product quality, analytical performance, ease of use, price, customer service and reputation. Industry competition is based on these and the following additional factors:

- patent protection;
- scientific expertise;
- ability to develop and market products and processes;
- ability to obtain required regulatory approvals;
- ability to manufacture cost-effective products that meet applicable regulatory requirements;
- access to adequate capital; and,
- ability to attract and retain qualified personnel.

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We believe our scientific capabilities and proprietary know-how relating to our patented DPP technology and lateral flow technology are very strong, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases, and other diseases.

Our ability to develop and market other products is in large measure dependent on our having additional resources and/or collaborative relationships. Some of our product development efforts have been funded on a project or milestone basis. We believe that our proprietary know-how relating to our patented DPP technology has been instrumental in our obtaining the collaborations we have and that we continue to pursue. We believe that our patent protection enhances our ability to both develop more profitable, collaborative relationships and expand licensing revenue. However, there are a number of competitive technologies used and/or seeking to be used by others in point-of-care settings.

Although we have no specific knowledge of any other competitors' products that could render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use the products developed by our competitors, which could result in a loss of revenues and cash flow.

Employees

As of December 31, 2018, we had 295 full-time equivalent employees, of whom 15 were in administration, 215 were in manufacturing, 45 were in research and development, and 20 were in sales and marketing and customer service. Of these employees, approximately 240 were located in the United States, 27 were located in Malaysia, 20 were located in Germany, and 3 were located in other countries.

We have never had a work stoppage, and none of our employees are represented by a labor organization or subject to any collective bargaining arrangements. We consider our employee relations to be good.

Governmental Regulation

Certain of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, and export of diagnostic products. Our clinical laboratory customers are subject to oversight by Centers for Medicare and Medicaid Services, or CMS, pursuant to CLIA, as well as agencies in various states. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions, and criminal prosecution.

FDA Approval/Clearance Requirements

Unless an exemption applies, each medical device that we market or wish to market in the United States must receive 510(k) clearance or Premarket Approval, or PMA. Medical devices that receive 510(k) clearance are "cleared" by the FDA to market, distribute, and sell in the United States. Medical devices that obtain a PMA by the FDA are "approved" to market, distribute and sell in the United States. We cannot be certain that 510(k) clearance or PMA approval will ever be obtained for any products that have not already obtained 510(k) clearance or PMA approval. Descriptions of the PMA and 510(k) clearance processes are provided below.

The FDA decides whether a device line must undergo either the 510(k) clearance or PMA based on statutory criteria that utilize a risk-based classification system. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and, in many cases, Class II medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The FDA uses these criteria to decide whether a PMA or a 510(k) is appropriate, including the level of risk that the agency perceives is associated with the

device and a determination by the agency of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II. In many cases, the FDA requires the manufacturer to submit a 510(k) requesting clearance (also referred to as a premarket notification), unless an exemption applies. The 510(k) must demonstrate that the manufacturer's proposed device is "substantially equivalent" in intended use and in safety and effectiveness to a legally marketed predicate device. A "predicate device" is a pre-existing medical device to which equivalence can be drawn, that is either in Class I or Class II or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application.

Device classification depends on the device's intended use and its indications for use. In addition, classification is risk-based, that is, the risk the device poses to the patient and/or the user is a major factor in determining the class to which it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the FDA's quality system regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) process described below.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) process. Pursuant to the Medical Device User Fee and Modernization Act of 2002, unless a specific exemption applies, 510(k) submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process.

Class III includes devices with the greatest risk. Devices in this class must meet all of the requirements in Classes I and II. In addition, Class III devices cannot be marketed until they receive Premarket Approval.

The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices require formal clinical studies to demonstrate safety and effectiveness. Under Medical Device User Fee and Modernization Act of 2002, PMA applications (and supplemental premarket approval applications) are subject to significantly higher user fees than 510(k) applications, and they also require considerably more time and resources.

Rapid HIV tests intended for diagnostic use are regulated as Class III devices. Responsibility for assuring the safety and effectiveness of these tests lies within the Center for Biologics Evaluation and Research's Office of Blood Research and Review, with oversight by the Blood Products Advisory Committee. Approved rapid HIV tests must meet the regulations in the 21 CFR 800 series subparts, under the investigational device exemption, or IDE and PMA pathways.

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Premarket Approval Pathway

We manufacture, market and distribute three rapid HIV tests in the United States. Our HIV 1/2 STAT-PAK Assay, SURE CHECK HIV 1/2 Assay, and DPP HIV 1/2 Assay all have received FDA PMA approval. A PMA application must be supported by extensive data including, but not limited to, analytical, preclinical, clinical trials, manufacturing, statutory preapproval inspections, and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. Before a PMA is submitted, a manufacturer must apply for an IDE. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an IDE application with the FDA and obtain IDE approval prior to initiation of enrollment of human subjects for clinical trials. The IDE provides the manufacturer with a legal pathway to perform clinical trials on human subjects where without the IDE, only approved medical devices may be used on human subjects.

The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing information, and an Investigational Review Board (IRB) approved protocol showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. If the clinical trial design is deemed to have "non-significant risk," the clinical trial may be eligible for "abbreviated" IDE requirements. In some instances, clinical trials for in vitro diagnostic medical devices may be exempt from the more burdensome IDE requirements if certain labeling requirements are met.

A clinical trial may be suspended by either the FDA or the Investigational Review Board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, clinical testing results may not demonstrate the safety and efficacy of the device, or they may be equivocal or otherwise insufficient to obtain approval of the product being tested. After the clinical trials have been completed, if at all, and the clinical trial data and results are collected and organized, a manufacturer may complete a PMA application.

After a PMA application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The preapproval inspections conducted by the FDA include an evaluation of the manufacturing facility to ensure compliance with the FDA's quality systems regulations or QSR, as well as inspections of the clinical trial sites by the Bioresearch Monitoring group to evaluate compliance with good clinical practice and human subject protections. New PMA applications or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Significant changes to an approved PMA require a 180-day supplement, whereas less substantive changes may utilize a 30-day notice, or a 135-day supplement. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and it may not require as extensive clinical data or the convening of an advisory panel.

Our HIV 1/2 STAT-PAK Assay PMA application number BP050009/0 and our SURE CHECK 1/2 HIV Assay PMA application number BP050010/0 were approved by the FDA in May 2006. Our DPP HIV 1/2 Assay PMA application number BP120032/0 was approved by the FDA in December 2012.

510(k) Clearance Pathway

We are currently developing products that either will or are likely to require an FDA 510(k) clearance, and we anticipate submitting a 510(k) for each such product to demonstrate that such proposed device is substantially equivalent to a respective previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of 510(k). FDA's 510(k) clearance pathway usually takes from three to twelve months but could take longer. In some cases the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, a PMA. The FDA requires each device manufacturer to determine whether the proposed change requires submission of a new 510(k) or a PMA, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA of the modified device is obtained.

If the FDA requires us to submit a new 510(k) or PMA for any modifications to a previously cleared product, or if we obtain 510(k) clearance for a device in the future, we may be required to submit a separate new 510(k) or PMA application for such modifications.

Clinical Laboratory Improvement Amendments of 1988

A manufacturer of a test categorized as moderately complex may request that categorization of the test be waived through a CLIA Waiver by Application, or CW, submission to the FDA. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, such as a physician’s office outreach setting. In a CW submission, the manufacturer provides evidence to the FDA that a test meets the CLIA statutory criteria for waiver CLIA, a walk-in clinic or an emergency room provides CMS authority over all laboratory testing, except research that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group under the CMS, has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention or treatment of disease, or impairment of, or assessment of health. Under the CLIA program, unless waived, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections and pay fees. We have received a CLIA waiver for all of our lateral flow rapid HIV tests that we market in the United States. Specifically, the CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK in November 2006,for SURE CHECK HIV 1/2 in October 2007, and for DPP HIV 1/2 in October 2014.

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Pervasive and Continuing FDA Regulation

A host of regulatory requirements apply to our approved devices, including: the quality system regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures; the Medical Reporting Regulations, which require manufacturers to report to the FDA specified types of adverse events involving their products; labeling regulations; and the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Some Class II devices are subject to special controls-such as performance standards, post-market surveillance, patient registries, and FDA guidelines-that do not apply to Class I devices.

The regulatory requirements that apply to our approved products classified as medical devices include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control,
- documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and,
- notices of corrections or removals.

Our Medford, New York facility is currently registered as an establishment with the FDA. We and any third-party manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with QSR and other regulations.

21st Century Cures Act

The 21st Century Cures Act, enacted in December 2016, contains several sections specific to medical device innovations. We believe that implementation of the 21st Century Cures Act may have a positive impact on its businesses by facilitating innovation and/or reducing the regulatory burden imposed on medical device manufacturers.

Government Regulation of Medical Devices for Animal Subjects

We currently sell, market or distribute two veterinary devices in the United States: DPP VetTB Assay for Cervids and DPP VetTB Assay for Elephants. Diagnostic tests for animal health infectious diseases, including our veterinary devices for the prevention and/or treatment of animal disease, are regulated in the U.S. by the Center for Veterinary Biologics within the U.S. Department of Agriculture Animal and Plant Health Inspection Service, or APHIS, under the Virus, Serum, and Toxin Act of 1913. As a requirement, our veterinary devices were approved by APHIS before they could be sold in the U.S.

The APHIS regulatory approval process involves the submission of product performance data and manufacturing documentation. Following regulatory approval to market a product, APHIS requires that each lot of product be submitted for review before release to customers. In addition, APHIS requires special approval to market products where test results are used in part for government-mandated disease management programs.

Environmental Laws

We believe that we are in compliance with all foreign, federal, state, and local environmental regulations with respect to our manufacturing facilities. The cost of ongoing compliance with such regulations does not have a material effect on our operations.

Intellectual Property

Intellectual Property Strategy

Our intellectual property strategy is to: (1) build our own intellectual property portfolio around our DPP technology and optical analyzers; (2) pursue licenses, trade secrets and know-how within the area of rapid point-of-care testing; and, (3) develop and acquire proprietary positions to certain reagents.

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DPP® Intellectual Property

We have obtained patent coverage on our DPP technology, including numerous patents in the United States, China, Malaysia, Eurasia, Mexico, Singapore, Japan, Australia, Indonesia, Korea and the U.K. Additional patent applications on our DPP technology are pending in the United States, as well as in foreign countries such as Brazil, Canada, the European Union, India, Israel, and South Africa.

DPP technology provides us with freedom to operate, which enables us to develop tests with better performance and capabilities compared with tests built on traditional lateral flow platforms. These advantages have allowed us to enter into multiple technology collaborations based upon DPP technology, which we believe will provide new manufacturing and marketing opportunities. We have filed additional patent applications that we believe will strengthen the DPP intellectual property and have also filed for patent protection for certain other point-of-care technologies or applications thereof.

We have also obtained patent coverage on our optical-based analyzer technology in the United States, with patents pending in several foreign countries.

Trademarks

We have filed and obtained trademarks for our products, including DPP, SURE CHECK, STAT-VIEW, and STAT-PAK, and NEXT GENERATION DPP, as well as for the SampleTainer and DPP Micro Reader, which are used with certain DPP products. Our trademarks have been obtained in the United States and certain other countries around the world.

Trade Secrets and Know-How

We have developed a substantial body of trade secrets and know-how relating to the development and manufacture of lateral flow and DPP-based diagnostic tests, including the sourcing and optimization of materials for such tests, and methods to maximize sensitivity, speed-to-result, specificity, stability and reproducibility of our tests. We possess proprietary know-how to develop tests for multiple conditions using colored particles. Our formulations enable long shelf lives of our rapid HIV and other tests, providing us with an important competitive advantage.

Lateral Flow Technology and Reagent Licenses

We seek licenses and/or redesigns of products that we believe to be in our best interests. Because of the costs and other negative consequences of time-consuming patent litigation, we often attempt to obtain a license on reasonable terms.

The peptides used in our rapid HIV tests were licensed to us by one or more third parties. We also have licensed the antigens used in other tests including our Syphilis, Tuberculosis, Leptospirosis, Leishmaniasis and Chagas tests, and we may enter into other license agreements. In prior years, we concluded license agreements related to intellectual property rights owned by the United States associated with HIV-1 and a sub-license agreement for HIV-2 with Bio-Rad Laboratories N.A., the exclusive licensee of the Pasteur Institute's HIV-2 intellectual property estate.

Available Information

We are required to file annual, quarterly and current reports, proxy statements and other information with the U.S. Securities and Exchange Commission. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and amendments to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange

Act of 1934, are also available free of charge on our website at www.chembio.com as soon as reasonably practicable after such reports are electronically filed with or furnished to the SEC.

Investors should note that we currently announce material information to our investors and others using filings with the SEC, press releases, public conference calls, webcasts or our website (www.chembio.com), including news and announcements regarding our financial performance, key personnel, our brands and our business strategy. Information that we post on our corporate website could be deemed material to investors. We encourage investors to review the information we post on these channels. We may from time to time update the list of channels we will use to communicate information that could be deemed material and will post information about any such change on www.chembio.com. The information on our website is not, and shall not be deemed to be, a part hereof or incorporated into this or any of our other filings with the SEC.

Corporate Information

Our principal executive offices are located at 3661 Horseblock Road, Medford, New York 11763. Our telephone number is (631) 924-1135. Our website address is www.chembio.com. The information contained in, or accessible through, our corporate website does not constitute part of this report.

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ITEM 1A. RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information provided in this Form 10-K in considering whether to make or continue to hold an investment in our Common Stock. The risks described below are those we currently believe may materially affect us. An investment in our Company involves a high degree of risk, and should be considered only by persons who can afford the loss of their entire investment. Although we believe that these risks are the most important for you to consider, you should read this section in conjunction with our financial statements, the notes to those financial statements and our management's discussion and analysis of financial condition and results of operations included in our periodic reports and incorporated into this Form 10-K by reference.

Risks Related to Our Business

Important competitive factors for our products include price, quality, performance, ease of use, and customer service. A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented.

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More generally, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. As new technologies become introduced into the point-of-care diagnostic testing market, we may be required to commit considerable additional efforts, time and resources to enhance our current product portfolio or develop new products. We may not have the available time and resources to accomplish this, and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, which would materially harm our operating results.

Although we own DPP patents, lateral flow technology is still a competitive platform to DPP, and lateral flow technology has a lower cost of manufacture than DPP products. Although the DPP platform has shown improved sensitivity as compared with conventional lateral flow platforms in a number of studies, several factors go into the development and performance attributes of products. Therefore the ability of our products to successfully compete will depend on several other factors, including our having a patented rapid test platform technology that differentiates DPP from lateral flow as well as from other diagnostic platform technologies.

There can be no assurance that our DPP patents or our products incorporating those patents will not be challenged at some time in the future.

Our Competitors may Develop and Commercialize More Effective or Successful Products, and Our Research, Development and Commercialization Efforts may not Succeed.

We regularly commit substantial resources to research and development and the commercialization of our new or enhanced products. The research and development process usually takes a long time from inception to commercial launch. During each stage of this process there is a substantial risk that we will not achieve our goals in a timely fashion, or at all, and we may have to abandon a new or enhanced product in which we have invested substantial time and money. We expect to continue to incur significant costs related to our research and development activities.

Our products require significant development and investment prior to commercialization, including testing to demonstrate the products' performance capabilities, cost-effectiveness or other benefits. We must obtain regulatory approval before most products may be sold and additional development efforts on these products may be required before the products will be reviewed. However, regulatory authorities may not approve these products for commercial sale or may substantially delay or condition such approval. There may be little or no market for the product and entry into or development of new markets for our products may require an investment of substantial resources even if all applicable regulatory approvals are obtained. Furthermore, we may spend a significant amount of money on advertising or other activities and still fail to develop a market for the product. The success of our efforts may be affected by our ability to manufacture products in a cost-effective manner, whether we can obtain necessary intellectual property rights and protection and our ability to obtain reimbursement authorizations in the markets where the product will be sold. Therefore, if we fail to develop and gain commercial acceptance for our products, or if competitors develop more effective products or a greater number of successful new products, customers may decide not to purchase our products.

Our Products may not be Able to Compete with New Diagnostic Products or Existing Products Developed by Well-Established Competitors, which would Negatively Affect Our Business.

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Important competitive factors for our products include price, quality, performance, ease of use, and customer service.

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented.

Some of our principal competitors may have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including Abbott (Alere), OraSure Technologies and Trinity Biotech. Some competitors offer broader product lines and may have greater name recognition than we have. These and other companies have or may have products incorporating molecular or other advanced technologies that over time could directly compete with our testing product line. We also face competition from certain of our distributors or former customers that have created or may decide to create, their own products to compete with ours.

As new products incorporating new technologies enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold. If our competitors' products take market share from our products through more effective marketing or competitive pricing, our revenues, margins and operating results could be adversely affected. In addition, our revenues and operating results could be negatively impacted if some of our customers internally develop or acquire their own sample collection devices and use those devices in place of our products in order to reduce costs.

Our Future Revenues and Operating Results may be Negatively Affected by Ongoing Consolidation in the Healthcare Industry.

There has been a significant amount of consolidation in the healthcare industry. This consolidation has increased the competition to provide goods and services to customers. In addition, group purchasing organizations and integrated health delivery networks have served to concentrate purchasing decisions for some customers, which has also placed pricing pressure on medical device suppliers. Due to ongoing consolidation, there could be additional pressure on the prices of our products.

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Our Continued Growth Depends on Retaining Our Current Key Employees and Attracting Additional Qualified Personnel, and We may not be Able to do so.

Our success depends to a large extent upon the skills and experience of our executive officers, management and sales, marketing, operations and scientific staff. We may not be able to attract or retain qualified employees due to the intense competition for qualified personnel among medical products businesses and academic and other research institutions, as well as to geographic considerations, our ability to offer competitive compensation, and benefits, and other reasons.

If we are not able to attract and retain the necessary qualified personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products to meet the demands of our strategic partners in a timely fashion, or to support internal research and development programs.

We have entered into employment contracts with our Chief Executive Officer, John Sperzel; our Chief Financial Officer, Neil Goldman; and our Chief Science & Technology Officer, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market generally and to our company specifically, the loss of the services of any one of these executives could have a material adverse effect on us. We have not obtained a key man insurance policy on any officer other than Mr. Esfandiari.

We may not Generate the Expected Benefits of Our Acquisition of opTricon GmbH, and the integration of the Acquisition could Disrupt Our Ongoing Business, Distract Our Management and Increase Our Expenses.

We acquired opTricon GmbH, or opTricon, in November 2018 with the expectation that the acquisition will result in various benefits, including securing global commercial rights and reducing cost of goods. Achieving the anticipated benefits of the opTricon acquisition is subject to a number of uncertainties, including whether our business and the business of opTricon can be integrated in an efficient and effective manner. We cannot assure you that we will be able to accurately forecast the performance or ultimate impact of the opTricon acquisition.

It is possible that the integration process could take longer than anticipated and could result in the loss of valuable employees, additional and unforeseen expenses, the disruption of our ongoing business, processes and systems, or inconsistencies in standards, controls, procedures, practices, policies and compensation arrangements, any of which could adversely affect our ability to achieve the anticipated benefits of the opTricon acquisition. There may be increased risk due to integrating financial reporting and internal control systems. The integration process is subject to a number of uncertainties, and no assurance can be given that the anticipated benefits, expense savings and synergies will be realized or, if realized, the timing of their realization. Failure to achieve these anticipated benefits could result in increased costs or decreases in the amount of expected revenues and could adversely affect our future business, financial condition, operating results and prospects.

We have incurred and will continue to incur non-recurring expenses in connection with the opTricon acquisition, including legal, accounting and other expenses. Additional unanticipated costs may be incurred following consummation of the opTricon acquisition in the course of the integration of the business of opTricon into our business. We cannot be certain that the realization of efficiencies related to the integration of the two businesses will offset the transaction and integration costs in the near term or any losses from undiscovered liabilities not covered by an indemnification from the sellers of opTricon.

We may not Generate the Expected Benefits of Future Acquisitions or Investments, and they could Disrupt Our Ongoing Business, Distract Our Management, Increase Our Expenses and Negatively Affect Our Business.

As a way for us to grow our business, we may pursue strategic acquisitions or investments. These activities, and their impact on our business, are subject to many risks, including the following: (i) the benefits expected to be derived from an acquisition or investment may not materialize and could be affected by numerous factors, such as regulatory developments, insurance reimbursement, our inexperience with new businesses or markets, general economic conditions and increased competition; (ii) we may be unable to successfully integrate an acquired company’s

personnel, assets, management, information technology systems, accounting policies and practices, products and/or technology into our business; (iii) we may not be able to accurately forecast the performance or ultimate impact of an acquired business; and (iv) an acquisition may result in the incurrence of unexpected expenses, stockholder lawsuits, the dilution of our earnings or our existing stockholders' percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business.

If these factors occur, we may be unable to achieve all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our financial condition, results of operations and ability to grow our business or otherwise achieve our financial and strategic objectives.

Third-Party Reimbursement Policies and Potential Cost Constraints could Negatively Affect Our Business.

The list of our product end-users includes hospitals, physicians and other healthcare providers. If these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors.

Hospitals, physicians and other healthcare providers who purchase diagnostic products in the United States generally rely on third-party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product. Due to the overall escalating cost of medical products and services, there is increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States, available levels of reimbursement may change for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors, may reduce the demand for our products or our ability to sell our products on a profitable basis.

To the Extent that We are Unable to Collect Our Outstanding Accounts Receivable, Our Operating Results could be Materially Harmed.

There may be circumstances and timing that require us to accept payment terms, including delayed payment terms, from distributors or customers, which, if not satisfied, could cause financial losses.

We generally accept payment terms which require us to ship product before the contract price has been paid fully, and there also are circumstances pursuant to which we may accept further delayed payment terms pursuant to which we may continue to deliver product. To the extent that these circumstances result in significant accounts receivables and those accounts receivables are not paid on a timely basis, or are not paid at all, especially if concentrated in one or two customers, we could suffer financial losses.

Ongoing Changes in Healthcare Regulation could Negatively Affect Our Revenues, Business and Financial Condition.

There have been several proposed changes in the United States at the federal and state level for comprehensive reforms regarding the payment for, the availability of and reimbursement for healthcare services. These proposals have ranged from fundamentally changing federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs. One example is the Patient Protection and Affordable Care or the Affordable Care Act, the Federal healthcare reform law enacted in 2010.

Healthcare reform initiatives will continue to be proposed, and may reduce healthcare related funding in an effort. It is impossible to predict the ultimate content and timing of any healthcare reform legislation and its resulting impact on us. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those

reforms may increase our costs or otherwise negatively effect on our financial condition and results of operations.

In April 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the European Union Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the European Economic Area, which we refer to as the EEA, member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will, however, only become fully applicable three years after publication (in May 2020). Once applicable, the Medical Devices Regulation will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Once applicable, the Medical Devices Regulation may impose increased compliance obligations for us to access the EU market.

We Believe Our Success Depends in Part on the Continued Funding of, and Our Ability to Participate in, Large Testing Programs in the U.S. and Worldwide, the Funding of which may be Reduced or Discontinued or Otherwise be Unavailable to Us.

We believe it to be in our best interests to meaningfully participate in large testing programs. Moreover many of these programs are funded by governments and other donors, and there can be no assurance that funding will not be reduced or completely discontinued. Participation in these programs also requires alignment and engagement with the many other participants in these programs, including WHO, CDC, the U.S. Agency for International Development, foreign governments and their agencies, non-governmental organizations, and HIV service organizations. If we are unsuccessful in our efforts to participate in these programs, our operating results could be materially harmed.

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In December 2013 President Obama signed into law the PEPFAR Stewardship and Oversight Act, which is the most recent reauthorization of PEPFAR. However, unlike the 2008 PEPFAR authorization, which authorized approximately $45 billion in funding, the new law did not authorize a specific dollar amount for funding.

Developing Testing Guidelines could Negatively Affect Sales of Our Products.

Government agencies may issue diagnostic testing guidelines or recommendations, which can alter the usage of our HIV testing products. New laws or guidelines, or changes to existing laws or guidelines, and the manner in which these new or changed laws and guidelines are interpreted and applied, could impact the degree to which our testing products are used. These developments could affect the frequency of testing, the number of people tested and whether the testing products are used broadly for screening large populations or in a more limited capacity. These factors could in turn affect the level of sales of our products and our results of operations.

Legislative and Other Regulatory Changes could have an Effect on Our Business.

The current U.S. Presidential Administration has promised to repeal and replace the Affordable Care Act, expressed concerns with respect to existing trade agreements, and has indicated a desire to make other regulatory changes during his administration. Changes in regulatory or economic conditions or in the laws and policies governing foreign trade, taxes, manufacturing, and development in the United States could impact our business. Economic and regulatory changes could also affect foreign currency exchange rates which, in turn, could affect our reported financial results and our competitiveness on a worldwide basis.

Developments Related to the U.K.’s Referendum On Membership in the E.U. Could Adversely Affect Us.

On June 23, 2016, the United Kingdom voted in favor of leaving the European Union, or E.U. Following this “Brexit” referendum there has been increased political and economic uncertainty, particularly in the U.K. and E.U. and this uncertainty may last for the foreseeable future. Until the terms and timing of the U.K.’s exit from the E.U. are finalized, it will be difficult to predict the impact of Brexit. Our business in the U.K., the E.U. and world-wide could be negatively affected during this period of uncertainty, and perhaps longer. The decision of voters in the U.K. to exit the E.U. could cause volatility in global financial markets, such as global currency exchanges, resulting in a slow-down in economic activity in the U.K., Europe or globally, and result in significant regulatory changes and uncertainty. These events could make it more difficult or costly to sell our products, particularly in the U.K. and Europe, and negatively affect our revenues and results of operations. The Brexit referendum may also influence other countries and result in additional countries deciding to leave the E.U. This in turn could result in additional changes and uncertainty, any or all of which could negatively impact our business.

We could be Exposed to Liability if We Experience Security Breaches or Other Disruptions, which could Harm Our Reputation and Business.

We may be subject to cyber-attacks whereby computer hackers may attempt to access our computer systems or our third party IT service provider’s systems and, if successful, misappropriate personal or confidential information. In addition, a contractor or other third party with whom we do business may attempt to circumvent our security measures or obtain such information, and may purposefully or inadvertently cause a breach involving sensitive information. We will continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, but cyber-attacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Even though we take cyber-security measures that are continuously reviewed and updated, our information technology networks and infrastructure may still be vulnerable due to sophisticated attacks by hackers or breaches.

Even the most well protected IT networks, systems, and facilities remain potentially vulnerable because the techniques used in security breaches are continually evolving and generally are not recognized until launched against a target and,

in fact, may not be detected. Any such compromise of our or our third party's IT service providers' data security and access, public disclosure, or loss of personal or confidential business information, could result in legal claims proceedings, liability under laws to protect, privacy of personal information, and regulatory penalties, disrupt our operations, require significant management attention and resources to remedy any damages that result, damage our reputation and customers willingness to transact business with us, any of which could adversely affect our business.

Our Ability to Efficiently Operate Our Business is Reliant on Information Technology, and Any Material Failure, Inadequacy, Interruption or Security Breach of that Technology could Harm Our Business.

We rely heavily on complex information technology systems across our operations and on the internet, including for management of inventory, invoices, purchase orders, shipping, interactions with our third-party logistics provider, revenue and expense accounting, consumer call support, online business, and various other processes and transactions. Our ability to effectively manage our business, coordinate the production, distribution and sale of our products, respond to customer inquiries, and ensure the timely and accurate recording and disclosure of financial information depends significantly on the reliability and capacity of these systems and the internet.

If any of the foregoing systems fails to operate effectively, problems with transitioning to upgraded or replacement systems, or disruptions in the operation of the internet, could cause delays in product sales and reduced efficiency of our operations. Significant expenditures could be required to fix any such problem.

If there is an Increase in Demand for Our Products, it could Require Us to Expend Considerable Resources or Harm Our Customer Relationships if We are Unable to Meet that Demand.

If there are significant or unexpected increases in the demand for our products, we may not be able to meet that demand without expending additional capital resources. This would increase our capital costs, which could negatively affect our earnings in the short term. In addition, new manufacturing equipment or facilities may require FDA, WHO, and other regulatory approvals before they can be used to manufacture our products. To the extent we are unable to obtain or are delayed in obtaining such approvals, our ability to meet the demand for our products could be adversely affected. Furthermore, our suppliers may be unable or unwilling to expend the necessary capital resources or otherwise expand their capacity, which could negatively affect our business.

Our business could be negatively affected if we or our suppliers are unable to develop necessary manufacturing capabilities in a timely manner. If we fail to increase production volumes in a cost effective manner or if we experience lower than anticipated yields or production problems as a result of changes that we or our suppliers make in our manufacturing processes to meet increased demand, we could experience shipment delays or interruptions and increased manufacturing costs, which could also have a material adverse effect on our revenues and profitability.

If there are unexpected increases in demand for our products, we may be required to obtain additional raw materials in order to manufacture products to meet the increase in demand. However, some raw materials require significant ordering lead time and some are currently obtained from a sole supplier or a limited group of suppliers. It is also possible that one or more of our suppliers may become unwilling or unable to deliver materials to us. Any shortfall in our supply of raw materials and components, or our inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on our ability to meet increased demand for our products. This could negatively affect our total revenues or cost of sales and related profits.

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If we are unable to meet customer demand for our products, it could also harm our relationships with our customers and impair our reputation within the industry. This, in turn, could have a material adverse effect on our business.

Risks Related to Our Products

For Our Business to Succeed in the Future, Our Current and Future Products Must Receive Market Acceptance.

Market acceptance and the timing of such acceptance, of our new products or technologies is necessary for our future success. To achieve market acceptance, we and our distributors will likely be required to undertake substantial efforts and spend significant funds to inform every one of the existence and perceived benefits of our products. We also may require government funding for the purchase of our products to help create market acceptance and expand the use of our products.

It may be difficult evaluate the market reaction to our products and our marketing efforts for new products may not be successful. The government funding we receive may be limited for new products. As such, there can be no assurance that any products will obtain significant market acceptance and fill the market need that is perceived to exist on a timely basis, or at all.

We may not have Sufficient Resources to Effectively Introduce and Market Our Products, which could Materially Harm Our Operating Results.

Introducing and achieving market acceptance for our new products will require substantial marketing efforts and will require us and/or our contract partners, sales agents, and/or distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, sales agents, and distributors. If they do not have or commit the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

New Developments in Health Treatments and Non-Diagnostic Products may Reduce or Eliminate the Demand for Our Products.

The development and commercialization of products outside of the diagnostics industry could adversely affect sales of our products. For example, the development of a safe and effective vaccine to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce or eventually eliminate the demand for our HIV or other diagnostic products and result in a loss of revenues.

Sales Cycles for Our Products can be Lengthy, which can Cause Variability and Unpredictability in Our Business.

Some of our products may require lengthy and unpredictable sales cycles, which makes it more difficult to accurately forecast revenues in a given period and may cause revenues and operating results to vary from period to period. Our products may involve sales to large public and private institutions which may require many levels of approval and may be dependent on economic or political conditions and the availability of grants or funding from government or public health agencies which can vary from period to period. There can be no assurance that purchases or funding from these agencies will occur or continue, especially if current negative economic conditions continue or intensify. As a result, we may expend considerable resources on unsuccessful sales efforts or we may not be able to complete transactions at all or on a schedule and in an amount consistent with our objectives.

We May Face Product Liability Claims for Injuries.

The testing, manufacturing and marketing of medical diagnostic products involves an inherent risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities

or be required to limit or cease sales of our products. We cannot be sure that we will not incur liabilities in excess of the policy limits of our existing product liability insurance coverage or that we will be able to continue to obtain adequate product liability insurance coverage in the future at an acceptable cost, or at all. In addition, a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injury and otherwise. Any substantial underinsured loss resulting from such a claim could have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

Our Customers may not Adopt Rapid Point-of-Care Diagnostic Testing.

Rapid point-of-care tests are beneficial because, among other things, they can be administered by healthcare providers in their own facilities or used by consumers at home without sending samples to central laboratories. But currently the majority of diagnostic tests used by physicians and other healthcare providers in the U.S. are provided by clinical reference laboratories and hospital-based laboratories. In some international markets, such as Europe, diagnostic testing is performed primarily by centralized laboratories. Future sales of our products will depend, in part, on our ability to expand market acceptance of rapid point-of-care testing and successfully compete against laboratory testing methods and products. However, we expect that clinical reference and other hospital-based laboratories will continue to compete vigorously against our rapid point-of-care products. Even if we can demonstrate that our products are more cost effective, save time, or have better performance or other benefits, physicians, other healthcare providers and consumers may resist changing to rapid point-of-care tests and instead may choose to obtain diagnostic results through laboratory tests. If we fail to achieve and expand market acceptance of our rapid point-of-care diagnostic tests with customers, it would have a negative effect on our future sales growth.

Customer Concentration Creates Risks for Our Business.

A significant portion of our revenues each year comes from a few large customers. To the extent that such a large customer fails to meet its purchase commitments, changes its ordering patterns or business strategy, or otherwise reduces its purchases or stops purchasing our products, or if we experience difficulty in meeting the demand by these customers for our products, our revenues and results of operations could be adversely affected.

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If Our Products do not Perform Properly, It may Affect Our Revenues, Stock Price and Reputation.

Our products may not perform as expected. For example, a defect in one of our diagnostic products or a failure by a customer to follow proper testing procedures may cause the product to report inaccurate information. Identifying the root cause of a product performance or quality issue can be difficult and time consuming.

If our products do not to perform in accordance with the applicable label claims or otherwise in accordance with the expectations or needs of our customers, customers may switch to a competing product or otherwise stop using our products, and our revenues could be negatively affected. If this occurs, we may be required to implement holds or product recalls and incur warranty obligations. Furthermore, the poor performance by one or more of our products could have an adverse effect on our reputation, our continuing ability to sell products and the price of our Common Stock.

If We Expand Our International Presence, It may Increase Our Risks and Expose Our Business to Regulatory, Cultural or Other Challenges.

We will continue to try to increase revenue derived from international sales of our products. There are several of factors that could adversely affect the performance of our business and/or cause us to incur substantially increased costs because of our international presence and sales, including: (i) uncertainty in the application of foreign laws and the interpretation of contracts with foreign parties; (ii) cultural and political differences that favor local competitors or make it difficult to effectively market, sell and gain acceptance of our products; (iii) exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on international distributors or representatives; (iv) trade protection measures, trade sanctions and import/export licensing requirements; (v) our inability to obtain or maintain regulatory approvals or registrations for our products; (vi) Economic conditions, political instability, the absence of available funding sources, terrorism, civil unrest, war and natural disasters in foreign countries; (vii) Reduced protection for, or enforcement of, our patents and other intellectual property rights in foreign countries; (viii) our inability to identify international distributors and negotiate acceptable terms for distribution agreements; and (ix) restrictions on our ability to repatriate investments and earnings from foreign operations.

Economic, cultural and political conditions and foreign regulatory requirements may slow or prevent the manufacture of our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply. Foreign currency fluctuations and economic conditions in foreign countries could also increase the costs of manufacturing our products in foreign countries.

Financial Results, Economic, and Financing Risks

We incurred an operating loss each year from 2014 through 2018. Under our operating plan, we have made, and plan to continue to make, significant investments in our production capacity, including in expanding facilities and automating manufacturing, and in our sales and marketing, regulatory approval, and research and development activities. Our ability to achieve profitability and generate cash flow in the future will depend on our ability to increase sales of our existing products and to successfully introduce new and enhanced products into the marketplace, all while controlling and managing our expenses consistent with our operating plan.

If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, our operating results would be harmed and we may not be able to generate the cash flow needed to fund the investments in our production capacity and other activities, we will be required to implement one or both of the following:

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We could reduce the level, or otherwise delay the timing, of the anticipated investments in our production capacity and other activities, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow.

- We could raise additional funds through public or private financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we succeed in raising additional funds through the issuance of equity or convertible securities, then the issuance could result in substantial dilution to existing stockholders. Furthermore, the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of our Common Stock.

In such circumstances, we also would need to forego acquisition opportunities, which could impede our ability to grow our business.

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We Base Our Estimates or Judgments Relating to Critical Accounting Policies on Assumptions that can Change or Prove to be Incorrect.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and our discussion and analysis of financial condition and results of operations is based on such statements. The preparation of financial statements requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We continuously evaluate significant estimates used in preparing our financial statements, including those related to (i) revenue recognition; (ii) stock-based compensation; (iii) allowance for uncollectible accounts receivable; (iv) inventory reserves and obsolescence; (v) customer sales returns and allowances; (vi) contingencies; and (vii) income taxes.

Our estimates are based on historical experience and various other assumptions that we believe to be reasonable, as set forth in our discussion and analysis of financial condition and results of operations, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these and other estimates if our assumptions change or if actual circumstances differ from those in our assumptions. If our operating results fall below the expectations of securities analysts and investors, the price of our Common Stock may decline.

Our Financial Results may Fluctuate.

From quarter to quarter and year to year, our operating results can fluctuate, which could cause our growth or financial performance to fail to meet the expectations of investors and securities analysts. Sales to our distributors and other customers may not meet expectations because of lower than expected customer demand or other factors, including continued economic volatility and disruption, reduced governmental funding, and other circumstances described elsewhere in this report. A variety of factors could also contribute to the variability of our financial results, including infrequent, unusual or unexpected changes in revenues or costs.

Different products provide dissimilar contributions to our gross product margin. Accordingly, our operating results could also fluctuate and be negatively affected by the mix of products sold and the relative prices and gross product margin contribution of those products. Failure to achieve operating results consistent with the expectations of investors and securities analysts could adversely affect our reputation and the price of our Common Stock.

Our Operating Results may be Negatively Affected by Changes in Foreign Currency Exchange Rates.

In the past our exposure to foreign currency exchange rate risk has not been material. Nevertheless, sales of our products are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. The fluctuations in the exchange rate could negatively impact international sales of our products, as could changes in the general economic conditions.

The revenues and expenses of Chembio Diagnostics Malaysia, one of our subsidiaries, are recorded in Malaysian Ringgit. The revenues and expenses of opTricon are recorded in Euros. Revenues and expenses denominated in foreign currencies are translated into U.S. dollars for purposes of reporting our consolidated financial results. Our expectation is that the Chembio Diagnostics Malaysia and opTricon businesses will continue to grow and, consequently, our exposure to foreign currency exchange rates may grow as well.

Our foreign subsidiaries' revenues and expenses and the translation of their financial results into U.S. dollars may be negatively affected by fluctuations in the exchange rate. Favorable movement in exchange rates have benefited us in prior periods. However, where there are unfavorable currency exchange rate fluctuations, our consolidated financial statements could be negatively affected. Furthermore, fluctuations in exchange rates could affect year-to-year comparability of operating results. In the past, we have not generally entered into hedging instruments to manage our

currency exchange rate risk, but we may need to do so in the future. However, our attempts to hedge against these risks may not be successful. If we are unable to successfully hedge against unfavorable foreign currency exchange rate movements, our consolidated financial results may be adversely impacted.

Changes in Interpretation or Application of U.S. Generally Accepted Accounting Principles may Adversely Affect Our Operating Results.

We prepare our financial statements to conform to U.S. generally accepted accounting principles. These principles are subject to interpretation by the Financial Accounting Standards Board, the American Institute of Certified Public Accountants, the Public Company Accounting Oversight Board, the Securities and Exchange Commission and various other regulatory or accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. Additionally, as we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period. For example, upon adoption of Accounting Standards Codification (“ASC”) 606 Revenue from Contracts with Customers of the Financial Accounting Standards Board (“FASB”), we now recognize revenue upon transfer of control, which is generally at time of delivery. Under the previous accounting guidance, we recognized revenue upon acceptance when and if we had production responsibilities. If circumstances change over time or interpretation of the revenue recognition rules change, we could be required to adjust the timing of recognizing revenue and our financial results could suffer.

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Our Business may be Negatively Affected by Terrorist Attacks or Natural Disasters.

Terrorist attacks or natural disasters could cause economic instability. These events could negatively affect economic conditions both within and outside the United States and harm demand for our products. The operations of our customers and suppliers could be negatively impacted and eliminate, reduce or delay our customers' ability to purchase and use our products and our suppliers' ability to provide raw materials and finished products.

Our facilities, including some pieces of manufacturing equipment and our computer systems, may be difficult to replace. Various types of disasters, including fires, earthquakes, floods and acts of terrorism, may affect our facilities and computer systems. In the event our existing facilities or computer systems are affected by man-made or natural disasters, we may have difficulty operating our business and may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or shut down entirely, it would seriously harm our business.

We Operate in Countries where there is or may be Widespread Corruption.

We have a policy in place prohibiting our employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the U.S. Foreign Corrupt Practices Act. Nevertheless, because we work through independent sales agents and distributors outside the United States, we do not have control over the day-to-day activities of such independent agents and distributors. In addition, in the donor-funded markets in Africa where we sell our products, there is significant oversight from PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols. This is a process that includes an overall assessment of a product which includes extensive product performance evaluations including five active collaborations and manufacturer's quality systems, as well as price and delivery. In Brazil, where we have had numerous product collaborations with FIOCRUZ, the programs through which our products may be deployed are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with the Brazilian Ministry of Health, and is its sole customer, FIOCRUZ is not the exclusive supplier for the Ministry of Health. However, because each of our previous collaborations with FIOCRUZ incorporates a technology transfer aspect, we believe we have a competitive advantage versus other suppliers to the Brazilian Ministry of Health, assuming other aspects of our product offering through FIOCRUZ are otherwise competitive in comparison. We have no knowledge or reason to know of any activities by our employees, distributors or sales agents of any actions which could be in violation of the FCPA, although there can be no assurance of this.

Our subsidiary Chembio Diagnostics Malaysia Sdn. Bhd. is located in Malaysia. There have been numerous high-profile corruption cases, and corruption is one of the most problematic factors for doing business in Malaysia. While the Malaysian government has acknowledged the problem, it appears that endemic corruption is continuing and that market-based principles are not applied in cases involving individuals with high-level political access. To the extent bribery and similar practices continue to exist in Malaysia, U.S. companies such as ours, which are subject to U.S. laws making it illegal to pay bribes to foreign officials, may make us less competitive in winning business in Malaysia when competing with non-U.S. companies.

Risks Related to Intellectual Property

Our Success Depends on Our Ability to Protect Our Proprietary Technology. We Rely on Trade Secret Laws and Agreements with Our Key Employees and Other Third Parties to Protect Our Proprietary Rights, and We cannot be sure that these Laws or Agreements will Adequately Protect Our Rights.

Our industry places considerable importance on obtaining patent, trademark and trade secret protection, as well as other intellectual property rights, for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong intellectual property portfolio or obtain licenses to patents and technologies,

both in the United States and in other countries. If we cannot continue to develop, obtain and protect intellectual property rights, our revenues and gross profits could be adversely affected. Moreover, our current and future licenses or other rights to patents and other technologies may not be adequate for the operation of our business.
As appropriate, we intend to file patent applications and obtain patent protection for our proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for our products, methods of making those products, methods of using those products and apparatuses relating to the use or manufacture of those products. However, there have been changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, which may impact our ability to protect our technology and enforce our intellectual property rights. For example, in 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the U.S. from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

We believe that factors such as the technological and creative skills of our personnel, strategic relationships, new product developments, frequent product enhancements and name recognition are essential to our success. All our management personnel are bound by non-disclosure agreements. If personnel leave our employment, in some cases we would be required to protect our intellectual property rights pursuant to common law theories which may be less protective than provisions of employment, non-competition or non-disclosure agreements.

We seek to protect our proprietary products under trade secret and copyright laws, enter into license agreements for various materials and methods employed in our products, and enter into strategic relationships for distribution of the products. These strategies afford only limited protection. We currently have some foreign patents issued, and we are seeking additional patent protection in several other foreign jurisdictions for our DPP and optical technology. We have licenses to reagents (antigens and peptides) used in several of our products and products under development. Despite our efforts to protect our proprietary assets, and respect the intellectual property rights of others, we participate in several markets where intellectual property rights protections are of little or no value. This can place our products and our company at a competitive disadvantage.

Moreover, issued patents remain in effect for a fixed period and after expiration will not provide protection of the inventions they cover. Once our patents expire, we may be faced with increased competition, which could reduce our revenues. We may also not be able to successfully protect our rights to unpatented trade secrets and know-how.

To facilitate development and commercialization of a proprietary technology base, we may need to obtain additional licenses to patents or other proprietary rights from other parties. Obtaining and maintaining these licenses, which may not be available, may require the payment of up-front fees and royalties. In addition, if we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed or precluded.

Any Future Intellectual Property Disputes could Require Significant and Limit or Eliminate Our Ability to Sell Products or Use Certain Technologies.

We may be required to expend substantial resources in asserting or protecting our intellectual property rights, or in defending suits related to intellectual property rights. We may seek to enforce our patents or other intellectual property rights through litigation. Such litigation is prevalent and is expected to continue. In our business, there are a large number of patents and patent applications similar to our products, and additional patents may be issued to third parties relating to our product areas. We, our customers or our suppliers may be sued for infringement of patents or misappropriation of other intellectual property rights with respect to one or more of our products. We may also have disputes with parties that license patents to us if we believe the license is no longer needed for our products or the licensed patents are no longer valid or enforceable.

There are a large number of patents in our industry, and the claims of these patents appear to overlap in many cases. Therefore there is a significant amount of uncertainty regarding the extent of patent protection and infringement.

Companies may have pending patent applications, which are typically confidential for the first eighteen months following filing that cover technologies we incorporate in our products. Accordingly, we may be subjected to substantial damages for past infringement or be required to modify our products or stop selling them if it is ultimately determined that our products infringe a third party's proprietary rights. In addition, governmental agencies could commence investigations or criminal proceedings against our employees or us relating to claims of misuse or misappropriation of another party's proprietary rights.

If we are involved in litigation or other legal proceedings with respect to patents or other intellectual property and proprietary technology, it could adversely affect our revenues, results of operations, market share and business because (1) it could consume a substantial portion of managerial and financial resources; (2) its outcome would be uncertain and a court may find that our patents are invalid or unenforceable in response to claims by another party or that the third-party patent claims are valid and infringed by our products; (3) the pendency of any litigation may in and of itself cause our distributors and customers to reduce or terminate purchases of our products; (4) a court could award a preliminary and/or permanent injunction, which would prevent us from selling our current or future products; and (5) an adverse outcome could subject us to the loss of the protection of our patents or to liability in the form of past royalty payments, penalties, reimbursement of litigation costs and legal fees, special and punitive damages, or future royalty payments, any of which could significantly affect our future earnings.

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Under certain contracts with third parties, we may indemnify the other party if our products or activities have actually or allegedly infringed upon, misappropriated or misused another party's proprietary rights. Furthermore, our products may contain technology provided to us by third parties, and we may be unable to determine in advance whether such technology infringes the intellectual property rights of a third party. These other parties may also not be required or financially able to indemnify us in the event that an infringement or misappropriation claim is asserted against us.

There may also be other types of disputes that we become involved in regarding intellectual property rights, including state, federal or foreign court litigation, and patent interference, patent reissue, patent reexamination, or trademark opposition proceedings in the United States Patent and Trademark Office. Opposition or revocation proceedings could be instituted in a foreign patent office as well. These proceedings permit certain persons to challenge the validity of a patent on the grounds that it was known from the prior art. The filing of such proceedings, or the issuance of an adverse decision in such proceedings, could result in the loss of valuable patent rights that could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Third Party Collaborators

Our Use of Third-Party Suppliers, some of which may Constitute Our Sole Supply Source, for Certain Important Product Components and Materials Presents Risks that Could Have Negative Consequences for Our Business.

We purchase certain HIV antigens, a syphilis antigen, the nitrocellulose, and certain other critical components used in our STAT-PAK, STAT-VIEW, SURE CHECK and DPP product lines from a sole or limited number of sources. If for any reason these suppliers become unwilling or unable to supply our antigen, nitrocellulose, or other critical component needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in any of the antigens, nitrocellulose or other critical components used in our products would require additional development work and approval by the FDA and other regulatory agencies. In addition, it may be difficult to find such an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. As a result, the termination or limitation of our relationship with one or more of these suppliers could require significant time to complete, increase our costs, and disrupt or discontinue our ability to manufacture and sell the affected products.

With some of these suppliers, we do not have long-term agreements and instead purchase components and materials through a purchase order process. As a result, these suppliers may stop supplying us components and materials, limit the allocation of supply and equipment to us due to increased industry demand, or significantly increase their prices at any time with little or no advance notice. Our reliance on a limited number of suppliers could also result in delivery problems, reduced control over product pricing and quality, and our inability to identify and qualify another supplier in a timely manner.

Moreover, some of these suppliers may experience financial difficulties that could prevent them from supplying us with components or subassemblies used in the design and manufacture of our products. In addition, these suppliers may experience manufacturing delays or shut downs due to circumstances beyond their control, such as labor issues, political unrest or natural disasters.

Any supply deficiencies could materially and adversely affect our ability to fulfill customer orders and our results of operations. The availability of critical components and materials from sole- or limited source suppliers could reduce our control over pricing, quality and timely delivery, increase our costs, could disrupt our ability to manufacture and sell, and preclude us from manufacturing and selling, certain of our products into one or more markets. Any such event could have a material adverse effect on our results of operations, cash flow and business.

We May Work with Strategic Collaborators to Assist in Developing and Commercializing Our Products, which could Limit Rights We Receive from the Collaborations and Exposes Us to Other Risks Outside Our Control.

Some business opportunities that require a technology controlled by a third party, a significant level of investment for development and commercialization or a distribution network beyond our existing sales force may necessitate involving one or more strategic collaborators. As part of our strategy for development and commercialization of our products, we may enter into arrangements with distributors or other third-parties. Relying on such collaborative relationships could be risky to our business for a number of reasons, including: (i) we may be required to transfer material rights to such strategic collaborators, licensees and others; (ii) our collaborators may not obtain regulatory approvals necessary to continue the collaborations in a timely manner; (iii) our collaborators may decide to terminate our collaborative arrangement or become insolvent; (iv) our collaborators may develop technologies or components competitive with our products; (v) disagreements with collaborators could result in the termination of the relationship or litigation; and (vi) we may not be able to agree to future collaborative arrangements, or renewals of existing collaborative agreements, on acceptable terms or at all.

We expect our collaborators will have an economic motivation to succeed in performing their contractual responsibilities under our agreements, there is no assurance that they will do so. Due to our reliance on strategic agreements, it can make it difficult to accurately forecast our future revenues and operating results.

Our Ability to Grow Our Business will be Limited if We Fail to Maintain Existing Distribution Channels or Develop New Distribution Channels.

We collaborate with laboratories, diagnostic companies and distributors in order to sell our products. The sale of our products depends in large part on our ability to sell products to these customers and on the marketing and distribution abilities of the companies with which we collaborate and work with.

By relying on distributors or third-parties to market and sell our products could negatively impact our business for various reasons, including: (i) we may not be able to find suitable distributors for our products on satisfactory terms, or at all; (ii) agreements with distributors may prematurely terminate or may result in litigation between the parties; (iii) our distributors or other customers may not fulfill their contractual obligations and distribute our products in the manner or at the levels we expect; (iv) our distributors may prioritize their own private label products that compete with our products; (v) Our existing distributor relationships or contracts may preclude or limit us from entering into arrangements with other distributors; and (vi) we may not be able to negotiate new or renew existing distribution agreements on acceptable terms, or at all.

We will try to maintain and expand our business with distributors and customers and make every effort to require that they fulfill their contractual obligations, but there can be no assurance that such companies will do so or that new distribution channels will be available on satisfactory terms. If we are unable to do so, our business will be negatively impacted.

Our U.S. Government Contracts Require Compliance with Numerous Laws and Increases Our Risk and Liability.

We are currently receiving funding from the U.S. government related to DPP Zika, and our growth strategy targets sales to U.S. government entities. As a result of our U.S. government funding and potential product sales to the U.S. government, we must comply with laws and regulations relating to the award, administration and performance of U.S. government contracts. U.S. government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on government contracts. As a U.S. government contractor, we are subject to increased risks of investigation, criminal prosecution and other legal actions and liabilities to which purely private sector companies are not. The results of any such actions could adversely impact our business and have an adverse effect on our consolidated financial performance.

A violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of our contracts, as well as suspension or debarment. The suspension or debarment in any particular case may be limited

to the facility, contract or subsidiary involved in the violation or could be applied to our entire enterprise in certain severe circumstances. Even a narrow scope suspension or debarment could result in negative publicity that could adversely affect our ability to renew contracts and to secure new contracts, both with the U.S. government and private customers, which could materially and adversely affect our business and results of operations. Fines and penalties could be imposed for failing to follow procurement integrity and bidding rules, employing improper billing practices or otherwise failing to follow rules relating to billing on cost-plus contracts, receiving or paying kickbacks, or filing false claims, among other potential violations. In addition, we could suffer serious reputational harm and the value of our Common Stock could be negatively affected if allegations of impropriety related to such contracts are made against us.

Our U.S. Government Contracts are Subject to Future Funding and the Government's Choice to Exercise Options, and may be Terminated at the Government's Convenience.

Our contracts with the U.S. government are subject to future funding and are subject to the right of the government to terminate the contracts in whole or in part for its convenience. There is pressure for the U.S. government to reduce spending. The non-appropriation of funds or the termination for the government's convenience of our contracts could negatively affect our financial results. If levels of U.S. government expenditures and authorizations for emerging diseases decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under its contracts with us, our business, revenues and other operating results would suffer.

Risks Related to Regulations

Because We may not be Able to Obtain or Maintain the Necessary Regulatory Approvals for Some of Our Products, We may not Generate Revenues in the Amounts We Expect, or in the Amounts Necessary to Continue Our Business. Our Existing Products as well as Our Manufacturing Facility Must Meet Quality Standards and are Subject to Inspection by a Number of Domestic Regulatory and Other Governmental and Non-Governmental Agencies.

All of our proposed and existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration, the U.S. Department of Agriculture and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. The process of obtaining required approvals or clearances varies according to the nature of, and uses for, a specific product. These processes can involve lengthy and detailed laboratory testing, human or animal clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for that product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may determine to devote our resources to different products.

Changes in government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.

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Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

We can manufacture and sell our products only if we comply with regulations and quality standards established by government agencies such as the FDA and the U.S. Department of Agriculture as well as by non-governmental organizations such as the ISO and WHO. We have implemented a quality control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with FDA QSRs and that also require meeting certain documentary requirements regarding the approval of the product in export markets.

If We do not Comply with FDA or Other Regulatory Requirements, We may be Required to Suspend Production or Sale of Our Products or Institute a Recall, which could Result in Higher Costs and a Loss of Revenues.

Regulations of the FDA and other federal, state and foreign regulatory agencies have significant effects on many aspects of our operations, and the operations of our suppliers and distributors, including packaging, labeling, manufacturing, adverse event reporting, recalls, distribution, storage, advertising, promotion and record keeping. We are subject to routine inspection by the FDA and other agencies to determine compliance with QSRs and FDA regulatory requirements in the United States and other applicable regulations worldwide, including but not limited to ISO standards. We believe that our facilities and procedures are in material compliance with the FDA requirements and ISO standards, but the regulations may be unclear and are subject to change, and we cannot be sure that the FDA or other regulators will agree with our compliance with these requirements. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved or cleared products or impose conditions on any product clearances or approvals that could restrict the distribution or commercial applications of those products. Regulatory agencies may impose restrictions on our or our distributors' advertising and promotional activities or preclude these activities altogether if a noncompliance is believed to exist. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product or additional regulatory actions, including withdrawal of the product from the market.

Our inability to comply with the applicable requirements of the FDA can result in, among other things, 483 notices, warning letters, administrative or judicially imposed sanctions such as injunctions, recall or seizure of products, civil penalties, withdrawal of product registrations, total or partial suspension of production, refusal to grant premarket clearance or PMA approval for devices, marketing clearances or approvals, or criminal prosecution. The ability of our suppliers to supply critical components or materials and of our distributors to sell our products could also be adversely affected if their operations are determined to be out of compliance. Such actions by the FDA and other regulatory bodies could adversely affect our revenues, costs and results of operations.

We must frequently make judgment decisions with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with how we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. Our reputation could be substantially impaired if we are assessed any civil and criminal penalties and limit our ability to manufacture and market our products which could have a material adverse effect on our business.

Our Inability to Respond to Changes in Regulatory Requirements could Adversely Affect Our Business.

We believe that our products and procedures are in material compliance with all applicable FDA regulations, ISO requirements, and other applicable regulatory requirements, but the regulations regarding the manufacture and sale of

our products, the QSR and ISO requirements, and other requirements may be unclear and are subject to change. Newly promulgated regulations could require changes to our products, necessitate additional clinical trials or procedures, or make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to change the requirements for obtaining product approval and/or impose new or additional requirements as part of the approval process. These changes or new or additional requirements may occur after the completion of substantial clinical work and other costly development activities. The implementation of such changes or new or additional requirements may result in additional clinical trials and substantial additional costs and could delay or make it more difficult or complicated to obtain approvals and sell our products. In addition, the FDA may revoke an Emergency Use Authorization under which our products are sold, where it is determined that the underlying health emergency no longer exists or warrants such authorization. Such revocation would preclude the sale of our affected products unless and until a further regulatory approval or authorization is obtained. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.

Demand for Our Products may be Affected by FDA Regulation of Laboratory-Developed Tests and Genetic Testing.

Regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories is covered by the FDA. The FDA has previously taken the position that it has regulatory authority over laboratory-developed tests, or LDTs, but has exercised enforcement discretion by not regulating most LDTs performed by high complexity CLIA-certified laboratories. LDTs are tests designed, developed, and performed in-house by a laboratory. These laboratories are subject to CLIA regulation but such laboratories have previously not been subject to regulation by FDA under the agency’s medical device requirements.

However, the FDA has announced that it would begin regulating LDTs, and in October 2014 the FDA issued proposed guidance on the regulation of LDTs for public comment. But, on November 18, 2016, the FDA announced that it would not finalize the proposed guidance prior to the end of the Obama administration. On January 13, 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. We cannot predict what policies the Trump administration will adopt with respect to LDTs. If the FDA increases regulation of LDTs, it could make it more difficult for laboratories and other customers to continue offering LDTs that involve genetic or molecular testing. This, in turn, could reduce demand for our products and adversely impact our revenues.

In Addition to FDA Requirements, We Are Subject to Several Government Regulations, Compliance with which could Increase Our Costs and Affect Our Operations.

In addition to the FDA regulations previously described, laws and regulations in some states may restrict our ability to sell products in those states.

We must comply with numerous laws related to safe working conditions, environmental protection, disposal of hazardous substances, fire hazard control, manufacturing practices and labor or employment practices. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Due to the number of laws and regulations governing our industry, and the actions of a number of government agencies that could affect our operations, it is impossible to reliably predict the full nature and impact of these laws and regulations. To the extent the costs and procedures associated with complying with these laws and requirements are substantial or it is determined that we do not comply, our business and results of operations could be adversely affected.

We may Incur Additional Costs if We do not Comply with Privacy, Security and Breach Notification Regulations.

We believe that we are not a covered entity nor a business associate of a covered entity and are not responsible for complying with the Health Insurance Portability and Accountability Act of 1996, or HIPAA. Even though we likely

are not a covered entity under HIPAA, we do have in place administrative, technical and physical safeguards to protect the privacy and security of consumers' personal information.] We are required to comply with varying state privacy, security and breach reporting laws. If we fail to comply with existing or new laws and regulations related to properly transferring data containing consumers' personal information, we could be subject to monetary fines, civil penalties or criminal sanctions. Also, there are other federal and state laws that protect the privacy and security of consumers' personal information, and we may be subject to enforcement by various governmental authorities and courts resulting in complex compliance issues. We could incur damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of consumers' personal information.

Failure to Comply With Recent European Data Protection Requirements could Increase Our Costs.

The EU has adopted a comprehensive overhaul of its data protection regime from the prior national legislative approach to a single European Economic Area Privacy Regulation called the General Data Protection Regulation, or GDPR, which came into effect on May 25, 2018. The new EU data protection regime extends the scope of the EU data protection law to all foreign companies processing data of EU residents. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide turnover and €20 million and includes new rights such as the "portability" of personal data. Although the GDPR will apply across the EU without a need for local implementing legislation, as had been the case under the prior data protection regime, local data protection authorities will still have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. We are evaluating these new requirements and implementing a plan to ensure compliance. Complying with the enhanced obligations imposed by the GDPR may result in significant costs to our business and require us to amend certain of our business practices. Further, we have no assurances that violations will not occur, particularly given the complexity of the GDPR, as well as the uncertainties that accompany new, comprehensive legislation.

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If We are not Able to Manufacture Products in Accordance with Applicable Requirements, It could Adversely Affect Our Business.

Our products must meet detailed specifications, performance standards and quality requirements. As a result, our products and the materials used in their manufacture or assembly undergo regular inspections and quality testing. Factors such as defective materials or processes, mechanical failures, human errors, environmental conditions, changes in materials or production methods, and other events or conditions could cause our products or the materials used to produce or assemble our products to fail inspections and quality testing or otherwise not perform in accordance with our label claims or the expectations of our customers.

If we are not able to meet the applicable specifications, performance standards, quality requirements or customer expectations could adversely affect our ability to manufacture and sell our products or comply with regulatory requirements. These events could, in turn, adversely affect our revenues and results of operations.

Healthcare Fraud and Abuse Laws Could Adversely Affect Our Business and Results of Operations.

There are various federal and state laws targeting fraud and abuse in the healthcare industry to which we are subject, including anti-kickback laws, laws constraining the sales, false claims laws, marketing and promotion of medical devices by limiting the kinds of financial arrangements that manufacturers of these products may enter into with physicians, hospitals, laboratories and other potential purchasers of medical devices. There are other laws we are subject to that require us to report certain transactions between it and healthcare professionals. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs. Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. We could face enforcement action and fines and other penalties, and could receive adverse publicity, unless and until we are in full compliance with these laws, all of which could materially harm us. Furthermore, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

Our Compliance with Regulations Governing Public Companies is Complex and Expensive.

Public companies are subject to various laws and regulations, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. For example, we are subject to the Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and the requirements of The NASDAQ Global Market. The implementation of certain aspects of these laws and regulations has required and will continue to require substantial management time and oversight and may require us to incur significant additional accounting and legal costs. We continually review changes with respect to new and proposed rules and cannot predict or estimate the amount of additional costs, and the timing of such costs, we may incur. There are several interpretations of these laws and regulations, in many cases due to their lack of specificity, and as a result, their application in practice may change as new guidance is provided by regulatory and governing bodies. This may result in continuing uncertainty regarding compliance matters and higher costs. We are committed to maintaining high standards of corporate governance and public disclosure, but if we fail to comply with any of these requirements, legal proceedings may be initiated against us, which may adversely affect our business.

Risks Related to Our Common Stock

Our Common Stock has Limited Liquidity, and Investors may not be Able to Sell as Much Stock as They Want at Prevailing Market Prices or at all.

The liquidity of our Common Stock depends on several factors, including but not limited to our financial results and overall market conditions, so it is not possible to predict whether this level of liquidity will continue, be sustained, or decrease. Decreased trading volume in our stock would make it more difficult for investors to sell their shares in the public market at any given time at prevailing prices. Our management and larger stockholders exercise significant control over our company.

The Price of Our Common Stock could Continue to be Volatile.

The price of our Common Stock has been volatile and may be volatile in the future. The following factors, among others, could have a significant impact on the market for our Common Stock: (1) the performance of our business; (2) clinical results with respect to our products or those of our competitors; (3) the gain or loss of significant contracts and availability of funding for the purchase of our products; (4) actions undertaken by the Congress or the Presidential Administration; (5) changes in our relations with our key customers, distributors or suppliers; (6) developments in patent or other proprietary rights; (7) litigation or threatened litigation; (8) general market and economic conditions; (9) the relatively low trading volume for our Common Stock; (10) changes in competition; (11) Complaints or concerns about the performance or safety of our products and publicity about those issues, including publicity expressed through social media or otherwise over the internet; (12) failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders; (13) announcement of regulatory or enforcement actions by the FDA or other agencies against us, our products or our customers; (14) changes in our operating results; and (15) terrorist attacks, civil unrest, war and national disasters.

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Overall, the stock market has experienced price and volume fluctuations that have affected the market price of our Common Stock, as well as the stock of many other similar companies. Such price fluctuations are generally unrelated to the operating performance of the specific companies whose stock is affected.

After the volatility in the market price of a company's stock, class action litigation has occurred against the issuing company. If we were subject to this type of litigation in the future, we could incur substantial costs and the attention and resources of our management could be diverted, each of which could have a material adverse effect on our revenue and earnings. Any adverse determination in this type of litigation could also subject us to significant liabilities.

Sales of Our Common Stock by Existing Stockholders, Executive Officers or Directors could Depress the Market Price of Our Common Stock.

If our existing stockholders, officers or directors sell our Common Stock in the public market, or the perception that such sales may occur, it could negatively affect the price of our Common Stock. We are unable to estimate the number of shares of our Common Stock that may actually be resold in the public market since this will depend on the market price for our Common Stock, the individual circumstances of the sellers and other factors.

Institutional stockholders own significant amounts of our Common Stock. If one or more of these stockholders sell large portions of their holdings in a relatively short time, the prevailing price of our Common Stock could be negatively affected. In addition, it is possible that one or more of our executive officers or non-employee members of our Board of Directors could sell shares of our Common Stock during an open trading window. These transactions and the perceived reasons for these transactions could have a negative effect on the prevailing market price of our Common Stock.

We do not Intend to Pay Cash Dividends on Our Common Stock.

We do not expect to pay any cash dividends on our Common Stock and currently intend to retain our earnings, if any, to finance the expansion of our business. Therefore, the success of an investment in our Common Stock will depend entirely upon any future increase in value of our Common Stock. There is no guarantee that our Common Stock will gain value or even maintain the price at which investors purchased their shares.

If We or Our Independent Registered Public Accounting Firm Concludes That Our Internal Control Over Financial Reporting is Not Effective, Investor Confidence and the Value of Our Common Stock May be Adversely Impacted.

The SEC has adopted rules requiring us, as a public company, to include a report in our Annual Reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, our independent registered public accounting firm must report on the effectiveness of these internal controls.

We believe our internal controls will continue to evolve as our business develops. We continue to review our internal control over financial reporting in an effort to ensure compliance with SEC rules and regulations, any control system, regardless of how well designed and operated, can provide only reasonable assurance that its objectives will be met. In addition, the overall quality of our internal controls may be affected by the internal control over financial reporting implemented by any business we acquire and our ability to assess and successfully integrate the internal controls of any such business.

If our independent registered public accounting firm is not satisfied with our internal control over financial reporting or the level at which our controls are documented, designed, implemented, or tested, or if the independent registered public accounting firm interprets the requirements, rules or regulations differently than we do, then it may issue a report noting such dissatisfaction. We also could conclude that our internal control over financial reporting is not

effective. These events could result in an adverse reaction in the financial marketplace, which ultimately could negatively impact the market price of our Common Stock.

Any Future Issuances of Shares of Our Common Stock by Us Could Harm the Price of Our Common Stock and Our Ability to Raise Funds in New Equity Offerings.

Any future sales of a substantial number of our shares of Common Stock or other equity-related securities, or the perception that such sales may occur, could adversely affect the price of our Common Stock, and could impair our ability to raise capital through future offerings of equity or equity-related securities.

Our Management and Larger Stockholders Exercise Significant Control Over Us.

As of December 31, 2018, our named executive officers, directors and 5% stockholders beneficially owned approximately 14.21% of our voting power, which includes 1 large investor that beneficially owns approximately 8.73%, of the outstanding stock. For the foreseeable future, and assuming these ownership percentages continue to apply, to the extent that these parties vote similarly, they may be able to exercise significant control over many matters requiring approval by the board of directors or our stockholders. As a result, they may be able to:

- control the composition of our board of directors;
- control our management and policies;
- determine the outcome of significant corporate transactions, including changes in control that may be beneficial to stockholders; and,
- act in each of their own interests, which may conflict with or differ from the interests of each other or the interests of the other stockholders.

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ITEM 2. PROPERTIES

Our corporate headquarters and U.S. manufacturing, administrative offices, and research facilities are located in leased space in Medford, New York, pursuant to a lease covering approximately 39,650 square feet and expiring on April 30, 2019. We also lease nearby warehouse space and additional administrative offices in Holbrook, New York, pursuant to a lease covering approximately 21,700 square feet and expiring on April 30, 2020.

On February 5, 2019, we entered into a commercial real estate lease for new corporate headquarters comprised of 70,000 square feet of office, research and development, and warehouse space located at 555 Wireless Boulevard, Hauppauge, New York. The lease has an initial term of eleven years that can be extended, at our option, for two additional terms of five years each. Rent under the lease, which is payable in monthly installments, totals approximately $900,000 for the initial year and then increases by approximately three percent each succeeding year. On February 5, 2019, we also entered into an agreement to sublet the space at Holbrook, New York. The sublease has a term that will (a) commence on the date we vacate the premises and (b) terminate on April 29, 2020. The sublessee will pay us 50% of our rent and additional rent payments, which will total approximately $100,000 per year during the term of the sublease.

Our European headquarters and Center of Excellence for Optical Technology is located in leased office and manufacturing space in Berlin, Germany. Our Southeast Asia manufacturing, warehouse, and commercial facilities are located in leased space in Kuala Lumpur, Malaysia. We regularly review our real estate portfolio and develop footprint strategies to support our customers' global plans, while at the same time supporting our technical needs and controlling operating expenses.

ITEM 3. LEGAL PROCEEDINGS

From time to time we may become involved in legal proceedings or may be subject to claims arising in the ordinary course of our business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Listing Information

Our stock is listed on the NASDAQ Global Select Market of the NASDAQ Stock Market LLC under the symbol "CEMI."

Holders

As of March 1, 2019, there were 132 record owners of our Common Stock (including nominee holders such as banks and brokerage firms who hold shares for beneficial owners).

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during the quarter ended December 31, 2018.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended December 31, 2018.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the audited consolidated financial statements and related notes included in this report. In addition to historical information, the following discussion contains forward-looking statements that involves risks, uncertainties and assumptions. See "Special Note Regarding Forward-Looking Statements" at page [2] of this report. Please read "Item1A. Risk Factors" for a discussion of factors that could cause our actual results to differ materially from our expectations.
The following discussion is presented in six sections:

- Executive Overview
- Consolidated Results of Operations
- Liquidity and Capital Resources
- Recent Developments
- Significant Accounting Policies and Critical Accounting Estimates
- Recently Issued Accounting Pronouncements

Executive Overview

Through our wholly owned subsidiaries, Chembio Diagnostic Systems Inc., Chembio Diagnostics Malaysia Sdn Bhd and opTricon, we develop, manufacture and commercialize point-of-care diagnostic tests that are used to detect or diagnose diseases. All products that are currently being developed are based on our patented DPP technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology. Chembio was formed in 1985.

Recent operational accomplishments and highlights include:

- Achieved total revenue of $33.4 million for full year 2018, an increase of 39% over prior year
- Achieved product sales of $26.7 million for full year 2018, also an increase of 38% over prior year
- Acquired opTricon, a developer and manufacturer of hand-held analyzers that when used in combination with our DPP tests, provide quantitative results
- Advanced technology collaborations with AstraZeneca, Lumira Dx, FIND and others
- Purchased a fully-automated DPP test manufacturing line
- Hosted analyst and investor day and introducing five-year targets for $100 million of revenue in 2023 and 50% gross margins for year end 2023

We strengthened our balance sheet from underwritten public offerings that generated net proceeds of $10.9 million in February 2018 and $16.5 million in November 2018. See "—Recent Developments."
Our product commercialization and product development efforts are focused in two areas: infectious diseases (which includes both sexually transmitted disease and tropical/fever disease) and technology collaborations. In infectious

disease, we are commercializing tests for HIV and Syphilis. In tropical and fever disease, we are commercializing tests for dengue virus, Zika virus, chikungunya virus, and ebola virus, individually or as part of an advanced multiplex test. We are also developing tests for lassa, Marburg, malaria, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of a fever panel test, and hepatitis C. Through technology collaborations, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for eosinophilic respiratory disease, the latter in collaboration with global biopharmaceutical company AstraZeneca.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are indispensable for large scale prevention and treatment programs. Our product development is focused on areas where the availability of rapid point-of-care screening, diagnostic, or confirmatory results can improve health outcomes. More generally, we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

Our products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally, under our STAT-PAK, SURE CHECK, STAT-VIEW or DPP registered trademarks, or under the private labels of our marketing partners.

Consolidated Results of Operations

The results of operations for the years ended December 31, 2018 and 2017 were as follows:

	Year Ended December 31,			
	2018		2017	
TOTAL REVENUES	$33,409,251	100%	$24,015,427	100%
COSTS AND EXPENSES:				
Cost of product sales	21,427,243	64 %	12,921,157	54 %
Research and development expenses	8,526,256	26 %	8,555,381	36 %
Selling, general and administrative expenses	11,100,775	33 %	8,963,363	37 %
Acquisition costs	337,645	1 %	58,076	0 %
	41,391,919	124%	30,497,977	127%
LOSS FROM OPERATIONS	(7,982,668)	(24)%	(6,482,550)	(27)%
OTHER INCOME	49,498	0 %	22,485	0 %
LOSS BEFORE INCOME TAXES	(7,933,170)	(24)%	(6,460,065)	(27)%
Income tax (benefit) provision	(67,521)	0 %	(88,305)	0 %
NET LOSS	$(7,865,649)	(24)%	$(6,371,760)	(27)%

Percentages in the table reflect the percent of total revenues.

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Total Net Revenues

Total net revenues during the year ended December 31, 2018 were $33.4 million, an increase of $9.4 million, or 39% compared to 2017. The increase in total net revenues was comprised of the following:

- $7.4 million, or 38% increase in net product sales, reflecting gains in Africa, Latin America, and Europe. Africa benefited from or winning the single largest tender in our history for the supply of HIV tests to Ethiopia, together with meaningful commercial successes in other countries. Latin America gains reflect continued growth in Brazil, and Europe reflects the increasing trend of HIV self-testing. As part of these regional successes and as highlighted above, during November 2018, we completed the acquisition of opTricon. Refer to Note 2 – Acquisition to the audited consolidated financial statements included herein for further information regarding the acquisition.

- $2.0 million, or 42% increase in R&D and grant, and license and royalty revenues compared to 2017, reflecting our continued success in securing governmental, non-governmental, and commercial partnerships, in particular associated with our DPP technology platform.

Gross Product Margin

Cost of product sales is primarily comprised of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses. Gross product margin is net product sales less cost of product sales, and gross product margin percentage is gross product margin as a percentage of net product sales.

Gross product margin decreased by $1.1 million, or 17% compared to 2017. The following schedule calculates gross product margin:

	For the years ended December 31, 2018	December 31, 2017	Favorable/ (unfavorable)	% Change
	(in thousands)			
Net product sales	$26,741	$ 19,322	$ 7,419	38.4 %
Less: Cost of product sales	(21,427)	(12,921)	(8,506)	65.8 %
Gross product margin	$5,314	$ 6,401	$ (1,087)	(17.0)%
Gross product margin %	19.9 %	33.1 %		

The $1.1 million decrease in gross product margin was comprised of the following:

- $2.4 million from favorable product sales volume as described above, and

- $3.5 million from unfavorable product margins, related to increased labor (including contract labor) to manually assemble our products and the impact of geographic mix on average selling prices.

Research and Development

This category includes costs incurred for clinical and regulatory affairs and other research and development, as follows:

	For the years ended December 31, 2018	December 31, 2017	Favorable/ (unfavorable)	% Change
	(in thousands)			

Clinical and regulatory affairs	$ 1,307	$ 2,298	$ 991	43.1 %
Other research and development	7,219	6,257	(962)	(15.4)%
Total research and development	$ 8,526	$ 8,555	$ 29	0.3 %

The decrease in clinical & regulatory affairs costs for 2018 as compared to 2017 is primarily associated with our U.S. clinical trial evaluating our DPP HIV-Syphilis System, which we completed in December 2017. The increase in other research and development costs is primarily associated with spending associated with the 45% increase in revenue from externally-funded research and development projects.

Selling, General and Administrative Expense

Selling, general and administrative expense includes administrative expenses, sales and marketing costs including commissions, and other corporate items. The $2.1 million, or 23.8%, increase in selling, general and administrative expenses for the year ended December 31, 2018 as compared to 2017 is associated with increased personnel, sales commissions, and non-cash equity compensation expenses.

Acquisition Costs

Acquisition costs include legal, due diligence, audit, and related costs associated with acquisitions. The $0.3 million, or 481.4% increase in acquisition costs for the year ended December 31, 2018 as compared to 2017 is associated with spending related to the acquisition of opTricon in November 2018. The 2017 costs relate to completion of the acquisition of RVR Diagnostics in January 2017.

Other Income and Expense

Other income and expenses are principally interest income earned on our deposits, net of interest expense, which increased by approximately $27,000 for 2018 as compared to 2017.

Income Tax Provision

For 2018 we recognized a tax benefit of $67,521 primarily attributable to the loss generated by Chembio Diagnostics Malaysia. As of December 31, 2018 and 2017, our deferred tax assets include a full valuation allowance against our deferred tax assets.

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Liquidity and Capital Resources

During the year ended December 31, 2018, we funded our business operations, including capital expenditures and working capital requirements, principally from $27.5 million of net proceeds from two underwritten public offerings and $3.0 million of non-exchange transaction awards from research and development programs. Our operations used cash flow of $11.8 million. As of December 31, 2018, we had no outstanding debt other than a $0.4 million seller-financed note payable incurred in connection with our purchase of automated manufacturing equipment.

We believe our existing cash and cash equivalents and our cash flow from operating activities will be sufficient to meet our anticipated cash needs for at least the next twelve months. Our future working capital needs will depend on many factors, including the rate of our business and revenue growth, the timing of our automation of U.S. manufacturing, and the timing of investment in our research and development as well as sales and marketing.

If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, we may not be able to generate the cash flow needed to fund our automation of U.S. manufacturing and our investment in research and development and sales and marketing at the time contemplated by our operating plan. In such an event, we may elect to reduce the level, or otherwise delay the timing, of such funding and/or such investments, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow.

If we do not elect to reduce or delay such funding and/or investments, or if we determine to effect one or more acquisitions of businesses, technologies or products, we may be required to seek to raise additional funds through public or private financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we were to raise additional funds through the issuance of equity or convertible securities, the issuance could result in substantial dilution to existing stockholders, and the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of our Common Stock.

Sources of Funds

Equity and Equity-Related Securities. We received net proceeds of $10.9 million from an underwritten public offering of Common Stock in February 2018 and $16.5 million from an underwritten public offering of Common Stock in November 2018. We do not expect to raise additional capital from a public offering of Common Stock in 2019.

Research and Development Awards. We frequently seek research and development programs that may be awarded by government, non-governmental organizations, and non-profit entities, including private foundations.

Since 2015 we have earned over $10.8 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, FIOCRUZ and FIND, as well as U.S. government agencies such as CDC, BARDA and the U.S. Department of Agriculture. See “Item 1. Business—Products” above. During the year ended December 31, 2018, we recognized grant revenue totaling $3.0 from government, non-governmental organizations, and non-profit entities.

Working Capital. The following table sets forth selected working capital information:

	December 31, 2018 (in thousands)
Cash and cash equivalents	$ 12,525
Accounts receivable, net of allowance for doubtful amounts	7,374
Inventories, net	7,851
Prepaid expenses and other current assets	702
Total current assets	28,452
Less: Total current liabilities	(6,519)
Working capital	$ 21,933

Our cash and cash equivalents at December 31, 2018 were unrestricted and held for working capital purposes. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable balance fluctuates from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, client mix, and the timing of shipment of our products and the invoicing of our research and development activities.

Uses of Funds

Cash Flow Used in Operating Activities. Our operations used $11.8 million of cash during the year ended December 31, 2018, primarily due to the net loss adjusted for non-cash items of $6.4 million, a $5.2 million increase in accounts receivable related to the 39% increase in total revenue, and a $3.1 million increase in inventory, offset by a $2.6 million increase in accounts payable and accrued liabilities.

Acquisition. In November 2018, we acquired all of the equity interests of opTricon for a purchase price of $5.5 million in cash, of which (a) $100,000 was deposited in escrow for a potential purchase price adjustment based on the working capital of opTricon and (b) $750,000 was deposited in escrow to satisfy certain claims that we may make against the sellers in accordance with the terms of the related purchase agreement. See “—Recent Developments” below.

Capital Expenditures. During the year ended December 31, 2018, we continued to invest in manufacturing equipment and other fixed assets. Our capital expenditures totaled $1.5 million in 2018.

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Effects of Inflation

Inflation and changing prices have not had a material effect on our business, and we do not expect that they will materially affect our business in the foreseeable future. Any impact of inflation on cost of revenue and operating expenses, especially employee compensation costs, may not be readily recoverable in the price of our product offerings.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934.

Recent Developments

On November 5, 2018, we consummated an underwritten registered public offering of 2,726,000 shares of our Common Stock, including the underwriter's entire overallotment option of 355,565 shares, at a public offering price of $6.75 per share, for gross proceeds of approximately $18.4 million. The net proceeds, after underwriting discounts and commissions, and estimated expenses, were approximately $16.5 million.

On November 6, 2018, we acquired opTricon pursuant to a share purchase agreement dated October 17, 2018. Under the terms of the purchase agreement, we acquired all of the outstanding equity shares of opTricon for a purchase price of $5.5 million in cash, of which (a) $100,000 was deposited in escrow for a potential purchase price adjustment based on the working capital of opTricon and (b) $750,000 was deposited in escrow to satisfy certain claims that we may make against the sellers in accordance with the terms of the purchase agreement.

In accordance with the purchase agreement, each of Lutz Melchior and Volker Plickert, the founders of opTricon, entered into a managing director services agreement pursuant to which they agreed, among other things, to serve as employees of opTricon through November 5, 2021.

opTricon, which is 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. 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 handheld 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. As a result of the acquisition, we secured global commercial rights to opTricon’s offerings and technology and will be able to produce DPP Micro Readers at a reduced cost, which we believe will enable us to promote DPP tests and DPP Micro Readers more actively across global markets. We cannot assure you that we will achieve the intended benefits from the opTricon acquisition.

Significant Accounting Policies and Critical Accounting Estimates

Our significant accounting policies are described in Note 3 – Significant Accounting Policies to the audited consolidated financial statements included herein. Certain of our accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, our evaluation of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. We consider an accounting estimate to be critical if:

- It requires us to make assumptions about matters that were uncertain at the time we were making the estimate, and
-

Changes in the estimate or different estimates that we could have selected would have had a material impact on our financial condition or results of operations.

The following listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any viable alternative would not produce a materially different result.

Revenue Recognition

We recognize revenue for product sales in accordance with FASB ASC 606, Revenue from Contracts with Customers. Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon tendering to the customer. We expense incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial. Freight and distribution activities on products are performed after the customer obtains control of the goods. We have made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in Cost of Product Sales.

For certain contracts, we recognize revenue from research and development, milestone and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned. For certain collaborative research projects, we recognize revenue by defining milestones at the inception of the agreement and applying judgement and estimates in recognizing revenue for relevant contracts.

Stock-Based Compensation

We recognize the fair value of equity-based awards as compensation expense in our statement of operations. The fair value of restricted stock and restricted stock unit awards are their fair value on the date of grant. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This valuation model's computations incorporate highly subjective assumptions, such as the expected stock price volatility and the estimated life of each award. The fair value of equity-based awards, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the option.

Research and Development Costs

Research and development activities consist primarily of new product development, continuing engineering for existing products, and regulatory and clinical trial costs. Costs related to research and development efforts on existing or potential products are expensed as incurred.

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Inventories

Inventories are stated at the lower of cost and net realizable value, using the first-in, first-out method, or FIFO, to determine cost. Our policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a reserve for any inventory considered slow moving or obsolete. For example, each additional 1% of obsolete inventory would reduce such inventory by approximately $78,000.

Accounts Receivable

Our policy is to review our accounts receivable on a periodic basis, no less frequently than monthly. On a quarterly basis an analysis is made of the adequacy of our allowance for doubtful accounts and adjustments are made accordingly. The current allowance is approximately 0.6% of accounts receivable. For example, each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $74,000.

Acquisitions

In accordance with accounting guidance for the provisions in FASB ASC 805, Business Combinations, we allocate the purchase price of an acquired business to its identifiable assets and liabilities based on estimated fair values. The excess of the purchase price over the amount allocated to the assets and liabilities, if any, is recorded as goodwill. In addition, an acquisition may include a contingent consideration component. The fair value of the contingent consideration is estimated as of the date of the acquisition and is recorded as part of the purchase price. This estimate is updated in future periods and any changes in the estimate, which are not considered an adjustment to the purchase price, are recorded in our consolidated statements of operations.

We use all available information to estimate fair values. We typically engage outside appraisal firms to assist in the fair value determination of identifiable intangible assets and any other significant assets or liabilities. We adjust the preliminary purchase price allocation, as necessary, up to one year after the acquisition closing date as we obtain more information regarding asset valuations and liabilities assumed.

Our purchase price allocation methodology contains uncertainties because it requires management to make assumptions and to apply judgment to estimate the fair value of acquired assets and liabilities. Management estimates the fair value of assets and liabilities based upon quoted market prices, the carrying value of the acquired assets and widely accepted valuation techniques, including discounted cash flows and market multiple analyses. Unanticipated events or circumstances may occur which could affect the accuracy of our fair value estimates, including assumptions regarding industry economic factors and business strategies.

Other estimates used in determining fair value include, but are not limited to, future cash flows or income related to intangibles, market rate assumptions, actuarial assumptions for benefit plans and appropriate discount rates. Our estimates of fair value are based upon assumptions believed to be reasonable, but that are inherently uncertain, and therefore, may not be realized. Accordingly, there can be no assurance that the estimates, assumptions, and values reflected in the valuations will be realized, and actual results could vary materially.

Goodwill and Intangible Assets

We periodically review goodwill for impairment indicators. We review goodwill for impairment annually in the fourth quarter or more frequently if events or changes in circumstances indicate that goodwill might be impaired. We perform the goodwill impairment review at the reporting unit level. We perform a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. If not, no further goodwill impairment testing is performed. If so, we perform the step discussed hereafter. Our qualitative assessment involves

significant estimates, assumptions, and judgments, including, macroeconomic conditions, industry and market conditions, our financial performance, reporting unit specific events and changes in our share price.

If the fair value of the reporting unit is greater than its carrying amount, goodwill is not considered to be impaired. We would recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

Income Taxes

Income taxes are accounted for under FASB ASC 740, Income Taxes, authoritative guidance, which we refer to as the Guidance and which requires the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities. Deferred tax assets or liabilities at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered.

The Guidance also requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits.

The Guidance also prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the consolidated financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction.

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Recently Issued Accounting Pronouncements

Refer to Note 3 – Significant Accounting Policies to the audited consolidated financial statements included herein for a complete description of recent accounting standards which we have not yet been required to implement which may be applicable to our operations. Additionally, the significant accounting standards that have been adopted during the year ended December 31, 2018 are described.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and schedules that constitute Item 8 are attached at the end of this report. An index to the Consolidated Financial Statements and schedules is also included on page F-1 of this report.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2018. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2018 at the reasonable assurance level.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by the board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. As a result, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013). Based on its assessment, our management believes that, as of December 31, 2018, our internal control over financial reporting was effective based on those criteria.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

None.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Securities Exchange Act of 1934 during the period covered by this Annual

Report on Form 10-K that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Chembio Diagnostics, Inc.
Medford, New York

Opinion on Internal Control over Financial Reporting

We have audited Chembio Diagnostics, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the years then ended, and the related notes and our report dated March 18, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

Melville, NY
March 18, 2019

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required in response to this Item 10 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required in response to this Item 11 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required in response to this Item 12 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required in response to this Item 13 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required in response to this Item 14 is incorporated herein by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A of the Exchange Act not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) See "Item 8. Financial Statements and Supplementary Data – Index to Consolidated Financial Statements" above.

(b) Exhibits

Exhibit No.	Description
3.1	Articles of Incorporation, as amended, of Chembio Diagnostics, Inc.
3.2	Amended and Restated Bylaws, of Chembio Diagnostics, Inc.
10.1(a)*	2008 Stock Incentive Plan, as amended
10.1(b)*	Form of Option for 2008 Stock Incentive Plan
10.2(a)*	2014 Stock Incentive Plan
10.2(b)*	Form of Option for 2014 Stock Incentive Plan
10.3*	Restated Annual Incentive Bonus Plan of Chembio Diagnostics, Inc., adopted as of March 15, 2019
10.4*	Employment Agreement dated March 13, 2017 between Chembio Diagnostics, Inc. and John J. Sperzel III
10.5*	Employment Agreement dated March 5, 2016 between Chembio Diagnostics, Inc. and Javan Esfandiari
10.6*	Employment Agreement dated September 14, 2017 between Chembio Diagnostics, Inc. and Sharon Klugewicz
10.7(a)*	Employment Agreement dated December 18, 2017 between Chembio Diagnostics, Inc. and Neil A. Goldman
10.7(b)*	Amendment No. 1 dated January 21, 2019 between Chembio Diagnostics, Inc. and Neil A. Goldman, amending Employment Agreement dated December 18, 2017
10.8*	Offer Letter dated October 19, 2016 between Worldwide Workplace Ireland and Robert Passas, with respect to employment by Chembio Diagnostics Systems, Inc.
10.9(a)	Lease Agreement, dated February 15, 2017, between Horseblock Associates and Chembio Diagnostics, Inc. with respect to 3661 Horseblock Road, Medford, New York, as amended
10.9(b)	Agreement of Sublease dated February 5, 2019 between Chembio Diagnostic Systems Inc., as sublessor, and Reliance Communications of New Jersey, LLC, as sublessee, with respect to 3661 Horseblock Road, Medford, New York, as amended
10.10	Lease Agreement, dated February 4, 2013, between Sherwood Corporate Center LLC and Chembio Diagnostics, Inc. with respect to 91-1A Colin Drive, Holbrook, New York, as amended on September 19, 2017
10.11	Lease Agreement dated February 5, 2019 between Myra Properties, LLC, as lessor, and Chembio Diagnostic Systems Inc., as lessee, with respect to 555 Wireless Boulevard, Hauppauge, New York.
10.12	Underwriting Agreement, dated February 9, 2018, between the Registrant and Craig-Hallum Capital Group LLC
10.13	Underwriting Agreement dated November 1, 2018 between the Registrant and Craig-Hallum Capital Group LLC
14.1	Ethics Policy
21.1	List of Subsidiaries of Chembio Diagnostics, Inc.
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF XBRL Taxonomy Definition Linkbase Document
101.LAB XBRL Taxonomy Label Linkbase Document
101.PRE XBRL Taxonomy Presentation Linkbase Document

*Indicates management contract or compensatory plan.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

March 18, 2019 By /s/ John J. Sperzel
John J. Sperzel III
Chief Executive Officer and President

In accordance with the requirements of the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ John J. Sperzel John J. Sperzel III	Chief Executive Officer, President and Director (Principal Executive Officer)	March 18, 2019
/s/ Neil A. Goldman Neil A. Goldman	Executive Vice President and Chief Financial Officer (Principal Financial & Accounting Officer)	March 18, 2019
/s/ Katherine L. Davis Katherine L. Davis	Chair of the Board	March 18, 2019
/s/ Gail S. Page Gail S. Page	Director	March 18, 2019
/s/ Mary Lake Polan Mary Lake Polan	Director	March 18, 2019
/s/ John G. Potthoff John G. Potthoff	Director	March 18, 2019

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Chembio Diagnostics, Inc.
Medford, New York

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Chembio Diagnostics, Inc. (the "Company") and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated March 18, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2011.

Melville, NY
March 18, 2019
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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
AS OF

- ASSETS -

	December 31, 2018	December 31, 2017
CURRENT ASSETS:		
Cash and cash equivalents	$ 12,524,551	$ 3,790,302
Accounts receivable, net of allowance for doubtful accounts of $42,000 at December 31, 2018 and 2017, respectively	7,373,971	2,085,340
Inventories, net	7,851,222	4,423,618
Prepaid expenses and other current assets	702,010	554,383
TOTAL CURRENT ASSETS	28,451,754	10,853,643
FIXED ASSETS, net of accumulated depreciation	2,873,920	1,909,232
OTHER ASSETS:		
Intangible assets, net	3,884,831	1,597,377
Goodwill	4,983,127	1,666,610
Deposits and other assets	717,551	589,159
TOTAL ASSETS	$ 40,911,183	$ 16,616,021
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 5,888,681	$ 3,046,303
Deferred revenue	422,905	50,000
Current portion of note payable	207,694	-
TOTAL CURRENT LIABILITIES	6,519,280	3,096,303
OTHER LIABILITIES:		
Note payable	171,821	99,480
Deferred tax liability	892,308	341,042
TOTAL LIABILITIES	7,583,409	3,536,825
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - $.01 par value; 100,000,000 shares authorized, 17,166,459 and 12,318,570 shares issued and outstanding at December 31, 2018 and 2017, respectively	171,664	123,185
Additional paid-in capital	90,953,788	62,821,288
Accumulated deficit	(57,909,874)	(50,044,225)
Accumulated other comprehensive income	112,196	178,948
TOTAL STOCKHOLDERS' EQUITY	33,327,774	13,079,196

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 40,911,183	$ 16,616,021

See accompanying notes to consolidated financial statements

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31, 2018	December 31, 2017
REVENUES:		
Net product sales	$26,741,020	$ 19,322,302
License and royalty revenue	948,773	741,534
R&D and grant revenue	5,719,458	3,951,591
TOTAL REVENUES	33,409,251	24,015,427
COSTS AND EXPENSES:		
Cost of product sales	21,427,243	12,921,157
Research and development expenses	8,526,256	8,555,381
Selling, general and administrative expenses	11,100,775	8,963,363
Acquisition costs	337,645	58,076
	41,391,919	30,497,977
LOSS FROM OPERATIONS	(7,982,668)	(6,482,550)
OTHER INCOME (EXPENSE):		
Interest income, net	49,498	22,485
LOSS BEFORE INCOME TAXES (BENEFIT) PROVISION	(7,933,170)	(6,460,065)
Income tax (benefit) provision	(67,521)	(88,305)
NET LOSS	$(7,865,649)	$ (6,371,760)
Basic loss per share	$$ (0.55)	$ (0.52)
Diluted loss per share	$$ (0.55)	$ (0.52)
Weighted average number of shares outstanding, basic	14,432,505	12,300,031
Weighted average number of shares outstanding, diluted	14,432,505	12,300,031

See accompanying notes to consolidated financial statements
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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the years ended December 31, 2018	December 31, 2017
Net loss	$(7,865,649)	$ (6,371,760)
Other comprehensive income:		
Foreign currency translation adjustments	(66,752)	178,948
COMPREHENSIVE LOSS	$(7,932,401)	$ (6,192,812)

See accompanying notes to consolidated financial statements

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2018, AND 2017

	Common Stock		Additional Paid-in-Capital	Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2016	12,026,847	$120,268	$ 60,721,783	$(43,672,465)	$-	$17,169,586
Common Stock:						
Purchase of RVR Diagnostics Sdn Bhd	269,236	2,692	1,680,033	-	-	1,682,725
Options:						
Exercised	22,487	225	34,575	-	-	34,800
Stock option compensation	-	-	384,897	-	-	384,897
Comprehensive income	-	-	-	-	178,948	178,948
Net loss	-	-	-	(6,371,760)	-	(6,371,760)
Balance at December 31, 2017	12,318,570	$123,185	$ 62,821,288	$(50,044,225)	$178,948	$13,079,196
Common Stock:						
New stock from offerings	4,509,760	45,098	27,431,162	-	-	27,476,260
Restricted stock issued	266,839	2,668	(2,668)	-	-	-
Restricted stock compensation	-	-	281,249	-	-	281,249
Options:						
Exercised	71,290	713	71,201	-	-	71,914
Stock option compensation	-	-	351,556	-	-	351,556
Comprehensive loss	-	-	-	-	(66,752)	(66,752)
Net loss	-	-	-	(7,865,649)	-	(7,865,649)
Balance at December 31, 2018	17,166,459	$171,664	$ 90,953,788	$(57,909,874)	$112,196	$33,327,774

See accompanying notes to consolidated financial statements
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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED

	December 31, 2018	December 31, 2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	$ 28,632,084	$ 24,971,299
Cash paid to suppliers and employees	(40,452,110)	(30,028,299)
Income taxes paid	(10,913)	-
Interest received, net	69,930	22,485
Interest paid	(20,432)	-
Net cash used in operating activities	(11,781,441)	(5,034,515)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of opTricon GmbH, net of cash acquired	(5,491,204)	-
Purchase of RVR Diagnostics Sdn Bhd, net of cash acquired	-	(850,000)
Acquisition of and deposits on fixed assets	(1,467,192)	(1,026,954)
Net cash used in investing activities	(6,958,396)	(1,876,954)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	71,914	34,800
Proceeds from note payable	-	99,480
Payments on note payable	(64,481)	-
Proceeds from sale of common stock, net	27,476,260	-
Net cash provided by financing activities	27,483,693	134,280
Effect of exchange rate changes on cash	(9,607)	13,027
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	8,734,249	(6,764,162)
Cash and cash equivalents - beginning of the period	3,790,302	10,554,464
Cash and cash equivalents - end of the period	$ 12,524,551	$ 3,790,302
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	$ (7,865,649)	$ (6,371,760)
Adjustments:		
Depreciation and amortization	902,505	1,276,963
Fair value adjustment to contingent consideration	-	(148,000)
Share based compensation	632,805	384,897
Change in deferred tax asset	(78,432)	-
Changes in assets and liabilities, net of effects from purchase of opTricon GmbH:		
Accounts receivable	(5,150,072)	1,298,389
Inventories	(3,077,104)	(1,088,430)
Prepaid expenses and other current assets	(118,293)	285,762

Deposits and other assets	-	(512,272)
Accounts payable and accrued liabilities	2,599,894	182,453
Deferred revenue	372,905	(342,517)
Net cash used in operating activities	$ (11,781,441)	$ (5,034,515)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	$ 257,455	$ 174,399
Deposits and other assets transferred to intangible assets	118,899	-
Seller-financed equipment purchases	326,110	-
Accrual of contingent earn-out	-	148,000
Issuance of common stock for net assets of business acquired	-	1,682,725

See accompanying notes to consolidated financial statements

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NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiaries (collectively, the "Company" or "Chembio"), develop, manufacture, and commercialize point-of-care diagnostic tests that are used to detect and diagnose diseases. The Company is pursuing three corporate priorities: (1) expand its commercialization, (2) advance its research and development pipeline, and (3) prepare for future growth.

All products that are currently being developed are based on the Company's patented DPP® technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology.

The Company's product commercialization and product development efforts are focused on infectious disease testing and technology collaborations. In infectious disease, the Company is commercializing tests for HIV and Syphilis, Zika virus, and developing tests for malaria, dengue virus, chikungunya virus, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of fever panel tests. Through technology collaborations, the Company is developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for eosinophilic respiratory disease, the latter in collaboration with global biopharmaceutical company AstraZeneca.

Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are indispensable for large scale prevention and treatment programs. More generally, the Company believes there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

The Company's products are sold to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally, under the Company's STAT PAK®, SURE CHECK®, STAT-VIEW® or DPP® registered trademarks, or under the private labels of the Company's marketing partners.

The Company routinely enters into arrangements with governmental and non-governmental organizations for the funding of certain research and development efforts.

NOTE 2 — ACQUISITIONS:

opTricon

On November 6, 2018, pursuant to a share purchase agreement, the Company acquired all of the outstanding shares of opTricon GmbH ("opTricon"), a privately-held Germany based developer and manufacturer of handheld analyzers for rapid diagnostic tests, for $5.5 million in cash, subject to routine post-closing adjustments. Since 2015, the Company and opTricon have been parties to an agreement under which the Company has collaborated in developing its DPP Micro Reader, a handheld, battery-operated analyzer that uses an innovative image sensor to provide, when combined with the Company's DPP tests, a quantitative interpretation of diagnostic results. The Company purchased opTricon because it believes it will enable it to promote DPP tests and DPP Micro Reader more actively across global markets. The results of opTricon operations have been reflected in the consolidated financial statements since November 6, 2018.

As a result of the consideration paid exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of $3,337,000 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $2,260,000 in intangible assets associated with the addition of opTricon's developed technology and customer base. The Consolidated Statements of Operations for the year ended December

31, 2018 include $337,645 of transaction costs related to the opTricon acquisition.

The acquisition was accounted for using the purchase method of accounting. The following table summarizes the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of November 6, 2018:

	Amount
Net current assets	$ 404,204
Property, plant and equipment	125,000
Goodwill	3,337,000
Deferred tax liability	(635,000)
Other intangible assets (estimated useful life):	
Developed technology (7 years)	1,900,000
Customer contracts / relationships (10 years)	360,000
Total consideration	$5,491,204

The Company calculated the fair value of the fixed assets based on the net book value of opTricon as that approximates fair value. The developed technology and customer contracts/relationships were based on discounted cash flows using management estimates.

As indicated, the allocation of the purchase price shown above is preliminary, pending completion of an analysis of the deferred tax liability. Therefore, an adjustment may be required.

The following represents unaudited pro forma operating results for the year ended December 31, 2018 as if the operations of opTricon had been included in the Company’s Consolidated Statements of Operations as of January 1, 2018:

	Proforma December 31, 2018
Total revenues	$35,442,806
Net loss	(8,394,074)
Net loss per common share	$(0.58)
Diluted net loss per common share	$(0.58)

The pro forma financial information includes business combination accounting effects from the acquisition including amortization charges from acquired intangible assets of opTricon approximately $351,000 for the year ended December 31, 2018. The unaudited pro forma information as presented above is for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of fiscal 2018. Included in the proforma table above are opTricon's net revenues and pre-tax loss for the year ended December 31, 2018 which were approximately $2,214,000 and $213,000, respectively. opTricon's results of operations from the date of acquisition through December 31, 2018 are immaterial to the Company's Consolidated Statements of Operations.

RVR Diagnostics

On January 9, 2017, pursuant to a stock purchase agreement (the "Stock Purchase Agreement), the Company acquired all of the outstanding common stock of RVR Diagnostics Sdn Bhd ("RVR"), a privately-held Malaysia based

manufacturing company focused on assembly and sales of rapid medical assays, for $3,231,000. The Company acquired RVR, which subsequently changed its name to Chembio Diagnostics Malaysia Sdn Bhd ("CDM"), to have a better presence in Asia, access to lower cost, shorter approval time of in-country regulatory approvals, and a lower cost assembly operation.

Total consideration was: (i) a cash payment of $1,400,000, of which $550,000 was paid as a deposit in December 2016; (ii) 269,236 shares of Chembio's common stock, with a value at closing of $1,683,000, of which 7,277 shares were held back to satisfy certain potential claims under the Stock Purchase Agreement and became issuable to the sellers on the one-year anniversary of the closing; and, a contingent $148,000 milestone payment based on the achievement of performance goals related to sales by CDM during the 12 months ended December 31, 2017. The performance goals were not achieved and the related $148,000 accrual was reversed during the fourth quarter of 2017 and recognized in Selling, general, and administrative expenses associated with the change in fair value.

As a result of the consideration paid exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of $1,503,361 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $1,800,000 in intangible assets associated with the addition of CDM’s intellectual property, customer base and distribution channels, trade names, order backlog, industry reputation, and management talent and workforce. The Condensed Consolidated Statements of Operations for the year ended December 31, 2017 include $25,000 of transaction costs related to the CDM acquisition, which are reflected as Selling, general and administrative expenses.

The acquisition was accounted for using the purchase method of accounting. The following table summarizes the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of January 9, 2017:

	Amount
Property, plant and equipment	$235,141
Goodwill	1,651,361
Deferred tax liability	(307,636)
Contingent consideration	(148,000)
Other intangible assets (estimated useful life):	
Intellectual property (10 years)	800,000
Customer contracts / relationships (10 years)	700,000
Order backlog (3 months)	200,134
Trade name (11 years)	100,000
Total consideration	$3,231,000

The Company calculated the fair value of the fixed assets based on the net book value of CDM as that approximates fair value. The intellectual property, customer contracts and trade names were based on discounted cash flows using management estimates. The order backlog was based on an order that CDM had at the closing that was shipped in the first quarter of 2017, and valued at an estimated net income.

CDM's net revenues and pre-tax loss for the year ended December 31, 2017 were approximately $1,465,000 and ($406,000), respectively.

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NOTE 3 — SIGNIFICANT ACCOUNTING POLICIES:

(a) Principles of Consolidation:

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany transactions and balances are eliminated in consolidation. Certain amounts from prior years have been reclassified to conform to the 2018 presentation.

(b) Use of Estimates:

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make assumptions and estimates that affect the amounts reported in the consolidated financial statements and accompanying notes. Judgments and estimates of uncertainties are required in applying the Company's accounting policies in certain areas. Generally, matters subject to estimation and judgment include accounts receivable realization, inventory obsolescence, asset impairments, recognition of revenue persuant to milestones, useful lives of intangible and fixed assets, stock-based compensation, and deferred tax asset valuation allowances. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may be based upon amounts that differ from those estimates.

(c) Fair Value of Financial Instruments:

The carrying value for cash and cash equivalents, accounts receivable, and accounts payable, approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents is $4.7 million and $2.1 million as of December 31, 2018 and 2017, respectively, of money market funds that are Level 1 fair value measurements under the hierarchy. The fair value of the Company's notes payable approximates the recorded value as the rate is based upon the current rates offered to the Company for similar financial instruments.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

(d) Cash and Cash Equivalents:

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of three months or less.

(e) Concentrations of Credit Risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the FDIC insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's ability to obtain letters of credit from certain

foreign customers and its diverse customer base, both in number of customers and geographic locations.

(f) Inventories:

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost and net realizable value. Cost is determined on the first-in, first-out method. The Company's policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a write-down for any inventory considered slow moving or obsolete.

(g) Fixed Assets:

Fixed assets are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter. Deposits paid for fixed assets are capitalized and not depreciated until the related asset is placed in service.

(h) License Agreements:

The Company records up-front payments related to sublicense agreements as prepaids and amortizes them over their respective economic life. As of December 31, 2018 and 2017, total prepaids were $100,000 and $100,000, respectively.

Amortization expenses for the licenses above for the years ended December 31, 2018, and 2017 were $0, and $137,500, respectively.

(i) Valuation of Long-Lived Assets and Intangible Assets:

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. No impairment of long-lived tangible and intangible assets was recorded for the years ended December 31, 2018 and 2017.

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(j) Revenue Recognition:

In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and in certain circumstances, allowing estimates of variable consideration to be recognized before contingencies are resolved. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers.

The new revenue standards became effective for the Company on January 1, 2018 and were adopted using the modified retrospective method. The adoption of the new revenue standards as of January 1, 2018 did not change the Company's revenue recognition as its revenues continue to be recognized when the customer takes control of its product. As the Company did not identify any material accounting changes that impacted the amount of reported revenues with respect to its product revenue, license and royalty revenue, and R&D, milestone and grant revenues, no adjustment to retained earnings was required upon adoption.

The Company adopted the standards to contracts that were not completed at the date of initial application (January 1, 2018).
Under the new revenue standards, the Company recognizes revenues when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company recognizes revenues following the five-step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) the Company satisfies the performance obligation.

Product Revenues

Revenues from product sales are recognized and commissions are accrued when the customer obtains control of the Company's product, which occurs at a point in time, typically upon tendering to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial. Freight and distribution activities on products are performed after the customer obtains control of the goods. The Company has made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in Cost of Product Sales.

The Company's payment terms vary by the type and location of the Company's customer and products or services offered. Payment terms differ by jurisdiction and customer but payment is generally required in a term ranging from 30 to 60 days from date of shipment or satisfaction of the performance obligation.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers. The Company's process for estimating reserves established for these variable consideration components does not differ materially from its historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally related to discounts. Estimates of variable consideration and the determination of whether to include estimated amounts in the transaction price are based on all information (historical, current and forecasted) that is reasonably available to the Company, taking into consideration the type of customer, the type of transaction and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

Royalty Revenues

The Company receives royalty revenues on sales by its licensees of products covered under patents that it owns. The Company does not have future performance obligations under these license arrangements. The Company records these revenues based on estimates of the sales that occurred during the relevant period as a component of license and royalty revenues. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties that have been paid to the Company, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. Historically, adjustments have not been material when compared to actual amounts paid by licensees.

R&D and grant revenue

All such contracts are evaluated under the five-step model described above. For certain contracts that represent grants where the funder does not meet the definition of a customer, the Company recognizes revenue when earned in accordance with ASC 958. Such contracts are further described under Disaggregation of Revenue, below. Grants are invoiced and revenue is recognized as expenses are incurred as that is the depiction of the timing of the transfer of services. Performance obligations generally follow the major phases of product development processes: design feasibility & planning, product development & design optimization, design verification, design validation & process validation, and pivotal studies.

Disaggregation of Revenue

The following tables disaggregate Total Revenues for the year ended December 31, 2018:

	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	$26,741,020	$ -	$26,741,020
License and royalty revenue	948,773	-	948,773
R&D, milestone and grant revenue	2,687,210	3,032,248	5,719,458
	$30,377,003	$ 3,032,248	$33,409,251

Exchange transactions are recognized in accordance with ASC 606, while non-exchange transactions are recognized in accordance with ASC 985.

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	Total
Africa	$8,605,306
Asia	1,389,120
Europe & Middle East	4,726,691
Latin America	11,722,224
United States	6,965,910
	$33,409,251

Contract Liabilities

Deferred revenue relates to payments received in advance of performance under the contract. Deferred revenue is recognized as revenue as (or when) the Company performs under the contract. At December 31, 2017, the Company reported $50,000 in deferred revenue of which $50,000 was earned and recognized as R&D, milestone and grant revenue during the year ended December 31, 2018. At December 31, 2018, the Company reported $422,905 in deferred revenue which is expected to be recognized during the first quarter of 2019.

In April 2017, the Company entered into a $1.0 million agreement with FIND to develop a simple, point-of-care fever panel assay that can identify multiple life-threatening acute febrile illnesses common in the Asia Pacific region. The Company earned $0.1 million and $0.9 million for the year ended December 31, 2018, and from inception through December 31, 2018, respectively as R&D, milestone and grant revenue in the Company's Consolidated Statements of Operations.

In August 2016, the Company was awarded a grant of $5.9 million from BARDA, which is part of the U.S. Department of Health And Human Resources to develop a rapid Zika virus assay. The Company earned $2.6 million and $5.3 million for the year ended December 31, 2018 and from inception through December 31, 2018, respectively, as R&D, milestone and grant revenue in the Company's Consolidated Statements of Operations.

In September 2016, the Company was awarded a $0.7 million contract from the USDA to develop a Bovid TB assay. The Company earned $0.2 million and $0.5 million for the year ended December 31, 2018 and from inception through December 31, 2018, respectively, as R&D, milestone and grant revenue in the Company's Consolidated Statements of Operations.

(k) Research and Development:

Research and development (R&D) costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

(l) Stock-Based Compensation:

The fair value of restricted stock and restricted stock unit awards are their fair value on the date of grant. Stock-based compensation expense for stock options is calculated using the Black-Scholes valuation model based on awards ultimately expected to vest together with the fair value of restricted stock and restricted stock unit awards, are, reduced for actual forfeitures, and, expensed on a straight-line basis over the requisite service period of the grant. During 2017, the Company adopted ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting".

(m) Income Taxes:

The Company accounts for income taxes under an asset and liability approach that recognizes deferred tax assets and liabilities based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

The Company follows a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The guidance relates to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to uncertain tax positions are recorded in tax expense.

The Company assesses the realizability of its net deferred tax assets on an annual basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized, the Company will reduce the net deferred tax assets by a valuation allowance. The realization of net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of net operating loss carryforwards.

(n) Loss Per Share:

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period including outstanding restricted stock that by its terms is includible in the calculation. Diluted loss per share for the years ended December 31, 2018, and 2017 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 711,968, and 810,670 options outstanding as of December 31, 2018 and 2017, respectively, which were not included in the calculation of diluted income per share for the years ended because their effect would have been anti-dilutive.

(o) Goodwill and Intangible Assets:

Goodwill represents the excess of the purchase price the Company paid over the fair value of the net tangible and identifiable intangible assets acquired in the Company’s acquisition of opTricon in November 2018 and CDM in January 2017. Goodwill is not amortized but rather is tested annually as of the first day of the fiscal fourth quarter, or sooner if the Company believes that indicators of impairment exist. The Company makes a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If the Company concludes that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then it would recognize an impairment charge for the amount by which the carrying value exceeds the reporting unit’s fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

For the year ended December 31, 2018 and 2017, there was no impairment of goodwill and other intangible assets.

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Following is a table that reflects changes in Goodwill:

Beginning balance 1/1/18	$1,666,610
Acquisition of opTricon	3,337,000
Changes in foreign currency exchange rate	(20,483)
Balance at December 31, 2018	$4,983,127

Intangible assets consist of the following at:

	Weighted Average Remaining Life	December 31, 2018 Cost	Accumulated Amortization	Net Book Value	December 31, 2017 Cost	Accumulated Amortization	Net Book Value
Intellectual property	10	$1,089,688	$ 173,633	$916,055	$886,872	$ 88,687	$798,185
Developed technology	7	1,910,315	-	1,910,315	-	-	-
Customer contracts/relationships	8	1,121,600	151,929	969,671	776,013	77,601	698,412
Order backlog	-	217,187	217,187	-	221,867	221,867	-
Trade names	9	108,521	19,731	88,790	110,859	10,079	100,780
		$4,447,311	$ 562,480	$3,884,831	$1,995,611	$ 398,234	$1,597,377

Amortization expense for the year ended December 31, 2018 and 2017 was $233,734 and $398,234, respectively, and is recorded within Selling, General and Administrative expenses. Amortization expense, subject to changes in currency exchange rates, is expected to be $496,512 per year from 2019 through 2023, and total $1,402,271 for all of the years thereafter.

(p) Allowance for Doubtful Accounts:

The Company records allowances for doubtful accounts for the estimated probable losses on uncollectible accounts receivable. The allowance is based upon the credit worthiness of the Company’s customers, the Company’s historical experience, the age of the receivable and current market and economic conditions. Receivables are written off against these allowances in the period they are determined to be uncollectible.

(q) Acquisition Costs:

Acquisition costs include period expenses, primarily professional services, related to acquisition activities.

(r) Foreign Currency Translation:

The functional currency of a foreign subsidiary is the local currency. Assets and liabilities of foreign subsidiaries that use a currency other than U.S. dollars as their functional currency are translated to U.S. dollars at end of period currency exchange rates. The consolidated statements of operations of foreign subsidiaries are translated to U.S. dollars at average period currency exchange rates. The effect of translation for foreign subsidiaries is generally reported in Other comprehensive income. Foreign transaction gains are immaterial.

(s) Recent Accounting Pronouncements Affecting the Company:

In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and in certain circumstances, allowing estimates of variable consideration to be recognized before contingencies are resolved. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The standard is effective for the first interim period within annual reporting periods beginning after December 15, 2017.

The Company has completed its evaluation of the new standard and assessed the impact of adoption on its consolidated financial statements. The Company reviewed significant open contracts with customers for each revenue stream, and based on its evaluation, revenue recognition under the new standard did not have a material impact on the Company's consolidated financial statements because: i) product sales revenue is recognized when control of the goods is transferred to the customer (i.e., the date of shipment, which is consistent under ASC 605), and ii) R&D and grant revenue historically did not constitute exchange transactions and therefore the new standard did not apply to such revenue upon adoption. The Company also assessed its control framework as a result of adopting the new standard and noted minimal, insignificant changes to its systems and other controls processes.

The new standard permitted two adoption methods under ASU 2014-09. The guidance could be adopted through either retrospective application to all periods presented in the consolidated financial statements (full retrospective) or through a cumulative effect adjustment to retained earnings at the effective date (modified retrospective). The Company adopted the new standard effective January 1, 2018 using the modified retrospective transition method. Under that method, the Company applied the rules to all contracts existing as of January 1, 2018. The cumulative effect was not material.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740) Balance Sheet Classification of Deferred Assets. This ASU is intended to simplify the presentation of deferred taxes on the balance sheet and will require an entity to present all deferred tax assets and deferred tax liabilities as non-current on the balance sheet. Under the current guidance, entities are required to separately present deferred taxes as current or non-current. Netting deferred tax assets and deferred tax liabilities by tax jurisdiction will still be required under the new guidance. This guidance became effective for Chembio beginning in 2018. This new accounting standard update did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 requires the entity to recognize the assets and liabilities for the rights and obligations created by leased assets. Leases will be classified as either finance or operating, with classification affecting expense recognition in the income statement. In July 2018 the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, and ASU 2018-11, Leases (Topic 842) Targeted Improvements, which provide supplemental adoption guidance and clarification to ASU 2016-02, and must be adopted concurrently with the adoption of ASU 2016-02, cumulatively referred to as "Topic 842". Topic 842 is effective for the company in the first quarter of 2019, with early adoption permitted, and is to be applied using either a modified retrospective approach, or an optional transition method which allows an entity to apply the new standard at the adoption date with a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company will adopt Topic 842 on January 1, 2019 under the optional transition method and elect the short-term lease exception and available practical expedients. Under the transition method, the Company will not adjust its comparative period financial information or make the new required lease disclosures for periods before the effective date. Upon adoption, the Company expects the consolidated balance sheet to include a right of use asset and liability related to substantially all of the Company's lease arrangements. While the Company continues to evaluate the effects of adopting the provisions of Topic 842, including the impact that this new guidance will have on its processes and controls, the Company expects most existing operating lease commitments will be recognized as operating lease liabilities and right-of-use assets upon adoption. The adoption is not expected to be material to the consolidated financial statements, and based on the Company's ongoing assessment, is expected to increase total assets and total liabilities by no more than approximately $1.5 million, on a discounted basis.

Please see Note 15 – Subsequent Events, regarding the Company's entering into a commercial real estate lease for a new corporate headquarters and a sublease for one of its current facilities on February 5, 2019. The Company is currently analyzing the impact of Topic 842 on these transactions and expects to report on that during the first quarter of 2019. Based on the term and rental cost, the Company expects the application of Topic 842 to these transactions to have a material impact on the Company's total assets and total liabilities, and no impact on the Company's results of operations or cash flows.

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In March 2016, the FASB issued authoritative guidance under ASU 2016-09, Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 provides for simplification of several aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The Company adopted ASU 2016-09 on January 1, 2017. As the Company has a full valuation allowance against its U.S. net deferred tax assets, the adoption of this standard for recognition of the tax effect of deductions for employee share awards in excess of compensation costs ("windfall") did not have a material impact on its consolidated financial statements and related disclosures. See Note 8 – Income Taxes, for additional information. Should the full valuation allowance be reversed in future periods, the adoption of this new guidance could introduce more volatility in the calculation of the Company's effective tax rate, depending on the Company's share price at exercise or vesting of share-based awards as compared to grant date. The other provisions of ASU 2016-09 did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which provides guidance related to cash flows presentation. The Company adopted ASU 2016-15 in the first quarter of 2018. The guidance in ASU 2016-15 is generally consistent with the Company's current cash flow classifications, and did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, which requires an entity to no longer perform a hypothetical purchase price allocation to measure goodwill impairment. Instead, impairment will be measured using the difference between the carrying amount and the fair value of the reporting unit. This update will be effective for annual and interim periods in fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted ASU 2017-04 in the fourth quarter of 2017. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting, to provide clarity to which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted ASU 2017-09 in the first quarter of 2018. Adoption did not have a material effect on the Company's consolidated financial statements.

In July 2018, the FASB issued ASU 2018-08 Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made to clarify the accounting guidance related to contributions made or received. This guidance primarily affects not-for-profit entities, although it also applies to businesses to the extent that they make or receive contributions, including grants. ASU 2018-08 clarifies and improves the scope and accounting guidance for both contributions received and made in order to assist entities in evaluating if those transactions should be accounted for as contributions under the scope of Topic 958, or as an exchange transaction subject to other guidance. Public entities are required to apply the amendments on contributions received and contributions made to annual periods beginning after June 15, 2018, and December 15, 2018, respectively, each including interim periods within those annual periods. Early adoption is permitted, and the Company adopted ASU 2018-08 effective as of January 1, 2018. The impact of adoption was immaterial.

NOTE 4 — INVENTORIES:

Inventories consist of the following at:

	December 31, 2018	December 31, 2017
Raw Materials	$ 2,803,677	$ 1,767,684
Work in Process	263,043	286,413

Finished Goods	4,784,502	2,369,521
	$ 7,851,222	$ 4,423,618

NOTE 5 — FIXED ASSETS:

Fixed assets consist of the following at:

	December 31, 2018	December 31, 2017
Machinery and Equipment	$ 6,070,137	$ 4,582,759
Furniture and Fixtures	35,287	449,548
Computer Equipment	435,348	422,946
Leasehold Improvements	2,334,512	2,258,779
Enterprise Business Systems	462,420	-
Less: Accumulated Depreciation and Amortization	(6,463,784)	(5,804,800)
	$ 2,873,920	$ 1,909,232

There were no capital leases at the end of December 31, 2018. Fixed assets at December 31, 2018 also include $1,866,126 in equipment that is undergoing validation and as such is not yet being depreciated. Depreciation expense for the 2018 and 2017 years totaled $634,261 and $727,563, respectively.

As of December 31, 2018 and 2017, the Company had paid deposits on various pieces of equipment classified within Deposits and Other Assets aggregating $428,859 and $257,455, respectively.

NOTE 6 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at:

	December 31, 2018	December 31, 2017
Accounts Payable - suppliers	$ 3,622,765	$ 1,494,759
Accrued Commissions	588,131	126,827
Accrued Royalties / license fees	279,213	429,297
Accrued Payroll	48,867	187,305
Accrued Vacation	264,789	309,767
Accrued Bonuses	494,318	282,500
Accrued Expenses - Other	590,598	215,848
	$ 5,888,681	$ 3,046,303

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NOTE 7 — DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

The Company recognizes income from R&D milestones when those milestones are reached and non-milestone contracts and grants when earned. These projects are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of December 31, 2018 and 2017, there were $422,905 and $50,000 unearned advanced revenues, respectively.

NOTE 8 — INCOME TAXES:

The (benefit from) provision for income taxes for the years ended December 31, 2018 and 2017 is comprised of the following:

	2018	2017
Current		
Federal	$-	$(97,339)
State	10,914	9,034
Foreign	-	-
Total current (benefit) provision	10,914	(88,305)
Deferred		
Federal	-	-
State	-	-
Foreign	(78,435)	-
Total deferred (benefit) provision	(78,435)	-
Total (benefit) provision	$(67,521)	$(88,305)

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 34% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017. The Staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. As a result of the Tax Act, the Company remeasured its U.S. Federal deferred tax assets and liabilities at the rate they are expected to reverse in the future. The Company recorded a cumulative charge of $3,906,774 ($0 in 2018 and $3,906,774 in 2017), which was fully offset by an equivalent adjustment to the deferred tax valuation allowance. The Company recorded a cumulative benefit of $97,339 ($0 in 2018 and $97,339 in 2017) related to a credit for alternative minimum taxes (AMT) paid in prior years. During 2018, the Company finalized its computation of the impact of the Tax Act with no change to the provisional amount.

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low-taxed income ("GILTI") provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance allows companies to make an accounting policy election to either (1) account for GILTI as a component of tax expense in the period in which they are subject to the rules (the period cost method), or (ii) account for GILTI in the Company's measurement of deferred taxes (the deferred method). After completing the analysis of the GILTI provisions, the Company elected to account for GILTI using the period cost method.

The Company had an ownership change as described in Internal Revenue Code Sec. 382 during 2004 (“2004 change”). As a result, the Company’s net operating losses prior to the 2004 change of $5,832,516 were subject to an annual limitation of $150,608 and for the first five (5) years are entitled to a BIG (Built-In-Gains) of $488,207 per year. These net operating losses expire in 2019 through 2024.

The Company had a second ownership change during 2006 (“2006 change”). The net operating losses incurred between the 2004 change and the 2006 change of $8,586,861 were subject to an annual limitation of $1,111,831 and for the first five (5) years are entitled to a BIG of $1,756,842 per year. These net operating losses expire in 2024 through 2026.

After applying the above limitations, at December 31, 2018, the Company has post-change net operating loss carry-forwards of approximately $27,303,044 which expire between 2019 and 2037 and $5,432,085 which do not expire. In addition the Company has research and development tax credit carryforwards of approximately $1,696,870 for the year ended December 31, 2018, which expire between 2019 and 2036.
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The Company has state net operating loss carryforwards of approximately $1,784,554 which expire between 2025 and 2037. The Company has foreign net operating loss carryforwards of approximately $586,206 which do not expire.

	2018	2017
Inventory reserves	$204,206	$244,158
Accrued expenses	175,168	102,332
Net operating loss carry-forwards	7,122,576	5,800,144
Research and development credit	1,696,870	1,918,137
Stock-based compensation	215,797	167,522
Depreciation	139,362	91,258
Total deferred tax assets	9,553,979	8,323,551
Intangibles	(968,849)	(341,042)
Total deferred tax liabilities	(968,849)	(341,042)
Net deferred tax assets before valuation allowance	8,585,130	7,982,509
Less valuation allowances	(9,477,438)	(8,323,551)
Net noncurrent deferred tax liabilities	$(892,308)	$(341,042)

The components of (loss) before income taxes consisted of the following:

	Year Ending December 31,	
	2018	2017
United States operations	$(7,137,428)	$(6,054,002)
International operations	(795,742)	(406,063)
(Loss) before taxes	$(7,933,170)	$(6,460,065)

A reconciliation of the Federal statutory rate to the effective rate applicable to loss before income taxes is as follows:

	Year Ending December 31,			
	2018		2017	
Federal income tax at statutory rates	21.00	%	34.00	%
State income taxes, net of federal benefit	(.10	)%	(0.09	)%
Nondeductible expenses	(1.58	)%	(1.04	)%
Foreign rate differential	.36	%	(2.14	)%
Change in valuation allowance	(18.44	)%	(99.41	)%
Impact of Tax Act on valuation allowance	-	%	60.48	%
AMT refund under Tax Act	-	%	1.51	%
Tax credits	-	%	7.07	%
Other	(.39	)%	0.99	%
Income tax benefit	.85	%	1.37	%

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2018, the Company does not have a liability for uncertain tax positions.

The Company files Federal and state income tax returns, opTricon files in Germany and CDM files in Malaysia and has been on tax holiday which expired on December 31, 2018. With few exceptions, tax years for fiscal 2015 through 2018 are open and potentially subject to examination by federal, state and foreign taxing authorities.

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) Common Stock

In February 2018, the Company closed on an underwritten registered public offering of 1,783,760 shares of its common stock at $6.75 per share. The net proceeds of the offering, after deducting the underwriter's discounts and other offering expenses payable by the Company, was approximately $10.9 million.

In November 2018, the Company closed on an underwritten public offering of 2,726,000 shares of its common stock, including the underwriter's exercise of its overallotment of 355,565 shares, at $6.75 per share. The net proceeds of the offering, after deducting the underwriter's discounts and other offering expenses payable by the Company, was approximately $16.5 million.

During 2018, options to purchase 144,947 shares of the Company's common stock were exercised for 71,290 shares of common stock at exercise prices ranging from $3.48 to $5.64 by surrendering options and shares of common stock already owned.

During 2017, options to purchase 56,969 shares of the Company's common stock were exercised for 22,487 shares of common stock at exercise prices ranging from $3.48 to $4.45 by surrendering options and shares of common stock already owned.

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(b) Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized and none outstanding. These shares can become issuable upon an approved resolution by the board of directors and the filing of a Certificate of Designation with the state of Nevada.

(c) Options, Restricted Stock, and Restricted Stock Units

The Board of Directors or its Compensation Committee may issue options, restricted stock, and restricted stock units pursuant to employee stock incentive plans that have been approved by the Company's stockholders.

(d) Warrants

As of December 31, 2018 and 2017, the Company had no warrants outstanding to purchase shares of common stock.

NOTE 10 — RIGHTS AGREEMENT:

In March 2016, the Company entered into a Rights Agreement (the "Rights Agreement") with Action Stock Transfer Corp., as Rights Agent. The Rights Agreement expired on March 7, 2019. Pursuant to the Rights Agreement, the Company declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of common stock as of March 8, 2016.

Rights Initially Not Exercisable. The Rights were not exercisable until a Distribution Date (as defined below). Until a Right was exercised, the holder thereof, as such, would have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

Separation and Distribution of Rights. The Rights were evidenced by the certificates for common stock, and were not to be evidenced by separate rights certificates until the close of business on the tenth business day (the “Distribution Date”) following either (i) a public announcement that a person or group acquired beneficial ownership of 20% or more of the outstanding shares of common stock or (ii) a tender or exchange offer by any person or group is first published, sent or given within the meaning of Rule 14d-3(a) under the Securities Exchange Act of 1934, the consummation of which would result in the person or group having beneficial ownership of 20% or more of the outstanding shares of common stock.

NOTE 11 — STOCK INCENTIVE PLANS:

Effective June 3, 2008, the Company’s stockholders voted to approve the 2008 Stock Incentive Plan (“SIP”), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 the Company’s stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, which expired during 2018, the Board of Directors or its Compensation Committee had the discretion to select the persons to whom awards were to be granted. Awards could be stock options, restricted stock and/or restricted stock units ("Equity Award Units"). The awards became vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2018, there were 508,889 options exercised, and at December 31, 2018, 99,132 options were outstanding and no Equity Award Units were available to be issued under the SIP.

Effective June 19, 2014, the Company’s stockholders voted to approve the 2014 Stock Incentive Plan (“SIP14”), with 800,000 shares of common stock available to be issued. Under the terms of the SIP14, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of Equity Award Units. The awards become vested at such times and under such conditions as determined by the Board

or its Compensation Committee. Cumulatively through December 31, 2018, there were 85,407 options exercised, and at December 31, 2018, 405,968 options were outstanding and 21,061 Equity Award Units were still available to be issued under the SIP14. During 2018, 266,839 shares of restricted stock and 20,725 restricted stock units were awarded under SIP14.

The Company's results for the years ended December 31, 2018 and 2017 include stock-based compensation expense totaling $632,805 and $384,897, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($25,615 and $47,000, respectively), research and development ($78,831 and $89,400, respectively) and selling, general and administrative expenses ($528,360 and $248,497, respectively).

Stock option compensation expense in the years ended December 31, 2018 and 2017 represents the estimated fair value of options outstanding which is being amortized on a straight-line basis over the requisite vesting period of the entire award.

The weighted average estimated fair value of stock options granted in the years ended December 31, 2018 and 2017 were $3.76 and $2.77 per share, respectively. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of the Company’s stock and other contributing factors. The expected term is based on the Company’s historical experience with similar type options.

The weighted-average assumptions made in calculating the fair values of options are as follows for the respective years ended:

	December 31, 2018		December 31, 2017	
Expected term (in years)	4.96		5.48	
Expected volatility	39.91	%	43.31	%
Expected dividend yield	n/a		n/a	
Risk-free interest rate	2.70	%	1.78	%

The Company granted 93,750 new options during the year ended December 31, 2018.

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The following table provides stock option activity for the years ended December 31, 2018 and 2017:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2016	600,549	4.55	3.43 years	$ 1,463,052
Granted	267,875	6.40		
Exercised	56,969	4.19		100,018
Forfeited/expired/cancelled	785	5.56		
Outstanding at December 31, 2017	810,670	5.18	3.69 years	$ 2,477,853
Exercisable at December 31, 2017	371,295	4.44	2.62 years	$ 1,409,440
Outstanding at December 31, 2017	810,670	$ 5.18	3.69 years	$ 2,477,853
Granted	93,750	$ 9.80		352,220
Exercised	144,947	$ 4.83		523,327
Forfeited/expired/cancelled	47,505	$ 8.82		154,583
Outstanding at December 31, 2018	711,968	$ 5.62	3.33 years	$ 687,364
Exercisable at December 31, 2018	396,799	$ 4.70	2.66 years	$ 568,956

The following table summarizes information about stock options outstanding at December 31, 2018:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Shares Outstanding	Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	-	-	$ -	$ -	-	$ -	$ -
2.8 to 4.59999	304,343	1.90	3.45	672,896	254,343	3.46	560,711
4.6 to 6.39999	152,875	3.43	5.85	14,468	58,020	5.80	8,245
6.4 to 8.19999	207,875	5.05	7.31	-	75,041	7.21	-
8.2 to 12	46,875	4.60	11.45	-	9,375	11.45	-
Total	711,968	3.33	$ 5.62	$ 687,364	396,779	$ 4.70	$ 568,956

As of December 31, 2018, there was $710,376 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 2.45 years. The total fair value of shares vested during the year ended December 31, 2018, was $553,000.

The following table summarizes information about restricted stock and restricted stock units outstanding as of December 31, 2018:

	Number of Shares & Units	Weighted Average Grant Date Fair Value

Outstanding at December 31, 2017	-	$ -
Granted	287,564	9.65
Exercised	-	-
Forfeited/expired/cancelled	-	-
Outstanding at December 31, 2018	287,564	9.65
Exercisable at December 31, 2018	-	$ -

As of December 31, 2018, there was $1,688,746 of net unrecognized compensation cost related to restricted stock and restricted stock units that are not vested, which is expected to be recognized over a weighted average period of approximately 2.5 years. Stock based compensation cost related to restricted stock and restricted stock units recognized during the years ended December 31, 2018 and 2017 was $281,249 and $0, respectively.

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NOTE 12 — GEOGRAPHIC INFORMATION AND ECONOMIC DEPENDENCY:

The Company produces only one group of similar products known collectively as “rapid medical tests,” and it operates in a single business segment. Net product sales by geographic area are as follows:

	For the years ended December 31, 2018	December 31, 2017
Africa	$8,605,306	$ 3,568,455
Asia	1,389,120	1,626,750
Europe & Middle East	2,172,031	1,763,274
Latin America	11,722,224	8,476,003
United States	2,852,339	3,887,820
	$26,741,020	$ 19,322,302

Long-lived assets by geographic area are as follows:

	2018	2017
Asia	$466,185	$472,774
Europe & Middle East	123,752	-
United States	2,283,983	1,436,458
	$2,873,920	$1,909,232

NOTE 13 — COMMITMENTS, CONTINGENCIES AND CONCENTRATIONS:

Employment Contracts:

The Company has multi-year contracts with two key employees. The contracts call for salaries presently aggregating $770,000 per year, and they expire in March 2019 and March 2020. The following table is a schedule of future minimum salary commitments:

2019	$485,493
2020	85,000

Pension Plan:

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% (or 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $94,544 and $91,150 for the years ended December 31, 2018 and 2017, respectively.

Obligations Under Operating Leases:

The Company leases industrial space used for office, R&D and manufacturing facilities, currently with a monthly rent of $30,140. The current lease expires on April 30, 2019. The lease provides for annual increases of 2.5% percent each year starting May 1, 2016. In February of 2014, the Company entered into a lease for office and warehouse space, effective March 1, 2014, a short distance from its current facility currently with a monthly rent of $16,709. The space is used primarily for warehousing and provides for additional office space. The lease expires on April 30, 2020. The lease provides for annual increases of 3.0% percent each year starting March 1, 2016. The Company also leases office, warehouse, and manufacturing space in a single building in Kuala Lumpur, Malaysia persuant to two separate leases that each expire on April 30, 2020 and have an additional three year renewal option with combined

monthly rent of approximately $5,400. The Company also leases space in Germany for offices, manufacturing, and center of excellence for optical technology. The lease will automatically renew annually on May 31. The monthly cost is estimated at $13,445 with yearly increases of 2%.

The following is a schedule of future minimum rental commitments for the years ending December 31,

2019	$384,308
2020	88,576
2021	-
	$472,884

Rent expense was $653,155 and $586,730 for the years ended December 31, 2018 and 2017, respectively.

Economic Dependency:

Customers are considered major customers when net sales exceed 10% of the Company's total net sales for period or outstanding trade receivables exceed 10% of accounts receivable. The Company had the following major customers for the respective periods:

	For the years ended						Accounts Receivable	
	December 31, 2018		December 31, 2017			December 31, 2018	December 31, 2017	
	Sales	% of Sales	Sales	% of Sales				
Customer 1	$11,171,174	42 %	$ 8,065,217	42	%	$ 3,499,340	$	-
Customer 2	4,346,640	16 %	-	-	%	1,033,824		-

The following table delineates purchases the Company had with vendors in excess of 10% of total purchases for the periods indicated:

	For the years ended					Accounts Payable		
	December 31, 2018		December 31, 2017			December 31, 2018	December 31, 2017	
	Purchases	% of Purc.	Purchases	% of Purc.				
Vendor 1	$ *	*	$ *	*		$ *	$	*
Vendor 2	*	*	746,868	12	%	*		*
Vendor 3	*	*	849,966	14	%	164,312		*
Vendor 4	1,646,614	16 %	884,698	14	%	*		*

In the tables above, an asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated.

The Company purchases materials pursuant to intellectual property rights agreements that are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which could adversely affect operating results.

Litigation:

From time to time, the Company is involved in certain legal actions arising in the ordinary course of business. The outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on the Company’s future financial position or results of operations.

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NOTE 14 — NOTE PAYABLE:

In September 2017, the Company entered into an agreement with an equipment vendor to purchase automated assembly equipment for approximately $660,000. The terms call for prepayments of 30% down, 60% at time of factory acceptance testing and 10% after delivery. The vendor agreed to lend the Company 15%, 40%, and 10% of each originally scheduled payment, respectively. The Company will pay interest at an annual rate of 12% until delivery. Beginning in September 2018, the Company began making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a twenty-four month period.

NOTE 15 — SUBSEQUENT EVENTS:

On February 5, 2019, the Company entered into a commercial real estate lease for a new corporate headquarters comprised of 70,000 square feet of office, research and development, and warehouse space in Hauppauge, New York. The lease has an initial term of eleven years that can be extended, at the Company’s option, for two additional terms of five years each. Rent under the lease, which is payable in monthly installments, totals approximately $900,000 for the initial year and then increases by approximately three percent each succeeding year. Upon lease inception, the Company provided a security deposit and paid four months base rent that together totaled approximately $450,000. The base rent which will be deducted against the rent due following a nine-month free rent period.

On February 5, 2019, the Company also entered into an agreement of sublease with an affiliate of the Hauppauge, NY facility landlord to sublet the Company’s warehouse space and supplemental administrative office facility in Holbrook, New York. The sublease has a term that will (a) commence on the later of March 18, 2019 and the date the Company vacates the premises and (b) terminate on April 29, 2020, which is immediately prior to the termination of the Company’s lease for the facility. The sublessee will pay the Company 50% of the Company’s rent and additional rent payments, which will total approximately $100,000 per year during the term of the sublease.