CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 08, 2018
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, 2017
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
Preferred Share Purchase Rights	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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post 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. (Check one):

Large accelerated filer [ ]	Accelerated filer [X]
Non-accelerated filer [ ]	Smaller reporting company [ ]
(Do not check if a smaller reporting company)	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 Company's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates* was $56,453,579.

As of March 5, 2018, the registrant had 14,162,702 common shares outstanding.

* Without asserting that any of the issuer's directors or executive officers, or the entities that own more than five percent of the outstanding shares of the Registrant's common stock, are affiliates, the shares of which they are beneficial owners have not been included in shares held by non-affiliates solely for this calculation.

TABLE OF CONTENTS

Table of Contents

PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including exhibits that are being filed as part of this report, as well as other statements made by Chembio Diagnostics, Inc. ("Chembio", the "Company", "we", "us", and "our"), contain "forward-looking statements" that include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in tense, identify forward-looking statements.

These forward-looking statements include such things as: investment objectives and the Company's ability to make investments in a timely manner on acceptable terms; references to future success of the Company's products; the Company's business strategy; estimated future capital expenditures; sales of the Company's products; competitive strengths and goals; and, other similar matters.

These forward-looking statements reflect the Company's current beliefs and expectations with respect to future events and are based on assumptions and are subject to risks and uncertainties and other factors outside the Company's control that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 1A entitled "Risk Factors", matters described elsewhere in this Report, and the following: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulatory entities; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of our products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention and other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; changes in laws or regulations; global and regional economic conditions, including conditions affecting the credit markets, such as those resulting from the United Kingdom referendum held on June 23, 2016 in which United Kingdom voters approved an exit from the European Union; and general political, business and

market conditions.

Although the Company believes the expectations reflected in such forward-looking statements are based upon reasonable assumptions, these are only assumptions, and forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Investors are cautioned that forward-looking statements may not be reliable and speak only as of the date they are made and that, except as required by law, the Company undertakes no obligation to update these forward-looking statements to reflect any future events or circumstances. All subsequent written or oral forward-looking statements attributable to the Partnership or to individuals acting on its behalf are expressly qualified in their entirety by this section.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information to securities analysts unless and until we have made it publicly available. Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of the Company.

We provide free of charge on our website at www.chembio.com our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable. Additional information about us can also be found on our website. Members of the public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, and Washington, DC 20549. Members of the public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800–SEC–0330. The Internet address of the Commission is www.sec.gov. That website contains reports, proxy and information statements and other information regarding issuers, like Chembio, that file electronically with the Commission. Visitors to the Commission's website may access such information by searching the EDGAR database.

For further information about these and other risks, uncertainties and factors, please review the disclosure included in this report under “Part I, Item 1A, Risk Factors.”

Our Business

General

Chembio Diagnostics develops, manufactures, and commercializes point-of-care (POC) diagnostic tests that are used to detect or monitor diseases. 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. POC tests, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POC tests can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

Our product commercialization and product development efforts are focused in three areas: sexually transmitted disease, tropical & fever disease, and technology collaborations. In sexually transmitted disease, we are commercializing tests for HIV and Syphilis. In tropical and fever disease, we are commercializing tests for Zika virus, dengue virus, and chikungunya virus, and developing tests for malaria, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of a fever panel test. Through technology collaborations, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for an undisclosed biomarker, the latter in collaboration with global biopharmaceutical company AstraZeneca.

2

Table of Contents

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 POC 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.

Our Products

Products: Commercially Available

Following is a summary of our point-of-care products, including regulatory and commercial status:

Product	Description	Regulatory Status	Commercial Status
DPP® HIV 1/2 Assay	A rapid, point-of-care assay for the detection of HIV-1 and HIV-2 antibodies in finger stick, venous blood, serum, plasma or oral fluid	Premarket approval (“PMA”) by U.S. FDA CLIA (Clinical Laboratory Improvement Amendments of 1988) waived CE marked (European Union/Caribbean) World Health Organization (“WHO”) pre-qualification Agência Nacional de Vigilância Sanitária (“ANVISA”) approved (Brazil) Also registered in various other countries	Marketed
DPP® HIV-Syphilis Assay	A rapid, point-of-care assay for the detection of HIV-1 and HIV-2 antibodies and for antibodies to Treponema pallidum (the causative agent of Syphilis) in finger stick, venous blood, serum or plasma	CE marked (European Union/Caribbean) ANVISA approved (Brazil) Also registered in various other countries	Marketed
DPP® Syphilis Screen and Confirm Assay	A rapid, point-of-care assay for the simultaneous detection of IgG and IgM antibodies to Treponema pallidum (the causative agent of Syphilis) and IgG and IgM antibodies to RPR in finger stick, venous	CE marked (European Union/Caribbean)	Marketed

	blood, serum or plasma	Also registered in various other countries PMA approved by U.S. FDA CLIA waived CE marked (European Union/Caribbean) WHO pre-qualification Designated eligible for procurement by Global Fund	
SURE CHECK® HIV 1/2 Assay	A rapid, point-of-care assay for the detection of HIV-1 and HIV-2 antibodies in finger stick or venous blood		Marketed
HIV 1/2 STAT-PAK® Assay	A rapid, point-of-care assay for the detection of HIV-1 and HIV-2 antibodies in finger stick, venous blood, serum or plasma	Also registered in various other countries PMA approved by U.S. FDA CLIA waived CE marked (European Union/Caribbean) WHO pre-qualification Designated eligible for procurement by Global Fund	Marketed
DPP® Dengue IgM/IgG Assay	A rapid, point-of-care assay for the simultaneous and separate detection of both IgG and IgM antibodies to Dengue virus in finger stick, venous blood, serum or plasma	Also registered in various other countries Malaysia Medical Device Authority ("MDA") approved Additional regulatory approvals pending	Marketed
DPP® Dengue NS1 Antigen Assay	A rapid, point-of-care assay for the detection of NS1 antigen to Dengue virus in finger stick, venous blood, serum or plasma	Malaysia MDA approved Additional regulatory approvals pending	Marketed

Table of Contents

DPP® Zika IgM Assay	A rapid, point-of-care assay for the detection of IgM antibodies to Zika virus in finger stick, venous blood, serum or plasma	U.S. FDA Emergency Use Authorized Additional regulatory approvals pending CE marked (European Union/Caribbean)	Marketed
DPP® Zika IgM/IgG Assay	A rapid, point-of-care assay for the separate and simultaneous detection of IgM and IgG antibodies to Zika virus in finger stick, venous blood, serum or plasma	ANVISA approved (Brazil) Additional regulatory approvals pending	Marketed
DPP® Chikungunya IgM/IgG Assay	A rapid, point-of-care assay for the separate and simultaneous detection of IgM and IgG antibodies to Chikungunya virus in finger stick, venous blood, serum or plasma	Malaysia MDA Approved Additional regulatory approvals pending	Marketed
DPP® Zika, Dengue, Chikungunya IgM/IgG Assay	A rapid, point-of-care assay for the separate and simultaneous detection of IgM and IgG antibodies to Zika, Dengue, Chikungunya virus in finger stick, venous blood, serum or plasma	Malaysia MDA Approved Additional regulatory approvals pending	Marketed
DPP® Vet TB Assay (Veterinary Application)	A rapid, point-of-care assay for the detection of Mycobacterium bovis antibodies in Elk, Red Deer, White-tailed Deer and Fallow Deer	USDA approved	Marketed
Chagas STAT-PAK® Assay	A rapid, point-of-care assay for the detection of antibodies to Trypanosoma cruzi in finger stick, venous blood, serum or plasma	CE marked (European Union/Caribbean) Additional regulatory approvals pending	Marketed
RVR® Dengue IgM/IgG Assay	A rapid, point-of-care assay for the detection of IgM and IgG antibodies to the Dengue virus in finger stick, venous blood serum or plasma	Malaysia MDA approved Additional regulatory approvals pending	Marketed
RVR® Dengue NS1 Assay	A rapid, point-of-care assay for the detection of NS1 antigen to Dengue virus in finger stick, venous blood, serum or plasma	Malaysia MDA approved Additional regulatory approvals pending	Marketed
RVR® Dengue Combo Assay	A rapid, point-of-care assay for the simultaneous and separate detection of IgG and IgM antibodies and NS1 antigen to Dengue virus in finger stick, venous blood, serum or plasma	Malaysia MDA approved Additional regulatory approvals pending	Marketed

Products: Under Clinical Evaluation

Following is a summary of our point-of-care products under clinical evaluation, including regulatory and commercial status:

Product	Description	Regulatory Status	Commercial Status
DPP®HIV-Syphilis Assay System	A rapid, point-of-care assay for the detection of HIV-1 and HIV-2 antibodies and for antibodies to Treponema pallidum (the causative agent of Syphilis) in finger stick, venous blood, serum or plasma	Filed Premarket Approval ("PMA") Application to U.S. FDA	Not Marketed
DPP® Malaria/Ebola Assay	A rapid, point-of-care assay for the separate and simultaneous detection of Ebola VP40 antigen and Malaria antigen P.f/P.v in finger stick, venous blood, serum or plasma	Under clinical evaluation	Not Marketed
DPP® Ebola Assay	A rapid, point-of-care assay for the detection of Ebola VP40 antigen in finger stick, venous blood, serum or plasma	Under clinical evaluation	Not Marketed
DPP® Fever Panel Assay - Africa	A rapid, point-of-care assay for the separate and simultaneous detection of antigens to Malaria pf/Pan species, Ebola, Lassa Fever, Marburg, Zika, Dengue and Chikungunya in finger stick, venous blood, serum or plasma	Under clinical evaluation	Not Marketed

Products: Under Development

Following is a summary of our point-of-care products under development, including regulatory and commercial status:

Product	Description	Regulatory Status	Commercial Status
DPP® Malaria Antigen P.f/P.V Assay	A rapid, point-of-care assay for the separate detection of Malaria antigen P.F/P.V in finger stick, venous blood, serum or plasma	Under development	Not Marketed

Table of Contents

DPP® Fever Panel Assay - Asia	A rapid, point-of-care assay for the separate and simultaneous detection of antigens to Malaria pf/Pan Rickettsia typhi, Orientia tsutsugamushi, Leptospira Burkholderia pseudomallei, Dengue virus, Chikungunya virus and Zika virus in finger stick, venous blood, serum or plasma	Under development	Not Marketed
DPP® Undisclosed Biomarker Assay	A rapid, semi-quantitative point-of-care assay for an undisclosed novel biomarker in finger stick, venous blood, serum or plasma	Under development	Not Marketed
DPP® Cancer Assay	A rapid, quantitative point-of-care assay for an undisclosed novel biomarker in finger stick, venous blood, serum or plasma	Under development	Not Marketed
DPP® Concussion Assay	A rapid, quantitative point-of-care assay for an undisclosed novel biomarker in finger stick, venous blood, serum or plasma	Under development	Not Marketed
DPP® BovidTB Assay (Veterinary Application)	A rapid, point-of-care assay for the detection of Mycobacterium bovis antibodies in serum of cattle	Under development	Not Marketed

DPP® Technology & Development

The Company's commercially available products employ either our patented Dual Path Platform (DPP®) technology or traditional lateral flow technology. We believe products developed using the Company's DPP® technology can provide superior diagnostic performance compared with products that utilize traditional lateral flow technology.

Chembio is executing its strategy to leverage the DPP® intellectual property, as well as the Company's scientific and operational expertise, to create new collaborations where Chembio will serve as an exclusive development and manufacturing partner. Examples of such collaborations include the following:

In October 2014, we entered into an agreement with an international diagnostics company to develop a POC diagnostic test for the early detection and monitoring of a specific type of cancer. At that time, the cancer project represented the first application of the DPP® technology outside the infectious disease field.
In January 2015, we entered into an agreement with the Concussion Science Group (CSG) Division of Perseus Science Group LLC to utilize our DPP® technology to develop a POC diagnostic test for traumatic brain injury (TBI), including sports-related concussions.
In January 2015, we were awarded a grant from The Bill & Melinda Gates Foundation to expedite the feasibility testing and development of a DPP® Malaria POC rapid diagnostic to accurately identify individuals infected with Plasmodium falciparum parasite.
In October 2015, we were awarded a grant from The Paul G. Allen Family Foundation to develop a POC test to identify multiple life-threatening febrile illnesses. Under the $2.1 million dollar grant, we used our DPP® technology to develop a DPP® Fever Panel Assay, a POC multiplex assay to simultaneously detect Malaria, Dengue, Zika, Chikungunya, Ebola, Lassa and Marburg.
In October 2015, we signed an agreement with opTricon (Berlin, Germany), a leading developer of mobile analysis devices for rapid diagnostic tests. The DPP® Micro Reader provides customers with various options to capture, record, transmit and store test results. With one-button operation, the palm-sized and battery-operated DPP® Micro Reader is simple, fast, portable, and cost-effective.
In October 2017, we signed a development agreement with AstraZeneca for the development of a quantitative point-of-care assay for a novel biomarker based on our DPP® assay and DPP® Micro Reader technologies.

Sales, Marketing & Distribution

We continue to target the following geographies: United States, Europe, Latin America, Africa and Southeast Asia. We reach our target markets through a combination of direct sales, strategic local distributors and OEM partners. Our efforts are focused on raising awareness of Chembio's products and technology through global and regional marketing activities such as tradeshows and working with local key opinion leaders, local distributors, and strategic partners. We are also increasing our digital and social media activities to drive awareness of our products.

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

Table of Contents

Ability to attract and retain qualified personnel

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 such as sexually transmitted diseases, fever and tropical 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.

Research and Development

During 2017, 2016 and 2015, we spent $8.6 million, $8.4 million and $6.4 million, respectively, on research and development (including regulatory activities). These expenses were in part funded by R&D milestone and grant revenues of $4.0 million in 2017, $3.7 million in 2016 and $2.3 million in 2015.

Employees

At December 31, 2017, we employed approximately 165 people.

Governmental Regulation

Certain of our activities are subject to regulatory oversight by the Food & Drug Administration (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 is subject to oversight by Centers for Medicare and Medicaid Services (CMS) pursuant to CLIA (defined below), 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 U.S. 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 sure 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, 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 (MDUFMA), as of October 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 MDUFMA, 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 (BPAC). Approved Rapid HIV tests must meet the regulations in the 21 CFR 800 series subparts, under the Investigational Device exemption (IDE) and PMA pathways.

Table of Contents

Premarket Approval Pathway

We manufacture, market, and distribute three rapid HIV tests in the U.S: our HIV 1/2 STAT-PAK® Assay, SURE CHECK® HIV 1/2 Assay, and DPP® HIV 1/2 Assay, all of which have received FDA PMA approval. A PMA application must be submitted if a device cannot be cleared through the 510(k) process. 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 investigational device exemption, or "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; and, in some instances, IVD clinical trials 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 IRB 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 Quality Systems Regulations (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 on May 25, 2006. Our DPP® HIV 1/2 Assay PMA application number BP120032/0 was approved by the FDA on December 19, 2012.

510(k) Clearance Pathway

We do not currently market, distribute, or sell a product that has market clearance by the FDA. However, 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 (CLIA)

A manufacturer of a test categorized as moderately complex may request that categorization of the test as waived through a CLIA Waiver by Application (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, 42 U.S.C. 263a(d)(3). Congress passed CLIA in 1988, which provided 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 both of our lateral flow rapid HIV tests that we market in the U.S. Specifically, the CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK® on November 20, 2006 and for SURE CHECK® HIV 1/2 on October 22, 2007. In 2008 the FDA revised its CLIA waiver requirements so that an additional prospective trial is required in order to demonstrate clinical utility by showing that the device is capable of identifying new infections when used by untrained users. Our DPP® HIV 1/2 test received a CLIA waiver under these newer requirements on October 29, 2014.

Table of Contents

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 (MDR) regulations (which require that manufacturers 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. Class II devices also can have special controls such as performance standards, post-market surveillance, patient registries, and FDA guidelines that do not apply to Class I devices.

A noncomprehensive list of the regulatory requirements that apply to our approved products classified as medical devices or IVDs includes:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires 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 quality system regulation and other regulations.

21st Century Cures Act

The 21st Century Cures Act, enacted in December 2016, contains several sections specific to medical device innovations. The Company believes 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 United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service

(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

To date, we have not encountered any costs relating to compliance with any environmental laws.

Intellectual Property

Intellectual Property Strategy

Our intellectual property strategy is to: (1) build our own intellectual property portfolio around our DPP® technology; (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.

Table of Contents

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 U.S., as well as in many foreign countries such as Brazil, Canada, the European Union, India, Israel, and South Africa.

The DPP® technology provides us with our own intellectual property. We believe it provides us with freedom to operate, which enables us to develop tests with better performance and unmatched capabilities compared with tests built on traditional lateral flow platforms. These advantages have allowed us to enter into multiple technology collaborations based upon the DPP® technology, which we believe will provide new manufacturing and marketing opportunities. We have filed other 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.

Trademarks

We have filed and obtained trademarks for our products, including DPP®, SURE CHECK®, STAT-VIEW®, and STAT-PAK®, as well as for the SampleTainer®, which is 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 but not limited to 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

As of February 3, 2015 the royalty expenses related to certain lateral flow technology expired. These now allow us to produce STAT-PAK®, SURE CHECK®, STAT-VIEW®, DIPSTICK®, and veterinary product lines free of those royalties.

Although we believe our DPP® IP is outside of the scope of all lateral flow patents of which we are aware, we consult with patent counsel, and 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. Nevertheless, there is no assurance that the Alere lateral flow patents we have licensed will not be challenged or that other patents containing claims relevant to our lateral flow or DPP® products will not be granted to third parties and that licenses to such patents, will be available on reasonable terms, if any.

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 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, during the first quarter of 2008, we entered into 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.

Corporate Information

We are a Nevada corporation that was formed in December 1985. Since inception, we have been involved in developing, manufacturing, selling and distributing medical diagnostic tests, including rapid tests that detect a number of diseases and other conditions in humans and animals.

Stockholder Rights Agreement

On March 8, 2016, we entered into a Rights Agreement (the "Rights Agreement") between us and Action Stock Transfer Corp., as Rights Agent. Pursuant to the Rights Agreement, we declared a dividend distribution of one Preferred Share Purchase Right (a "Right") for each outstanding share of our common stock, par value $0.01 (the "Common Stock"), in the manner described below. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2016, and the Rights were distributed to our shareholders of record on that date. The Rights Agreement also provides that Rights are issued with respect to any shares of our common stock that are newly issued after March 8, 2016, such as with respect to the Company's underwritten public offering in February 2018. The description and terms of the Rights are set forth in the Rights Agreement.

Rights Initially Not Exercisable

The Rights are not exercisable until a Distribution Date. Until a Right is exercised, the holder thereof, as such, has 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 are to be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) has acquired a Combined Ownership (as defined in the Rights Agreement) of 20% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 20% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

Table of Contents

Glossary

AIDS	Acquired Immunodeficiency Syndrome. AIDS is caused by the Human Immunodeficiency Virus, HIV.
ALGORITHM (parallel or serial)	For rapid HIV testing, this refers both to method or protocol (in developing countries to date) for using rapid tests from different manufacturers in combination to screen and confirm patients at the point-of-care, and may also refer to the specific tests that have been selected by an agency or ministry of health to be used in this way. A parallel algorithm uses two screening tests from different manufacturers and a tie-breaker test only if there is a discrepancy between the screening tests results. A serial algorithm only uses a second confirmatory test if there is a positive result from the screening test, meaning that the number of confirmatory tests used is equal to the positivity rate in the testing venue. A tie-breaker test resolves discrepancies between the screen and the confirmatory test.
ANTIBODY	A protein which is a natural part of the human immune system produced by specialized cells to neutralize antigens, including viruses and bacteria that invade the body. Each antibody-producing cell manufactures a unique antibody that is directed against, binds to and eliminates one, and only one, specific type of antigen.
ANTIGEN	Any substance which, upon entering the body, stimulates the immune system leading to the formation of antibodies. Among the more common antigens are bacteria, pollens, toxins, and viruses.
ANVISA	The National Health Surveillance Agency of Brazil.
ARVs	Anti-retroviral medications developed to fight AIDS.
CDC	United States Centers for Disease Control and Prevention.
CLIA waiver	Clinical Laboratory Improvement Act designation that allows simple tests to be performed in point-of-care settings such as doctor’s offices, walk-in clinics and emergency rooms.
DIAGNOSTIC	Pertaining to the determination of the nature or cause of a disease or condition. Also refers to reagents or procedures used in diagnosis to measure proteins in a clinical sample.
FIOCRUZ	The Oswaldo Cruz Foundation of Brazil.
FDA	United States Food and Drug Administration.
IgG	IgG or Immunoglobulin are proteins found in human blood. This protein is called an “antibody” and is an important part of the body’s defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
IgM	IgM or Immunoglobulin M are proteins found in human blood. This protein is called an "antibody" and is an important part of the body's defense against disease. When the body is attacked by harmful bacteria or viruses, antibodies help fight these invaders.
NGO	Non-Governmental Organization.
OTC	Over-the-Counter.
PEPFAR	The President’s Emergency Plan for AIDS Relief.
PMA	Pre-Marketing Approval –FDA approval classification for a medical device that is not substantially equivalent to a legally marketed device or is otherwise required by statute to have an approved application. Rapid HIV tests must have an approved PMA application before marketing of such a product can begin.
PROTOCOL	A procedure pursuant to which an immunodiagnostic test is performed on a particular specimen in order to obtain the desired reaction.
REAGENT	A chemical added to a sample under investigation in order to cause a chemical or biological reaction which will enable measurement or identification of a target substance.
RETROVIRAL	A type of virus which contains the enzyme Reverse Transcriptase and is capable of transforming infected cells to produce diseases in the host such as AIDS.
SENSITIVITY	Refers to the ability of an assay to detect and measure small quantities of a substance of interest. The greater the sensitivity, the smaller the quantity of the substance of interest the assay can detect. Also

	refers to the likelihood of detecting the antigen when present.
SPECIFICITY	The ability of an assay to distinguish between similar materials. The greater the specificity, the better an assay is at identifying a substance in the presence of substances of similar makeup.
USDA	U.S Department of Agriculture.
WHO	World Health Organization.

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

There are competing products that could significantly reduce our U.S. sales of rapid HIV tests.

In 2006 Alere, Inc. acquired a division from Abbott Diagnostic located in Japan that manufactured and marketed a rapid HIV test product line called Determine®. The Determine® format was developed for the developing world and remote settings and, central to the needs of that market. The format is essentially a test strip that is integrated into a thin foil wrapper. When opened, the underside of the wrapper serves as the test surface for applying the blood sample and performing the test. This design reduces costs and shipping weights and volumes and provides an advantage for the developing world markets it serves. Some of the disadvantages of the platform are the amount of blood sample that is needed (50 microliters versus 2.5, 5 and 10 for our lateral flow barrel, lateral flow cassette, and DPP® products respectively), the open nature of the test surface, and the absence of a true control that differentiates biological from other kinds of samples.

The so-called "3rd generation" version of this product has been marketed for many years and is the leading rapid HIV test that is used in a large majority of the national algorithms of countries funded by PEPFAR and the Global Fund, as well as many other countries in the world. That product is not FDA-approved though it is CE marked. The newest Determine® HIV version, which was developed and manufactured by Alere's subsidiary in Israel, Orgenics, is the so-called "4th Generation" version Determine® test. According to its claims, this product detects HIV antibodies and P24 HIV antigens. Because the P24 antigen is known to occur in HIV-positive individuals' blood samples before antibodies do, the 4th generation Determine® test is designed to detect HIV infection earlier than tests that solely rely on antibody detection. Chembio's tests, as well as all of the other currently FDA-approved rapid HIV tests, only detect antibodies. There are however laboratory tests that are FDA-approved that are "4th generation" tests, but they are neither rapid nor point-of-care.

Table of Contents

The initial "4th generation" Alere Determine® rapid test product that was also CE marked and that Alere launched internationally some years ago has not been successfully commercialized to the best of our knowledge and at least certain published studies were not favorable for this product. The 4th generation product that is now FDA-approved was apparently modified as compared to the initial international version, and it may perform more satisfactorily. Alere received FDA approval of this modified product in August 2013 and CLIA waiver for it in December 2014. Alere is also aggressively pursuing development of the market for this product. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and this product represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (OraSure and Trinity primarily).

During 2011, Biolytical, Inc. of Vancouver, Canada received FDA approval and in 2012 received CLIA waiver of a flow-through rapid HIV test called "INSTI". The flow-through technology used in the INSTI test is older than lateral flow, and requires handling of multiple components (3 vials of solution) to perform the test in multiple steps. However, these steps can be accomplished in less than ten minutes, and the actual test results occur in only one minute after those steps are completed. Therefore sample-to-result time is shorter than any of the competitive products. The product also has good performance claims. There are settings where that reduced total test time, despite the multiple steps required, may be a distinct advantage, and we believe Biolytical has made some progress in penetrating certain public health markets.

Therefore, even though our lateral flow products currently enjoy a substantial market share in the U.S. rapid HIV test market, and we have an additional rapid HIV test, the DPP® HIV 1/2 Assay, there a number of risks and uncertainties concerning current and anticipated developments in this market. Although we have no specific knowledge of any other new product that is a significant competitive threat to our products, or that will 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 products developed by our competitors, which could result in a loss of revenues and cash flow.

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 our DPP® patent, 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 but not limited to our having a patented rapid test platform technology that differentiates DPP® from lateral flow as well as from other diagnostic platform technologies.

We believe that our DPP® is outside of the scope of currently issued patents in the field of lateral flow technology, thereby offering the possibility of greater freedom to operate. However there can be no assurance that our patents or our products incorporating the patent claims 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 must 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. 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 but not limited to, OraSure Technologies, Alere and Trinity Biotech. Furthermore these and/or other companies have or may have products incorporating molecular and/or other advanced technologies that over time could directly compete with our testing product line. 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.

Our Business Prospects May be Negatively Affected if We Fail to Achieve Our Financial and Strategic Objectives.

There is no assurance that we will be successful in implementing our financial and strategic objectives, including our efforts to increase sales of our products. For example, the funds for research, clinical development and other projects have in the past come primarily from our business operations. If the sale of our products slows and we have less money available to fund research and development and clinical programs, we will have to cut certain programs. If adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our business. If our total revenue and gross profits do not correspondingly increase or if our technology, product, clinical and market development efforts are unsuccessful or delayed, our operations will be negatively affected. Furthermore, our failure to successfully introduce new or enhanced products and develop new markets could have a material adverse effect on our business and prospects.

Our Future Revenues and Operating Results May be Negatively Affected by the 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.

Table of Contents

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 will depend 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 in the future due to the intense competition for qualified personnel among medical products businesses, geographic considerations, our ability to offer competitive compensation, relocation packages, benefits, and/or other reasons.

If we are not able to attract and retain the necessary 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. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

We have entered into employment contracts with our Chief Executive Officer, John Sperzel; our Chief Financial Officer, Neil Goldman; our President of the Americas, Sharon Klugewicz; and our Chief Scientist & Technology Officer , Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of any one of them could have a material adverse effect on the Company. The contract with Mr. Sperzel expires March 2020. The contract with Mr. Esfandiari has a term of three years ending March 2019. The contract with Ms. Klugewicz expires May 2019. The contract with Mr. Goldman expires December 2018. The Company has obtained a key man insurance policy on Mr. Esfandiari.

We May Not Generate the Expected Benefits of Our 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.

The 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 Act, the Federal healthcare reform law enacted in 2010 (the “Affordable Care Act”).

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.

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. Funding of These and or Similar Programs May be Reduced, Discontinued and/or We May Not be Able to Participate for Other Reasons.

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, 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.

Table of Contents

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 does not authorize a specific dollar amount for funding.

Developing Testing Guidelines Could Negatively Affect The 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 (“U.K.”) 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 and it 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 addition, new manufacturing equipment or facilities may require FDA approval 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.

Table of Contents

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.

The 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/or 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 may be needed 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 rapid HIV tests and other 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/or 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.

Other Providers of Diagnostic Tests and Sample Collection Products Will Likely Provide Us with Substantial Competition.

Our competitors make similar products to ours. A number of our competitors are making investments in technologies and products, and may have a competitive advantage because of their greater financial, technical, research and other resources. Some competitors offer broader product lines and may have greater name recognition than we have. 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. 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.

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.

The 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.

Our Insurance May be Inadequate to Cover Our Potential Business Risks.

We believe that our present product liability and other insurance coverage is sufficient to cover our current estimated exposures, but we cannot be sure that we will not incur liabilities in excess of our policy limits. Although we believe that we will be able to continue to obtain adequate coverage in the future, there is no assurance that we will be able to do so.

Due to the Use of Our Products, We May Face Product Liability Claims for Injuries.

If any of our products, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage, we may subject to liability. We may not be successful in defending any product liability lawsuits brought against us. Regardless of merit or eventual outcome, product liability claims could result in (i) decreased demand for our products; (ii) damage to our image or reputation; (iii) lost revenues; and (iv) incurrence of damages payable to plaintiffs

Legal Proceedings May Cause Us to Suffer Monetary Damages or Incur Substantial Costs.

In the future we may become involved in various legal proceedings arising out of our businesses. These may include negligence claims, commercial disputes or other lawsuits arising in the ordinary course of business. These lawsuits may result in damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered. An adverse ruling or rulings in one or more such lawsuits could result in the termination or modification of a material contract or otherwise 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.

Table of Contents

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

The Success of Our Business Depends On, in Addition to the Market Success of Our Products, Our Ability to Raise Additional Capital Through the Sale of Debt or Equity or Through Borrowing, and We May Not be Able to Raise Capital or Borrow Funds on Attractive Terms and/or in Amounts Necessary to Continue Our Business, or At All.

We were profitable for five consecutive years through 2013. Nevertheless, prior to 2009 we sustained significant operating losses since 2004, and we incurred an operating loss each year for 2014 through 2017. We estimate that our resources are sufficient to fund our needs through the end of 2018 and beyond. We have already made, and may continue to make, significant financial commitments to invest in our sales and marketing organization, regulatory approvals, research and development including new technologies, and production capacity, including expanded facilities.

Our liquidity and cash requirements will depend on several factors. These factors include, among others, (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make; and (4) our investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. There are no assurances that we will generate positive cash flow for 2018 or, in the alternative, be successful in raising sufficient capital to fund our needs after 2018.

Our U.S. market sales are difficult to predict in 2018 given (i) our early June 2014 termination of the agreement with a third party for exclusive distribution of our cassette product in the U.S; and (ii) the May 31, 2016 termination of the agreement with a third party for exclusive distribution of our barrel product in the U.S. As a result of these terminations, we expect to continue to experience higher average revenue per unit, and a lower volume of U.S. sales, of the cassette and barrel products. Higher revenue per unit is anticipated because we previously sold these products to the exclusive U.S. distributor at a significantly lower price than the price at which the distributor resold these products to customers (including re-sellers and distributors) in the United States. However at this point with respect to the barrel product, this can occur only after any inventory that the exclusive U.S. distributor has accumulated is consumed, which may take several months. In addition, in marketing these products directly, we are incurring substantial costs associated with developing our sales and marketing organization and channel distribution partners.

We believe that underlying demand for HIV rapid testing in the United States remains strong, and that the restoration of some of the funding cutbacks from sequestration and the implementation of the Affordable Care Act and of the United States Preventive Services Task Force recommendations will have a positive impact on the development of the market. On the other hand, it is possible that changes to healthcare law in 2017 and thereafter could change this and/or have a negative impact on the market for our products. Further, our products are well established and relied upon by a large installed base of customers over many years of use in the U.S. global market, and we believe this is a strong advantage. We also believe that our DPP® HIV 1/2 Assay, for which CLIA waiver was obtained in October 2014, for use with oral fluid or bloods samples will be able to serve new customers that were previously unavailable to us with our lateral flow blood tests. However, development of new customers with this product is costly and time-consuming.

If we are unable to maintain or increase our revenues from domestic and/or international customers, our operating results will be materially harmed.

Although We Were Profitable From 2009 Through 2013, We Incurred a Net Loss For Each Year From 2014 Through 2017 and Cannot be Certain that We Will be able to Sustain Profitability in the Future.

From the inception of Chembio Diagnostic Systems, Inc. in 1985 through the period ended December 31, 2008, we incurred net losses. We were then profitable each year from 2009 through 2013. In 2014, 2015, 2016 and 2017, we made substantial expenditures for sales and marketing, regulatory submissions, product development, production and warehouse capacity, and other purposes, and we incurred a net operating loss. Our ability to re-achieve profitability in the future will primarily depend on our ability to increase sales of our products based on having made the aforementioned expenditures to reduce production and other costs, and to successfully introduce new products and enhanced versions of our existing products into the marketplace. If we are unable to increase our revenues at a rate that is sufficient to achieve profitability, or adequately control and reduce our operating costs, our operating results would be materially harmed.

Table of Contents

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) customer sales returns and allowances; (v) contingencies; and (vi) 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.

We May Fail to Meet Our Financial Projections and There May be Fluctuations in Our Financial Results.

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. Our financial projections are based on a number of assumptions, including the estimated demand for our products. However, 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 Form 10-K. 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. 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 business will continue to grow and, consequently, our exposure to foreign currency exchange rates may grow as well.

Chembio Diagnostics Malaysia’s revenues and expenses and the translation of Chembio Diagnostics Malaysia’s 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.

Economic Volatility Around the World Could Adversely Affect Our Results.

Volatility in the economy may continue or exist in the future. This could negatively impact our financial performance or those of our customers and suppliers. These circumstances could inhibit our access to liquidity needed to conduct or expand our business. Many of our customers rely on public funding provided by federal, state and local governments, and this funding has been and may continue to be reduced or deferred as a result of economic conditions. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. Even with the improvement of economic conditions, it may take time for our customers and suppliers to establish new budgets and return to normal purchasing and shipping patterns. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of an economic recovery.

The New U.S. Tax Cuts and Jobs Act of 2017 and Any Subsequent Tax Law Changes Could Adversely Affect Us.

On December 22, 2017, President Trump signed into law the “Tax Cuts and Jobs Act” (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA includes, among other matters, changes to U.S. federal tax rates, allows for the expensing of capital expenditures, imposes significant additional limitations on the deductibility of interest, and puts into effect the migration from a “worldwide” system of taxation to a territorial system. We do not expect tax reform to have a material impact to our projection of minimal cash taxes or to our net operating losses. Our net deferred tax assets and liabilities will be revalued at the newly enacted U.S. corporate rate of 21 percent, and the impact will be recognized in our tax expense in the year of enactment. We continue to evaluate the TCJA may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse. In addition, subsequent unforeseen changes in U.S. or other countries’ tax laws could adversely affect us. We urge our stockholders to consult with their legal and tax advisors with respect to the TCJA and the potential tax consequences of investing in our common stock.

We May Require Additional Capital in the Future.

Our liquidity and ability to meet capital requirements will depend on numerous factors, including, but not limited to, the following: (i) the costs and timing of expansion of sales and marketing activities; (ii) the extent to which we gain or expand market acceptance for existing, new or enhanced products; (iii) the timing and success of the commercial launch of new products; (iv) the success of our research and product development efforts; (v) changes in existing and potential relationships with distributors and other business partners; (vi) the costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses; and (vii) Competing technological and market developments.

If we require new financing, we may seek to raise funds by selling equity or other securities or through bank borrowings. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise will be available to us on satisfactory terms, or at all.

Table of Contents

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.

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 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 (the "AIA"), 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® 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.

If We Become Involved in Intellectual Property Disputes, Such Disputes Could Increase Our Costs 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 (i) it could consume a substantial portion of managerial and financial resources; (ii) 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; (iii) the pendency of any litigation may in and of itself cause our distributors and customers to reduce or terminate purchases of our products; (iv) a court could award a preliminary and/or permanent injunction, which would prevent us from selling our current or future products; and (v) 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.

Table of Contents

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 Presents a Risk That Could Have Negative Consequences for Our Business.

A number of our components and critical raw materials are provided by third-party suppliers, some of which may be sole-source suppliers, which impacts our ability to manufacture or sell certain products if our suppliers cannot or will not deliver those materials in a timely fashion, or at all, due to an interruption in their supply, quality or technical issues, or any other reason. If this occurs, we could incur substantial expense and time to be able to reestablish the appropriate quality, cost, regulatory and market-acceptance circumstances needed for commercial success. Even with the needed expense and time, we may not be able to reestablish any or all of these factors. The absence of any one or more of these factors could prevent us from being able to commercially produce and market the affected product or products.

If Needed, We May Work with Strategic Collaborators to Assist in Developing and Commercializing Our Products.

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.

If We Fail to Maintain Existing Distribution Channels, or Develop New Distribution Channels, It May Result in Lower Revenues.

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.

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.

Table of Contents

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 USDA 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 quality system regulation ("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.

FDA Regulations and regulations by other federal, state and foreign regulatory agencies has an effect 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.

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, the 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 we are not a covered entity nor a business associate of a covered entity and the Company is not responsible for complying with the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"). Even though the Company is likely not a covered entity under HIPAA, the Company does have in place administrative, technical and physical safeguards to protect the privacy and security of consumers' personal information.] The Company is 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.

Table of Contents

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 that the Company is subject to, 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 the Company is subject to that require the Company 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 the Company. 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, the requirements of The NASDAQ Global Market, and the SEC's requirements for public companies to provide financial statements in interactive data format using the eXtensible Business Reporting Language ("XBRL"). 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.

Although We Have an Ethics and Anti-Corruption Policy in Place, and Have No Knowledge or Reason to Know of Any Practices by Our Employees, Agents or Distributors That Could be Construed as in Violation of Such Policies,

Our Business Includes Sales of Products to 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 United States Foreign Corrupt Practices Act (the "FCPA"). 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 a total of six 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.

Risks Related to Our Common Stock

Our Common Stock continues to be illiquid, so investors may not be able to sell as much stock as they want at prevailing market prices.

The average daily trading volume of our Common Stock on the NASDAQ market was approximately 16,368 shares per day over the three months ended December 31, 2017 as compared with approximately 19,300 shares per day over the three months ended December 31, 2016. The liquidity of our stock depends on several factors, including but not limited to the financial results of the Company 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 the 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: (i) the performance of our business; (ii) clinical results with respect to our products or those of our competitors; (iii) the gain or loss of significant contracts and availability of funding for the purchase of our products; (iv) actions undertaken by the Congress or the Presidential Administration; (v) changes in our relations with our key customers, distributors or suppliers; (vi) developments in patent or other proprietary rights; (vii) litigation or threatened litigation; (viii) general market and economic conditions; (ix) the relatively low trading volume for our Common Stock; (x) changes in competition; (xi) 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; (xii) failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders; (xiii) announcement of regulatory or enforcement actions by the FDA or other agencies against us, our products or our customers; (xiv) changes in our operating results; and (xv) terrorist attacks, civil unrest, war and national disasters.

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, Therefore an Investor in Our Common Stock Will Benefit Only if the Value of Our Common Stock Increases.

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 and/or Our Independent Registered Public Accounting Firm Conclude 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.

Table of Contents

Our Stockholder Rights Agreement Could Make a Third-Party Acquisition of Us Difficult.

Our Stockholder Rights Agreement, which is described above under "BUSINESS: Stockholder Rights Agreement" contain provisions that could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders.

Our Management and Larger Stockholders Exercise Significant Control Over the Company.

As of December 31, 2017, our named executive officers, directors and 5% stockholders beneficially owned approximately 44.35% of our voting power, which includes four large investors that beneficially own approximately 13.97%, 10.42%, 7.46%, and 7.09%, respectively 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.

Table of Contents

ITEM 1B. Unresolved Staff Comments.

Not Applicable

ITEM 2. PROPERTIES

Our corporate headquarters and U.S. manufacturing, administrative offices, and research facilities are located in leased space in Medford, New York, together with nearby warehouse space and additional administrative offices in Holbrook, New York. 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 be involved in litigation relating to claims arising out of our operations in the normal course of business. We know of no material, existing or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest that is adverse to our interest.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

Table of Contents

PART II

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

Market Information

Our stock is listed on the NASDAQ Global Select Market of the NASDAQ Stock Market LLC under the symbol "CEMI." The table below sets forth the high and low prices per share of our common stock for each quarter of our two most recently completed fiscal years.

Fiscal Year 2017	High	Low
First Quarter	$6.80	$5.05
Second Quarter	$7.04	$5.15
Third Quarter	$6.70	$5.75
Fourth Quarter	$8.35	$5.90

Fiscal Year 2016	High	Low
First Quarter	$6.10	$4.03
Second Quarter	$9.40	$5.87
Third Quarter	$8.48	$5.08
Fourth Quarter	$7.45	$6.10

Holders

As of March 5, 2018, there were approximately 1,590 record owners of our common stock (including nominee holders such as banks and brokerage firms who hold shares for beneficial owners).

Dividends

The Company has never paid cash dividends on its common stock and has no plans to do so in the foreseeable future. Any future declaration of dividends will be determined by our Board of Directors in its sole discretion and will depend on, among other things, our earnings, capital requirements, financial condition, prospects and any other factors the Board of Directors may deem relevant.

Recent Sales of Unregistered Securities

There were no sales of unregistered securities during the year ended December 31, 2017 that were not previously reported on a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2017.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data were derived from our audited consolidated financial statements and should be read in conjunction with, and are qualified by reference to, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. The financial information presented may not be indicative of our future performance.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
SELECTED HISTORICAL FINANCIAL DATA
As of and For the Years Ended December 31,

Statement of Operations Data:	2017 (1)	(2)	2016 (3)	(2)	2015	(2)	2014	(2)	2013	(2)
TOTAL REVENUES	$24,015,427		$17,868,841		$24,255,485		$27,645,284		$29,549,609	
COSTS AND EXPENSES:										
Cost of product sales	12,921,157		9,417,505		13,768,658		16,831,261		17,249,450	
Research and development expenses	8,555,381	36 %	8,427,554	47 %	6,377,839	26 %	4,832,537	17%	5,834,249	20%
Selling, general and administrative expenses	9,021,439	38 %	7,595,559	43 %	7,663,035	32 %	7,531,739	27%	5,461,083	18%
	30,497,977		25,440,618		27,809,532		29,195,537		28,544,782	
INCOME (LOSS) FROM OPERATIONS	(6,482,550)		(7,571,777)		(3,554,047)		(1,550,253)		1,004,827	
OTHER INCOME (EXPENSES):	22,485		25,548		(3,238)		132		12,943	
INCOME (LOSS) BEFORE INCOME TAXES	(6,460,065)	(27)%	(7,546,229)	(42)%	(3,557,285)	(15)%	(1,550,121)	(6)%	1,017,770	3 %
Income tax provision (benefit)	(88,305)		5,800,818		(1,160,243)		(412,918)		486,952	
	$(6,371,760)		$(13,347,047)		$(2,397,042)		$(1,137,203)		$530,818	

NET INCOME (LOSS)					
Basic income (loss) per share	$(0.52)	$(1.26)	$(0.25)	$(0.12)	$0.06
Diluted income (loss) per share	$(0.52)	$(1.26)	$(0.25)	$(0.12)	$0.06
Weighted average number of shares outstanding, basic	12,300,031	10,622,331	9,626,028	9,530,320	8,994,080
Weighted average number of shares outstanding, diluted	12,300,031	10,622,331	9,626,028	9,530,320	9,519,968
Balance Sheet Data:					
Working capital [4]	$7,757,340	$14,707,876	$9,479,968	$12,372,169	$14,221,011
Total assets	16,616,021	20,575,236	20,816,344	25,010,192	24,486,592
Total liabilities	3,536,825	3,405,650	3,154,838	5,286,030	4,309,490
Shareholders' equity	13,079,196	17,169,586	17,661,506	19,724,162	20,177,102

(1) On January 9, 2017, we completed the acquisition of RVR Diagnostics Sdn Bhd, a Malaysia manufacturer and distributor of rapid medical assays, which subsequently changed its name to Chembio Diagnostic Malaysia Sdn Bhd. Accordingly, the acquisition impacts comparability to the results in prior years.

(2) Percentage shown reflects the percentage of Total Revenues.

(3) In 2016, we completed an underwritten public equity offering and issued 2.3 million common shares that raised approximately $12.5 million, net of underwriting commissions and other expenses.

(4) Working capital is calculated as total current assets minus total current liabilities.

Table of Contents

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

The following management's discussion and analysis of financial condition and results of operations ("MD&A") is intended to help you understand the business operations and financial condition of the Company for the three-year period ended December 31, 2017. This discussion should be read in conjunction with Item 8. Financial Statements and Supplementary Data. Our MD&A 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

Our Business

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

Business Strategy

Recent accomplishments and highlights:

Achieved total revenue of $24.0 million for full year 2017, an increase of 34% over prior year
Achieved product sales of $19.3 million for full year 2017, an increase of 41% over prior year
Received purchase commitment from Bio-Manguinhos related to DPP® HIV Assays and DPP® Leishmania Assays in Brazil, with a total value of $8.5 million in 2018
Received conditional award from UNICEF to purchase DPP® Zika System, for a total value of $1.5 million to $4.9 million, in 2018-2019
Submitted PMA Application to the FDA for the DPP® HIV-Syphilis Assay and DPP® Micro Reader following completion of U.S. clinical trials
Entered collaboration with AstraZeneca to develop a quantitative DPP® Assay to detect an undisclosed biomarker, from which Chembio will receive up to $2.9 million in R&D funding over 18 months
Won three-year tender from the Ethiopian Pharmaceuticals Fund and Supply Agency to deliver HIV STAT-PAK® Assay, with a total contract value of $15.8 million between 2018-2020

In addition, in February 2018, we strengthened our balance sheet with net proceeds of $11.0 million in capital from an underwritten public offering, which is more fully discussed under "Recent Developments".

Our product commercialization and product development efforts are focused in three areas: sexually transmitted disease, tropical & fever disease, and technology collaborations. In sexually transmitted disease, we are commercializing tests for HIV and Syphilis. In tropical and fever disease, we are commercializing a test for Zika virus, dengue virus, and chikungunya virus, and developing tests for malaria, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi, individually or as part of a fever panel test. Through technology collaborations, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for an undisclosed biomarker, 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 POC 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

2017 compared to 2016

The results of operations for the years ended December 31, 2017 and 2016 were as follows:

	December 31, 2017		December 31, 2016	
TOTAL REVENUES	$24,015,427	100%	$17,868,841	100%
COSTS AND EXPENSES:				
Cost of product sales	12,921,157	54 %	9,417,505	53 %
Research and development expenses	8,555,381	36 %	8,427,554	47 %
Selling, general and administrative expenses	9,021,439	38 %	7,595,559	43 %
	30,497,977		25,440,618	
LOSS FROM OPERATIONS	(6,482,550)		(7,571,777)	
OTHER INCOME	22,485		25,548	
LOSS BEFORE INCOME TAXES	(6,460,065)	(27)%	(7,546,229)	(42)%
Income tax (benefit) provision	(88,305)		5,800,818	
NET LOSS	$(6,371,760)		$(13,347,047)	

Percentages in the table reflect the percent of total revenues.

Table of Contents

Total Net Revenues

Total net revenues during the year ended December 31, 2017 were $24.0 million, an increase of $6.1 million, or 34% compared to 2016. The increase in total net revenues was comprised of the following:
$5.6 million, or 41.2% increase in net product sales, reflecting gains in every region of the world except North America, which in 2016 benefited on a one-time basis from a former U.S. distributor's "end-of-contract purchase" of certain products following our notice of termination of that distribution agreement. The last of those products reached their normal expiration date in February 2018, and the Company has been building its own distribution channels consistent with our commercial strategy. As part of these regional successes and as highlighted above, during 2017, the Company re-secured its DPP® HIV Assay and DPP® Leishmania Assay sales to Brazil and established both a commercial and lower cost manufacturing footprint with its acquisition of RVR Diagnostics Sdn Bhd (now Chembio Diagnostics Malaysia Sdn Bhd). Refer to Note 2 – Acquisition to the audited consolidated financial statements included herein for further information regarding the acquisition.
$0.5 million, or 12.0% increase in R&D milestone and grant, and license and royalty revenues compared to 2016, reflecting the Company’s continued success in securing governmental, non-governmental, and commercial partnerships, in particular associated with our DPP® technology platform.

Gross Product Margin

Cost of 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 increased by $2.1 million, or 50.2% compared to 2016. The following schedule calculates gross product margin:

	For the years ended December 31, 2017	December 31, 2016	Favorable/ (unfavorable)	% Change
Net product sales	$19,322,302	$ 13,680,107	$5,642,195	41.2 %
Less: Cost of product sales	(12,921,157)	(9,417,505)	(3,503,652)	37.2 %
Gross product margin	$6,401,145	$ 4,262,602	$2,138,543	50.2 %
Gross product margin %	33.13 %	31.16 %		

The $2.1 million increase in gross product margin was comprised of the following:
$1.7 million from favorable product sales volume as described above, and
$0.4 million from favorable product margins, principally related to favorable overhead application.

Research and Development

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

	For the years ended December 31, 2017	December 31, 2016	Favorable/ (unfavorable)	% Change
Clinical & regulatory affairs	$2,298,206	$ 1,444,410	$ (853,796)	(59.1 %)
Other research & development	6,257,175	6,983,144	725,969	10.4 %
Total Research and Development	$8,555,381	$ 8,427,554	$ (127,827)	(1.5 %)

The increase in clinical & regulatory affairs costs for the year ended December 31, 2017 as compared to 2016 is primarily associated with the Company's U.S. clinical trial evaluating its DPP® HIV-Syphilis System, which it completed in December 2017, as discussed above. The decrease in other research & development costs is primarily associated with a reduction in spending on materials & supplies associated with R&D milestone and grant revenue-related projects.

Selling, General and Administrative Expense

Selling, general and administrative expense ("SG&A") includes administrative expenses, sales and marketing costs including commissions, and other corporate items.

The $1.4 million, or 18.8%, increase in SG&A for the year ended December 31, 2017 as compared to 2016 is primarily associated with increases in the following: $0.7 million compensation, travel, entertainment, and trade show costs associated with the growth in our sales and commercial team, $0.4 million intangible asset amortization related to the acquisition of RVR Diagnostics in January 2017, and $0.3 million corporate regulatory costs.

Other Income and Expense

Other income and expenses are principally interest income earned on the Company's deposits, which decreased by approximately $3,000 for the year ended December 31, 2017 as compared to 2016.

Income Tax Provision

For the year ended December 31, 2017 the Company recognized a tax benefit of $88,000 associated with anticipated refunds of accumulated alternative minimum tax (AMT) credits to be received between 2019 and 2021 pursuant to recently enacted tax legislation net of state tax provisions. Accordingly, the benefit had no cash impact in 2017. In 2016, the Company recorded a non-cash income tax provision and decreased its deferred tax assets by $5.8 million as the Company took a full valuation allowance against its carryforward losses.

Table of Contents

2016 versus 2015

The results of operations for the years ended December 31, 2016 and 2015 were as follows:

	December 31, 2016		December 31, 2015	
TOTAL REVENUES	$17,868,841	100%	$24,255,485	100%
COSTS AND EXPENSES:				
Cost of product sales	9,417,505	53%	13,768,658	57%
Research and development expenses	8,427,554	47%	6,377,839	26%
Selling, general and administrative expenses	7,595,559	43%	7,663,035	32%
	25,440,618		27,809,532	
LOSS FROM OPERATIONS	(7,571,777)		(3,554,047)	
OTHER INCOME	25,548		(3,238)	
LOSS BEFORE INCOME TAXES	(7,546,229)	(42%)	(3,557,285)	(15%)
Income tax provision (benefit)	5,800,818		(1,160,243)	
NET LOSS	$(13,347,047)		$(2,397,042)	

Percentages in the table reflect the percent of total revenues.

Total Net Revenues

Total net revenues during the year ended December 31, 2016 were $17.9 million, a decrease of $6.4 million, or 26.3% compared to 2015. The decrease in total net revenues was comprised of the following:

$8.2 million, or 37.5% decrease in net product sales compared to 2015, reflecting decreased sales in Brazil and Mexico, partially offset by increased sales in the U.S., which in 2016 benefited on a one-time basis from a former U.S. distributor's "end-of-contract purchase" of certain products following our termination of that distribution agreement.

$1.8 million, or 76.8% increase in R&D milestone and grant revenues compared to 2015, reflecting the Company’s continued success in securing governmental, non-governmental, and commercial partnerships, in particular associated with our DPP® technology platform.

Gross Product Margin

Cost of 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 fell by $3.9 million, or 47.5% compared to 2015. The following schedule calculates gross product margin:

For the years ended December 31, 2016	December 31, 2015	Favorable/ (unfavorable)	% Change

Net product sales	$13,680,107	$ 21,886,688	$(8,206,581)	(37.5)%
Less: Cost of product sales	(9,417,505)	(13,768,658)	4,351,153	(31.6)%
Gross product margin	$4,262,602	$ 8,118,030	$(3,855,428)	(47.5)%
Gross product margin %	31.16%	37.09%		

The $3.9 million decrease in gross product margin was comprised of the following:
$3.0 million from unfavorable product sales volume as described above, and
$0.9 million from unfavorable product margins, reflecting the increased absorption of overhead at lower unit volumes.

Research and Development

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

	For the years ended December 31, 2016	December 31, 2015	Favorable/ (unfavorable)	% Change
Clinical & regulatory affairs	$1,444,410	$ 982,366	$(462,044)	(47.0)%
Other research development	6,983,144	5,395,473	(1,587,671)	(29.4)%
Total Research and Development	$8,427,554	$ 6,377,839	$(2,049,715)	(32.1)%

Expenses for Clinical & Regulatory Affairs increased by $0.5 million for the year ended December 31, 2016, as compared to 2015, primarily related to an increase in clinical trial expenses and additional wages and related costs.

Other R&D expenses increased by $1.6 million in the year ended December 31, 2016, as compared to 2015. The increase is primarily related to an increase in wages, benefits, materials, and supplies to support the growth in sponsored research and internal development programs.

Table of Contents

Selling, General and Administrative Expense

Selling, general and administrative expense ("SG&A") includes administrative expenses, sales and marketing costs including commissions, and other corporate items.

The $0.1 million decrease in SG&A for the year ended December 31, 2016 as compared to 2015 reflects reduced commissions (principally for lower sales in Brazil) and other selling costs related to the lower 2016 sales volume, somewhat offset by increases in wages and travel costs associated with the growth in our sales and commercial team.

Other Income and Expense

Other income and expenses are principally interest income earned on the Company's deposits, which increased by approximately $29,000 for the year ended December 31, 2016 as compared to 2015, reflecting interest on funds raised in the 2016 public offering.

Income Tax Provision

For the year ended December 31, 2016, the Company recognized a $5.8 million non-cash income tax provision and decreased its deferred tax assets by a corresponding amount, together with a full valuation allowance. By comparison, for the year ended December 31, 2015, the Company recognized a $1.2 million non-cash income tax benefit and increased its deferred tax assets by a corresponding amount.

Liquidity and Capital Resources

Overview

Our liquidity requirements are primarily to fund our business operations, including capital expenditures and working capital requirements, as well as to fund opportunistic investments that align with our focused business strategy. Our primary sources of liquidity are cash flows from operations, our existing cash balance, and as necessary, additional capital. We will continually explore ways to enhance our capital structure.

Acquisition

On January 9, 2017, Chembio acquired 100% of the equity interests of RVR Diagnostics Sdn Bhd, a Malaysia manufacturer and distributor of rapid medical assays, for $1.4 million in cash and for common shares with a value at closing of approximately $1.7 million. As further described in Note 2 – Acquisition to the audited consolidated financial statements contained herein, the acquisition was accounted for as a business combination, with the operating results of RVR Diagnostics included within the Company's operating results from the date of acquisition. The Company financed the cash portion of the acquisition with funds raised in its 2016 public equity offering. After the acquisition, RVR Diagnostics Sdn Bhd changed its name to Chembio Diagnostics Malaysian Sdn Bhd.

Government, Non-Governmental Organization, and Non-Profit Programs

Chembio commonly seeks research and development programs that may be awarded by government, non-governmental organization ("NGO"), and non-profit entities including private foundations. Chembio currently has or has recently undertaken development programs that are competitively awarded from agencies of the U.S. Federal Government including the U.S. Department of Health and Human Services and U.S. Department of Agriculture, as well as from FIND, the Bill & Melinda Gates Foundation, and The Paul G. Allen Family Foundation.

Contractual Commitments

The following table summarizes the Company's expected cash outflows resulting from financial contracts and commitments as of December 31, 2017, with amounts denominated in foreign currencies translated using foreign currency rates as of December 31, 2017.

	Payments due by period				
	Total	Less than one year	1 - 3 years	3-5 years	Thereafter
Operating leases[1]	$1,058,000	$603,000	$455,000	$-	$ -
Employment contracts[2]	1,341,000	770,000	571,000	-	-
Purchase obligations[3]	548,000	548,000	-	-	-
Minimum commitments under contracts[4]	239,000	56,000	112,000	51,000	20,000
Total	$3,186,000	$1,977,000	$1,138,000	$51,000	$ 20,000

[1]Represents payments required under our operating leases.
[2]Represents salary payments payable under the terms of employment agreements with certain executives with terms that extend beyond December 31, 2018.
[3]Represents payments required by non-cancellable purchase orders related to capital expenditures.
[4]Represents payments required pursuant to certain licensing agreements. Such agreements are cancellable within a specified number of days following notice by the Company.

Table of Contents

Cash Flows

As of December 31, 2017, we had cash and equivalents of $3.8 million and no outstanding debt except for a $0.1 million seller-financed note payable associated with automated manufacturing equipment.

	For the years ended December 31, 2017	December 31, 2016	Favorable/ (unfavorable)	% Change
Net cash used in operating activities	$(5,034,515)	$ (6,704,734)	$1,670,219	24.9 %
Net cash used in investing activities	(1,876,954)	(668,706)	(1,208,248)	(180.7)%
Net cash provided by financing activities	134,280	12,550,973	(12,416,693)	(98.9)%
Effect of exhange rate changes on cash	13,027	-	13,027	100.0 %
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$(6,764,162)	$ 5,177,533	$(11,941,695)	(230.6)%

The Company's cash as of December 31, 2017 decreased by $6.8 million vs. December 31, 2016, primarily due to net cash used in operating and investing activities.

Cash used in operating activities in 2017 was $5.1 million, primarily due to the net loss adjusted for non-cash items of $4.9 million and a $1.1 million increase in inventory, offset by a $1.3 million reduction in accounts receivable related to favorable collections.

Cash used in investing activities during 2017 related to the acquisition of RVR Diagnostics and the purchase of manufacturing equipment and other fixed assets.

During 2016, the Company completed an underwritten registered public offering, whereas no such offering occurred during 2017. Please see the “Recent Developments” section, below, for further information regarding the Company’s February 2018 underwritten registered public offering.

Off-Balance Sheet Arrangements

The Company does 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, as amended.

Recent Developments

As described in Note 16 – Subsequent Event to the audited consolidated financial statements included herein, on February 13, 2018, the Company consummated an underwritten registered public offering of 1,783,760 shares of its common stock at a public offering price of $6.75 per share for gross proceeds of approximately $12.0 million. The net proceeds, after underwriting discounts and commissions, and estimated expenses, are approximately $11.0 million.

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 of America, 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 ASC 605. Revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, we recognize revenue from R&D, 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 the milestone method of revenue recognition 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 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 the options, 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 & 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.

Table of Contents

Inventories

Inventories are stated at the lower of cost or market, using the first-in, first-out method (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 $44,000.

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 2% of accounts receivable. For example, each additional 1% of accounts receivable that becomes uncollectible would reduce such balance of accounts receivable by approximately $21,000.

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, such as our acquisition agreements for RVR Diagnostics. 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. The

Company performs 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, but not limited to, macroeconomic conditions, industry and market conditions, financial performance of the Company, reporting unit specific events and changes in the Company's 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.

We review indefinite-lived intangible assets for impairment annually or more frequently if events or changes in circumstances indicate the assets might be impaired. Similar to the goodwill assessment described above, the Company first performs a qualitative assessment of whether it is more likely than not that an indefinite-lived intangible asset is impaired. If necessary, the Company then performs a quantitative impairment test by comparing the estimated fair of the asset, based upon its forecasted cash flows, to its carrying value. Other intangible assets with definite lives are amortized over their useful lives and are subject to impairment testing only if events or circumstances indicate that the asset might be impaired, as described above.

Income Taxes

Income taxes are accounted for under ASC 740 authoritative guidance (“Guidance”), 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 Company believes that it likely will not be able to utilize its net operating loss carryforwards and maintains a full valuation allowance. The Company maintains a full valuation allowance on research and development tax credits.

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.

Table of Contents

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, 2017 are described.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.

The Company does not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, has no material derivative risk to report under this Item. As of December 31, 2017, the Company did not have any foreign currency exchange contracts nor purchase currency options to hedge local currency cash flows.

We are exposed to market risks from changes in currency exchange rates and certain commodity prices. All sales from our U.S. subsidiary, regardless of the customer location, are denominated in U.S. dollars. Sales denominated in foreign currencies are associated with a portion of the sales from our subsidiary Chembio Diagnostics Malaysia and comprised approximately 6.1% of our total net revenues for the year ended December 31, 2017.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and schedules that constitute Item 8 are attached at the end of this Annual Report on Form 10-K. An index to these Financial Statements and schedules is also included on page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures. Under the supervision and with the participation of our senior management, consisting of our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), as of the end of the period covered by this report (the "Evaluation Date"). Based on that evaluation, the Company’s management, including our chief executive officer and chief financial officer, concluded that as of the Evaluation Date our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting. The Company's management is responsible for establishing and maintaining an adequate system of internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)). Our internal control over financial reporting is a process, under the supervision of our chief executive officer and chief financial officer, 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 in the United States. These internal controls over financial reporting processes include policies and procedures that:

a. Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
b. 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
c. 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. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

Table of Contents

Management’s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). The Company has designed its internal control over financial reporting to provide reasonable assurance on the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles.

The Company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) 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 (iii) 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 can only provide reasonable assurance and 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.

Under the supervision and with the participation of our management, including the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO), we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017, based on the framework and criteria in the 2013 Internal Control – Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management’s evaluation and those criteria, the CEO and CFO concluded that its system of internal control over financial reporting was effective as of December 31, 2017.

BDO USA, LLP, the Company's independent registered public accounting firm that audited the Company's consolidated financial statements included in this report, has issued an attestation report on the effectiveness of the Company's internal control over financial reporting, a copy of which appears on the following page.

Table of Contents

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, 2017, 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, 2017, 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, 2017 and 2016, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and schedule and our report dated March 8, 2018 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

New York, NY
March 8, 2018

Table of Contents

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the Company's last fiscal quarter of the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

Table of Contents

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.

Table of Contents

PART IV
ITEM 15.

EXHIBITS INDEX

Number	Description
3.1	Articles of Incorporation, as amended. (1)
3.2	Bylaws and Bylaw Amendments. (2)
3.3	Certificate of Designation of Series D Preferred Stock (13)
4.1	2008 Stock Incentive Plan, as amended. (3)
4.2	Form of Option, for 2008 Stock Incentive Plan (4)
4.3	2014 Stock Incentive Plan (5)
4.4	Form of Option, for 2014 Stock Incentive Plan (6)
4.5	Rights Agreement, dated as of March 8, 2016 (7)
4.6	Form of Warrant under Rights Agreement (to be filed by amendment)
10.1*	Employment Agreement dated effective as of March 13, 2017 with John J. Sperzel III (15)
10.2*	Employment Agreement dated March 5, 2016 with Javan Esfandiari (8)
10.3*	Employment Agreement effective May 22, 2017 with Sharon Klugewicz (16)
10.4*	Employment Agreement dated December 18, 2017 with Neil Goldman
10.5*	Employment Agreement dated January 9, 2017 with Magentiren Vajuram (15)
10.6*	Employment Agreement dated January 9, 2017 with Avijit Roy (15)
10.7	HIV Barrel License, Marketing and Distribution Agreement, dated as of September 29, 2006, by and among the Registrant, Alere and StatSure. (10)
10.8	HIV Cassette License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.9	Non-Exclusive License, Marketing and Distribution Agreement, dated as of September 29, 2006, between the Registrant and Alere. (10)
10.10	Joint HIV Barrel Product Commercialization Agreement, dated as of September 29, 2006, between the Registrant and StatSure. (10)
10.11	2015 Omnibus Agreement (11)
10.12	Amended And Restated Stock Purchase Agreement, dated as of December 7, 2016, by and among Chembio Diagnostics, Inc., RVR Diagnostics Sdn Bhd, Avijit Roy and Magentiren Vajuram (14)
10.13	Underwriting Agreement, dated February 9, 2018, by and between the Registrant and Craig-Hallum Capital Group LLC (17)
14.1	Ethics Policy (12)
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

Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on July 29, 2010.

2 Incorporated by reference to the Registrant's registration statement on Form SB-2 (File No. 333-85787) filed with the Commission on August 23, 1999 and the Registrant's Forms 8-K filed on May 14, 2004, December 20, 2007 and April 18, 2008.

3 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on August 3, 2012.

4 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 8, 2014.

5 Incorporated by reference to the Registrant's definitive proxy statement on Schedule 14A filed with the Commission on April 29, 2014.

6 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on August 7, 2014.

7 Incorporated by reference to the Registrant's registration statement on Form 8-A filed with the Commission on April 7, 2016.

8 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on March 14, 2016.

9 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on June 27, 2017.

10 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on October 5, 2006.

11 Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 5, 2015.

12 Incorporated by reference to the Registrant's Annual Report on Form 10-KSB filed with the Commission on March 30, 2006.

13 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on April 7, 2016.

14 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on January 10, 2017.

15 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on May 9, 2017.

16 Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 8, 2017.

17 Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Commission on February 13, 2018.

(*) An asterisk (*) beside an exhibit number indicates the exhibit contains a management contract, compensatory plan or arrangement which is required to be identified in this report.

ITEM 16. Form 10-K Summary

None.

Table of Contents

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 8, 2017 By /s/ John J. Sperzel
John J. Sperzel III
President, Chief Executive Officer and
Member of the Board

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 Member Of The Board (Principal Executive Officer)	March 8, 2017
/s/ Neil A. Goldman Neil A. Goldman	Executive Vice President & Chief Financial Officer (Principal Financial & Accounting Officer)	March 8, 2017
/s/ Katherine L. Davis Katherine L. Davis	Director & Chair of the Board	March 8, 2017
/s/ Peter T. Kissinger Peter T. Kissinger	Director	March 8, 2017
/s/ Gail S. Page Gail S. Page	Director	March 8, 2017

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

—INDEX—

Table of Contents

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, 2017 and 2016, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and schedule (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, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017, 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, 2017, 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 8, 2018 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.

New York, NY
March 8, 2018

F-1

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
AS OF

- ASSETS -

	December 31, 2017	December 31, 2016
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,790,302	$ 10,554,464
Accounts receivable, net of allowance for doubtful accounts of $42,000 and $52,000 at December 31, 2017 and 2016, respectively	2,085,340	3,383,729
Inventories, net	4,423,618	3,335,188
Prepaid expenses and other current assets	554,383	840,145
TOTAL CURRENT ASSETS	10,853,643	18,113,526
FIXED ASSETS, net of accumulated depreciation	1,909,232	1,709,321
OTHER ASSETS:		
Intangible assets, net	1,597,377	-
Goodwill	1,666,610	-
Deposits and other assets	589,159	752,389
TOTAL ASSETS	$ 16,616,021	$ 20,575,236
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 3,046,303	$ 3,013,133
Deferred revenue	50,000	392,517
TOTAL CURRENT LIABILITIES	3,096,303	3,405,650
OTHER LIABILITIES:		
Note payable	99,480	-
Deferred tax liability	341,042	-
TOTAL LIABILITIES	3,536,825	3,405,650
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, 12,318,570 and 12,026,847 shares issued and outstanding at December 31, 2017 and 2016, respectively	123,185	120,268
Additional paid-in capital	62,821,288	60,721,783
Accumulated deficit	(50,044,225)	(43,672,465)
Accumulated other comprehensive income	178,948	-
TOTAL STOCKHOLDERS' EQUITY	13,079,196	17,169,586

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 16,616,021	$ 20,575,236

See accompanying notes to consolidated financial statements

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended December 31, 2017	December 31, 2016	December 31, 2015
REVENUES:			
Net product sales	$19,322,302	$ 13,680,107	$ 21,886,688
License and royalty revenue	741,534	449,685	52,753
R&D, milestone and grant revenue	3,951,591	3,739,049	2,316,044
TOTAL REVENUES	24,015,427	17,868,841	24,255,485
COSTS AND EXPENSES:			
Cost of product sales	12,921,157	9,417,505	13,768,658
Research and development expenses	8,555,381	8,427,554	6,377,839
Selling, general and administrative expenses	9,021,439	7,595,559	7,663,035
	30,497,977	25,440,618	27,809,532
LOSS FROM OPERATIONS	(6,482,550)	(7,571,777)	(3,554,047)
OTHER INCOME (EXPENSE):			
Other expense	-	-	(4,814)
Interest income	25,430	25,548	2,412
Interest expense	(2,945)	-	(836)
	22,485	25,548	(3,238)
LOSS BEFORE INCOME TAXES (BENEFIT)	(6,460,065)	(7,546,229)	(3,557,285)
Income tax provision (benefit)	(88,305)	5,800,818	(1,160,243)
NET LOSS	$(6,371,760)	$ (13,347,047)	$ (2,397,042)
Basic loss per share	$$ (0.52)	$ (1.26)	$ (0.25)
Diluted loss per share	$$ (0.52)	$ (1.26)	$ (0.25)
Weighted average number of shares outstanding, basic	12,300,031	10,622,331	9,626,028
Weighted average number of shares outstanding, diluted	12,300,031	10,622,331	9,626,028

See accompanying notes to consolidated financial statements
F-3

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the years ended December 31, 2017	December 31, 2016	December 31, 2015
Net loss	$(6,371,760)	$ (13,347,047)	$ (2,397,042)
Other comprehensive income:			
Foreign currency translation adjustments	178,948	-	-
COMPREHENSIVE LOSS	$(6,192,812)	$ (13,347,047)	$ (2,397,042)

See accompanying notes to consolidated financial statements

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2017, 2016 AND 2015

	Common Stock		Additional Paid-in-Capital	Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2014	9,611,139	$96,112	$47,556,426	$(27,928,376)	$-	$19,724,162
Options:						
Exercised	17,109	170	(170)	-	-	-
Stock option compensation	-	-	334,386	-	-	334,386
Net loss				(2,397,042)	-	(2,397,042)
Balance at December 31, 2015	9,628,248	$96,282	$47,890,642	$(30,325,418)	$-	$17,661,506
Common Stock:						
New stock from offering	2,300,000	23,000	12,470,398	-	-	12,493,398
Options:						
Exercised	98,599	986	56,589	-	-	57,575
Stock option compensation	-	-	304,154	-	-	304,154
Net loss	-	-	-	(13,347,047)	-	(13,347,047)
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

See accompanying notes to consolidated financial statements
F-5

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED

	December 31, 2017	December 31, 2016	December 31, 2015
CASH FLOWS FROM OPERATING ACTIVITIES:			
Cash received from customers and grants	$ 24,971,299	$ 16,947,194	$ 30,174,083
Cash paid to suppliers and employees	(30,028,299)	(23,677,476)	(28,382,681)
Interest received	22,485	25,548	2,412
Interest paid	-	-	(836)
Net cash (used in) provided by operating activities	(5,034,515)	(6,704,734)	1,792,978
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of license	-	-	(550,000)
Purchase of RVR Diagnostics Sdn Bhd	(850,000)	(550,000)	-
Acquisition of and deposits on fixed assets	(1,026,954)	(118,706)	(480,585)
Net cash used in investing activities	(1,876,954)	(668,706)	(1,030,585)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from option and warrant exercises	34,800	57,575	-
Proceeds from note payable	99,480	-	-
Proceeds from credit line	-	-	700,000
Repayment of credit line	-	-	(700,000)
Proceeds from sale of common stock, net	-	12,493,398	-
Net cash provided by financing activities	134,280	12,550,973	-
Effect of exchange rate changes on cash	13,027	-	-
(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(6,764,162)	5,177,533	762,393
Cash and cash equivalents - beginning of the period	10,554,464	5,376,931	4,614,538
Cash and cash equivalents - end of the period	$ 3,790,302	$ 10,554,464	$ 5,376,931
RECONCILIATION OF NET LOSS TO NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES:			
Net Loss	$ (6,371,760)	$ (13,347,047)	$ (2,397,042)
Adjustments:			
Depreciation and amortization	1,276,963	1,139,228	1,372,563
Provision for (benefit from) deferred taxes	-	5,800,818	(1,170,969)
Fair value adjustment to contingent consideration	(148,000)	-	-
Share based compensation	384,897	304,154	334,386
Changes in assets and liabilities:			
Accounts receivable	1,298,389	(960,758)	5,915,918
Inventories	(1,088,430)	242,837	60,274

Prepaid expenses and other current assets	285,762	(136,258)	(190,960)
Deposits and other assets	(512,272)	1,480	-
Accounts payable and accrued liabilities	182,453	211,701	(2,144,598)
Deferred revenue	(342,517)	39,111	13,406
Net cash (used in) provided by operating activities	$ (5,034,515)	$ (6,704,734)	$ 1,792,978
Supplemental disclosures for non-cash investing and financing activities:			
Deposits on manufacturing equipment transferred to fixed assets	$ 174,399	$ -	$ 20,017
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

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiaries (collectively, the “Company” or “Chembio”), develop, manufacture, and commercialize point-of-care (POC) diagnostic tests that are used to detect or monitor diseases. 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. POC tests, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POC tests can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

Our product commercialization and product development efforts are focused in three areas: sexually transmitted disease, tropical & fever disease, and technology collaborations. In sexually transmitted disease, we are commercializing tests for HIV and Syphilis. In tropical and fever disease, we are commercializing a test for 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, we are developing tests for a specific form of cancer, concussion, bovine tuberculosis, and for an undisclosed biomarker, 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, POC 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.

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

NOTE 2 — ACQUISITION:

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 (approximate 10 year weighted average)	800,000
Customer contracts / relationships (approximate 10 year weighted average)	700,000
Order backlog (3 months)	200,134
Trade names (approximate 11 year weighted average)	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.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

The following represents unaudited pro forma operating results for the year ended December 31, 2016 as if the operations of CDM had been included in the Company's Condensed Consolidated Statements of Operations as of January 1, 2016:

	Pro Forma
Total revenues	$19,151,653
Net loss	$(13,473,084)
Net loss per common share	$(1.26)
Diluted net loss per common share	$(1.26)

The pro forma financial information includes business combination accounting effects from the acquisition including amortization charges from acquired intangible assets of approximately $398,000. 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 2016. CDM's net revenues and pre-tax loss for the year ended December 31, 2017 were approximately $1,465,000 and ($406,000), respectively.

NOTE 3 — SIGNIFICANT ACCOUNTING POLICIES:

(a) Principles of Consolidation:

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries (Chembio Diagnostic Systems, Inc. and Chembio Diagnostics Malaysia Sdn Bhd). All significant intercompany transactions and balances are eliminated in consolidation.

(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. 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.

(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 or net realizable value. Cost is determined on the first-in, first-out method.

(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, 2017 and 2016, total prepaids were $100,000 and $237,500, respectively.

Amortization expenses for the licenses above for the years ended December 31, 2017, 2016 and 2015 were $137,500 $319,319, and $442,557, respectively.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

(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, 2017 and 2016.

(j) Revenue Recognition:

The Company recognizes revenue for product sales in accordance with ASC 605, whereby revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred, or services have been rendered, the sales price is fixed and determinable, and collectability is reasonably assured. Revenue typically is recognized at time of shipment. Sales are recorded net of discounts, rebates and returns.

For certain contracts, the Company recognizes revenue from non-milestone contracts and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned.

The Company follows the recognition of revenue under the milestone method for certain collaborative research projects defining milestones at the inception of the agreement.

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 $0.8 million for the year ended December 31, 2017, as R&D, milestone and grant revenue in our 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 $2.2 million and $2.7 million for the year ended December 31, 2017 and from inception through December 31, 2017, respectively, as R&D, milestone and grant revenue in our 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 $0.4 million and $0.7 million for the year ended December 31, 2017 and from inception through December 31, 2017, respectively, as R&D, milestone and grant revenue in our Consolidated Statements of Operations.

(k) Research and Development:

Research and development (R&D) costs are expensed as incurred.

(l) Stock-Based Compensation:

Stock-based compensation expense is calculated using the Black-Scholes valuation model based on awards ultimately expected to vest, reduced for 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. Diluted loss per share for the year ended December 31, 2017, 2016 and 2015 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 810,670, 600,549 and 658,631 options outstanding as of December 31, 2017, 2016 and 2015, 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 we paid over the fair value of the net tangible and identifiable intangible assets acquired in our acquisition of 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 we believe that indicators of impairment exist. We make a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If we conclude that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then we 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, 2017, the results of our goodwill impairment analysis did not result in any impairment.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

Following is a table that reflects changes in Goodwill:

Beginning balance 1/1/17	$-
Acquisition of CDM	1,651,361
Changes in foreign currency exchange rate	15,249
Balance at December 31, 2017	$1,666,610

In addition, the Company recorded certain intangible assets as part of the CDM acquisition which are as follows as of December 31, 2017:

	Cost	Accumulated Amortization	Net Book Value
Intellectual property	$886,872	$ 88,687	$ 798,185
Customer contracts/relationships	776,013	77,601	698,412
Order backlog	221,867	221,867	-
Trade names	110,859	10,079	100,780
	$1,995,611	$ 398,234	$ 1,597,377

Amortization expense for the year ended December 31, 2017 was $398,234.

(p) Foreign Currency Translation:

Assets and liabilities of non-U.S. 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 non-U.S. subsidiaries are translated to U.S. dollars at average period currency exchange rates. The effect of translation for non-U.S subsidiaries is generally reported in Other comprehensive income.

(q) 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, 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.

Except for expanded disclosures to be included in our first interim financial statements for the fiscal year end 2018, we have completed our evaluation of the new standard and assessed the impact of adoption on our consolidated financial statements. We reviewed significant open contracts with customers for each revenue stream, and based on our evaluation, revenue recognition under the new standard will 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, milestone and grant revenue do not generally constitute exchange transactions and therefore the new standard does not apply. The Company has also assessed its control framework as a result of adopting the new standard and notes minimal, insignificant changes to its systems and other controls processes.

The new standard permits two adoption methods under ASU 2014-09. The guidance may 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, we applied the rules to all contracts existing as of January 1, 2018. We estimated the cumulative effect recorded to the opening balance of retained earnings to be immaterial.

The disclosures in our notes to the consolidated financial statements related to revenue recognition will be expanded under the new standard, specifically around the quantitative and qualitative information about performance obligations, changes in contract assets and liabilities, and disaggregation of revenue. The Company expects to make these enhanced disclosures in its interim financial statements for the first quarter of 2018.

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 will be effective for Chembio beginning in 2018, with early adoption permitted. The Company does not believe this new accounting standard update will have a material impact on its consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, which amends the ASC and creates Topic 842, Leases. Topic 842 will require lessees to recognize lease assets and lease liabilities for those leases classified as operating leases under previous US GAAP on the balance sheet. This guidance is effective for annual periods beginning after December 15, 2018 and early adoption is permitted. We are in the initial stages of evaluating the effect of the standard on our financial statements and will continue to evaluate. While not yet in a position to assess the full impact of the application of the new standard, the Company expects that the impact of recording the lease liabilities and the corresponding right-to-use assets will have a significant impact on its total assets and liabilities with a minimal impact on equity.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

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 our 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 our 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 our 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 and is effective for annual reporting periods beginning after December 15, 2017. The guidance in ASU 2016-15 is generally consistent with our current cash flow classifications, and we do not expect the adoption of this standard will have a material impact on our 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 our 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. This update will be effective for annual periods and interim periods in fiscal years beginning after December 15, 2017 with early adoption permitted. We do not expect the adoption will have a material effect on our consolidated financial statements.

NOTE 4 — INVENTORIES:

Inventories consist of the following at:

	December 31, 2017	December 31, 2016
Raw materials	$ 1,767,684	$ 1,824,248
Work in process	286,413	535,320
Finished goods	2,369,521	975,620
	$ 4,423,618	$ 3,335,188

NOTE 5 — FIXED ASSETS:

Fixed assets consist of the following at:

	December 31, 2017	December 31, 2016
Machinery and equipment	$ 4,582,759	$ 3,962,051
Furniture and fixtures	449,548	437,962
Computer and telephone equipment	422,946	343,167
Leasehold improvements	2,258,779	2,012,945
	7,714,032	6,756,125
Less accumulated depreciation and amortization	(5,804,800)	(5,046,804)
	$ 1,909,232	$ 1,709,321

There were no capital leases at the end of December 31, 2017. Fixed assets at December 31, 2017 also include $538,406 in equipment, that is undergoing validation and as such is not yet being depreciated. Depreciation expense for the 2017, 2016 and 2015 years aggregated $727,563, $782,711 and $893,305, respectively.

As of December 31, 2017 and 2016, the Company had paid deposits on various pieces of equipment classified within Deposits and Other Assets aggregating $257,455 and $31,900, respectively.

NOTE 6 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at:

	December 31, 2017	December 31, 2016
Accounts payable – suppliers	$ 1,494,759	$ 1,437,290
Accrued commissions	126,827	221,982
Accrued royalties / license fees	429,297	352,660
Accrued payroll	187,305	167,575
Accrued vacation	309,767	289,587
Accrued bonuses	282,500	282,500
Accrued expenses - other	215,848	261,539
Total	$ 3,046,303	$ 3,013,133

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

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, 2017 and 2016, there were $50,000 and $392,517 unearned advanced revenues, respectively.

NOTE 8 — INCOME TAXES:

The (benefit from) provision for income taxes for the years ended December 31, 2017, 2016, and 2015 is comprised of the following:

	2017	2016	2015
Current			
Federal	$(97,339)	$-	$-
State	9,034	-	10,726
Total current (benefit) provision	(88,305)	-	10,726
Deferred			
Federal	-	5,778,185	(1,171,865)
State	-	22,633	896
Total deferred (benefit) provision	-	5,800,818	(1,170,969)
Total (benefit) provision	$(88,305)	$5,800,818	$(1,160,243)

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 Tax Act also puts in place new tax laws that will apply prospectively, which include, but are not limited to, (1) implementing a base erosion and anti-abuse tax, (2) generally eliminating U.S.federal income taxes on dividends from foreign subsidiaries, (3) a new provision designed to tax currently in the U.S. global intangible low-taxed income (“GILTI”) of foreign subsidiaries, which allows for the possibility of utilizing foreign tax credits to offset the income tax liability (subject to some limitations), and (4) a lower effective U.S. tax rate on certain revenues from sources outside the U.S.

The Company calculated its best estimate of the impact of the Act in accordance with its understanding of the Act and guidance available as of the date of this filing and recorded a $97,339 tax benefit in the period in which the legislation was enacted, related to a credit for alternative minimum taxes (AMT) paid in prior periods. A provisional amount related the remeasurement of certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future resulted in a charge of $3,906,774, which was fully offset by an equivalent adjustment to the deferred tax valuation allowance. No provisional amount related to the one-time transition tax on the mandatory

deemed repatriation of foreign earnings was deemed necessary.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US 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 Act. In accordance with SAB 118, the Company has determined that the $97,339 benefit recorded which relates to the AMT credit is a provisional amount and a reasonable estimate of December 31, 2017.

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 2020 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 2020 through 2026.

After applying the above limitations, at December 31, 2017, the Company has post-change net operating loss carry-forwards of approximately $26,660,530 which expire between 2018 and 2037. In addition the Company has research and development tax credit carryforwards of approximately $1,461,351 for the year ended December 31, 2017, which expire between 2025 and 2037.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

As referenced in Note 2 - Acquisition, the Company acquired the stock of RVR Diagnostics Sdn Bhd, a Malaysia corporation, during the current year. RVR is on tax holiday through December 31, 2018. Accordingly, no taxes nor (benefit) have been provided on RVR results.

	2017	2016
Inventory reserves	$244,158	$253,380
Accrued expenses	102,332	53,140
Net operating loss carry-forwards	5,800,144	7,487,937
Research and development credit	1,918,137	1,461,351
Other credits	-	97,339
Other	167,522	292,556
Depreciation	91,258	31,285
Deferred tax assets	8,323,551	9,676,988
Intangibles	(341,042)	-
Deferred tax liabilities	(341,042)	-
Net deferred tax assets before valuation allowance	7,982,509	9,676,988
Less valuation allowances	(8,323,551)	(9,676,988)
Net noncurrent deferred tax liabilities	$(341,042)	$-

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

	Year Ending December 31,		
	2017	2016	2015
United States operations	$(6,054,002)	$(7,546,229)	$(3,557,285)
International operations	(406,063)	-	-
(Loss) before taxes	$(6,460,065)	$(7,546,229)	$(3,557,285)

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

	Year Ending December 31,		
	2017	2016	2015
Federal income tax at statutory rates	(34.00)%	(34.00)%	(34.00)%
State income taxes, net of federal benefit	0.09 %	0.21 %	0.23 %
Nondeductible expenses	1.04 %	0.57 %	1.38 %
Foreign rate differential	2.14 %	-	-
Change in valuation allowance	99.41 %	114.81%	9.46 %
Impact of Tax Act on valuation allowance	(60.48)%	-	-
AMT refund under Tax Act	(1.51)%	-	-
Tax credits	(7.07)%	0.00 %	(9.46)%
Other	(0.99)%	0.04 %	0.34 %
Income tax (benefit)	(1.37)%	81.63 %	(32.05)%

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2017, the Company does not have a liability for uncertain tax positions.

The Company files Federal and state income tax returns. Tax years for fiscal 2014 through 2016 are open and potentially subject to examination by the federal and state taxing authorities.

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) Common Stock

In August of 2016, the Company closed on an underwritten public offering of 2,300,000 shares of its common stock at $6.00 per share. The net proceeds of the offering, after deducting the underwriters' discounts and other offering expenses payable by the Company, was approximately $12,493,000.

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.

During 2016, options to purchase 191,804 shares of the Company's common stock were exercised for 98,599 shares of common stock at exercise prices ranging from $2.80 to $5.56 by paying cash or surrendering options already owned.

During 2015, options to purchase 41,141 shares of the Company's common stock were exercised for 17,109 shares of common stock at exercise prices ranging from $2.16 to $3.60 by paying cash or surrendering options already owned

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

(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

The Compensation Committee of the Board of Directors may issues options persuant to employee stock option plans that have been approved by the Company's stockholders.

(d) Warrants

As of December 31, 2017 and 2016, the Company had no warrants outstanding to purchase shares of common stock.

NOTE 10 — RIGHTS AGREEMENT:

In March 2010, the Company entered into a Rights Agreement (the "Rights Agreement") between the Company and Action Stock Transfer Corp., as Rights Agent. The Rights Agreement expired at the end of November 2015. 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, $0.01 par value (the "Common Stock"), of the Company. The Board of Directors set the payment date for the distribution of the Rights as March 8, 2010, and the Rights were distributed to the Company’s shareholders of record on that date. The description and terms of the Rights are set forth in the Rights Agreement.

Rights Initially Not Exercisable. The Rights were not exercisable until a Distribution Date. 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 to be evidenced by the certificates for shares of Common Stock registered in the names of the holders thereof, and not by separate rights certificates until the earlier to occur of (i) the close of business on the tenth business day following a public announcement that an Acquiring Person (as defined in the Rights Agreement) acquired a Combined Ownership (as defined in the Rights Agreement) of 20% or more of the outstanding shares of the Common Stock (the "Shares Acquisition Date") or (ii) the later of (A) the close of business on the tenth business day (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) after the date that a tender or exchange offer or intention to commence a tender or exchange offer by any person is first published, announced, sent or given within the meaning of Rule 14d-4(A) under the Securities Exchange Act of 1934, as amended, the consummation of which would result in any person having Combined Ownership of 20% or more of the outstanding shares of the Common Stock, or (B) if such a tender or exchange offer has been published, announced, sent or given before the date of the Rights Agreement, then the close of business on the tenth business day after the date the Rights Agreement was entered into (or such later date as may be determined by action of the Board of Directors prior to such time as any person becomes an Acquiring Person); (the earlier of such dates referred to in (i) and (ii), which date may include any such date that is after the date of the Rights Agreement but prior to the issuance of the Rights, being called the "Distribution Date").

NOTE 11 — EMPLOYEE STOCK OPTION PLAN:

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), with 750,000 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, the Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted. Awards can be stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of December 31, 2017, there were 480,172 options exercised, 228,177 options outstanding and 41,651 options still 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 Compensation Committee of the Company's Board has the discretion to select the persons to whom awards are to be granted. Awards can be stock options, restricted stock and/or restricted stock units. The awards become vested at such times and under such conditions as determined by the Compensation Committee. As of December 31, 2017, there were 22,000 options exercised, 375,625 options outstanding and 402,375 options still available to be issued under the SIP14.

The Company's results for the years ended December 31, 2017, 2016 and 2015 include stock-based compensation expense totaling $384,897, $304,100, and $334,400 respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of goods sold ($47,000, $-, and $- respectively), research and development ($89,400, $89,200, and $62,700 respectively) and selling, general and administrative expenses ($248,497, $214,900, and $271,700 respectively).

Stock option compensation expense in the years ended December 31, 2017, 2016 and 2015 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, 2017 and 2016 were $2.77 and $2.75 per share, respectively. The Company did not grant any stock options during the year ended December 31, 2015. 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 our 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, 2017		December 31, 2016		December 31, 2015
Expected term (in years)	5.48		4.71		n/a
Expected volatility	43.31	%	45.78	%	n/a
Expected dividend yield	n/a		n/a		n/a
Risk-free interest rate	1.78	%	0.92	%	n/a

The Company granted 267,875 new options during the year ended December 31, 2017 to employees.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

The following table provides stock options activity for the years ended December 31, 2017, 2016, and 2015:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2014	691,869	3.66	3.97 years	$ 334,636
Granted	-	-		
Exercised	41,141	2.25		65,449
Forfeited/expired/cancelled	1,250	4.30		
Outstanding at December 31, 2015	649,478	3.75	3.21 years	$ 1,032,362
Exercisable at December 31, 2015	359,228	3.89	2.03 years	$ 522,039
Outstanding at December 31, 2015	649,478	3.75	3.21 years	$ 1,032,362
Granted	142,875	7.08		
Exercised	191,804	3.73		629,143
Forfeited/expired/cancelled	-	-		
Outstanding at December 31, 2016	600,549	4.55	3.43 years	$ 1,463,052
Exercisable at December 31, 2016	267,549	4.14	2.66 years	$ 731,997
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

The following table summarizes information about stock options outstanding at December 31, 2017:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Shares	Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	-	-	$ -	$-	-	$ -	$-
2.8 to 4.59999	362,750	2.68	3.51	1,702,125	244,000	3.55	1,135,255
4.6 to 6.39999	240,045	3.56	5.73	592,678	96,545	5.49	261,585
6.4 to 8.19999	161,000	6.26	7.06	183,050	12,000	7.15	12,600
8.2 to 10	46,875	3.44	8.86	-	18,750	8.86	-

Total	810,670	3.69	$ 5.18	$2,477,853	371,295	$ 4.44	$1,409,440

As of December 31, 2017, there was $735,946 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 2.57 years. The total fair value of shares vested during the year ended December 31, 2017, was $380,465.

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, 2017	December 31, 2016	December 31, 2015
Africa	$3,568,455	$ 2,363,944	$ 3,673,199
Asia	1,626,750	227,564	172,250
Europe	1,763,274	1,131,193	1,164,476
North America	3,887,820	5,082,319	6,525,951
South America	8,476,003	4,875,087	10,350,812
	$19,322,302	$ 13,680,107	$ 21,886,688

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

NOTE 13 — COMMITMENTS AND CONTINGENCIES:

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:

2018	$770,000
2019	485,500
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 $91,150, $96,051 and $90,915 for the years ended December 31, 2017, 2016, and 2015, respectively.

Obligations Under Operating Leases:

The Company leases industrial space used for office, R&D and manufacturing facilities, currently with a monthly rent of $29,773. 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 $16,017. 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 $3,600.

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

2018	$603,335
2019	371,036
2020	84,152
	$1,058,523

Rent expense was $586,730, $516,708 and $511,900 for the years ended December 31, 2017, 2016, and 2015, 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 current assets. The Company had the following major customers for the

respective periods:

	For the years ended						Accounts Receivable	
	December 31, 2017		December 31, 2016		December 31, 2015		December 31, 2017	December 31, 2016
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	$8,065,217	42 %	$4,801,577	35 %	$10,132,512	46 %	$ -	$ 828,848
Customer 2	-	-	1,796,477	13 %	4,526,908	21 %	-	-

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, 2017		December 31, 2016		December 31, 2015		December 31, 2017	December 31, 2016
	Purchases	% of Purc.	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$*	*	$ 652,273	11 %	$ *	*	$ *	$ *
Vendor 2	746,868	12 %	*	*	*	*	*	*
Vendor 3	849,966	14 %	*	*	*	*	*	*
Vendor 4	884,698	14 %	*	*	794,536	11 %	*	*

In the table 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.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

NOTE 14 — QUARTERLY FINANCIAL DATA (UNAUDITED):

The sum of the earnings per common share may not equal the corresponding annual amounts due to interim quarter rounding.

For the Quarters Ended in Fiscal 2017	March 31	June 30	September 30	December 31
Total revenues	$6,325,167	$4,114,814	$7,587,374	$5,988,072
Gross product margin	2,208,212	689,099	2,067,934	1,435,896
Net loss	(1,615,574)	(2,173,093)	(584,661)	(1,998,432)
Basic loss per share	(0.13)	(0.18)	(0.05)	(0.16)
Diluted loss per share	(0.13)	(0.18)	(0.05)	(0.16)

For the Quarters Ended in Fiscal 2016	March 31	June 30	September 30	December 31
Total revenues	$6,601,099	$3,266,405	$3,746,461	$4,254,876
Gross product margin	2,481,468	347,972	707,733	725,428
Net loss	(303,590)	(8,347,482)	(2,138,218)	(2,557,757)
Basic loss per share	(0.03)	(0.86)	(0.19)	(0.21)
Diluted loss per share	(0.03)	(0.86)	(0.19)	(0.21)

NOTE 15 — 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. Thirty days after delivery, the Company will begin making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a twenty-four month period.

NOTE 16 — SUBSEQUENT EVENT:

On February 13, 2018, the Company closed on an underwritten registered public offering of 1,783,760 shares of its common stock at a public offering price of $6.75 per share for gross proceeds of approximately $12.0 million. The net proceeds, after underwriting discounts and commissions, and estimated expenses are approximately $11.0 million. We intend to use the net proceeds for business expansion and working capital, including product development; operational expansion or improvements, such as new automated equipment and a facilities update; clinical trials and other related activities, and sales and marketing.

Table of Contents

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017, 2016, AND 2015

Schedule II
Valuation and Qualifying Accounts

Description	Balance at beginning of period	Additions Charged to statement of income	Charged to other accounts	Deductions	Balance at end of period
Year ended December 31, 2017:					
Allowance for doubtful accounts	$ 52,000	$ -	$ -	$ 10,000	$ 42,000
Inventory Reserve	$ 245,000	$ 119,920	$ -	$ 170,137	$ 194,783
Year ended December 31, 2016:					
Allowance for doubtful accounts	$ 52,000	$ -	$ -	$ -	$ 52,000
Inventory Reserve	$ 218,000	$ 221,478	$ -	$ 194,478	$ 245,000
Year ended December 31, 2015:					
Allowance for doubtful accounts	$ 52,000	$ -	$ -	$ -	$ 52,000
Inventory Reserve	$ 218,000	$ 256,302	$ -	$ 256,302	$ 218,000