CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 06, 2014
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, 2013

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
None	None

Securities registered pursuant to section 12(g) of the Act:
Common Stock, $0.01 par value
(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ]	Smaller reporting company [X]
(Do not check if a smaller reporting company)	

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 $38,000,000.

As of March 4, 2014, the registrant had 9,324,783 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.

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PART I

ITEM 1. BUSINESS
FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words "intends," "estimates," "predicts," "potential," "continues," "anticipates," "plans," "expects," "believes," "should," "could," "may," "will" or the negative of these terms or other comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our research and development activities, distributor channels, market demand for our products, compliance with regulatory impositions; and our capital needs. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

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

The Company (Chembio Diagnostics, Inc. and its wholly-owned subsidiary, Chembio Diagnostic Systems, Inc., are collectively referred to herein as the "Company") develops, manufactures, markets and licenses rapid point-of-care diagnostic tests (POCTs) that detect infectious diseases. The Company's main products presently commercially available are four rapid tests for the detection of HIV 1/2 antibodies, two rapid tests for the detection of syphilis antibodies, and a multiplex rapid test for the detection of HIV and Syphilis antibodies. Three of the HIV 1/2 rapid tests employ in-licensed and proprietary lateral flow technologies (see "Our Rapid Test Technologies"), can be used with all blood matrices as samples, and are manufactured in a standard cassette format, a dipstick format, and a proprietary barrel format. The tests employing the cassette and proprietary barrel formats were approved by the FDA in 2006 and are exclusively distributed by Alere, Inc. ("Alere") in the United States and by Chembio outside the United States. As discussed below (see Partners Involved in Marketing Our Products), we are considering changes to our exclusive agreements with Alere based on Alere's introduction of a competitive product, which introduction has triggered provisions in those agreements, permitting us to make certain changes. Our fourth HIV 1/2 rapid antibody detection test incorporates our patented Dual Path Platform® (DPP®) POCT technology, and this POCT platform does not require in-licensing. The DPP® HIV 1/2 Assay detects antibodies to HIV 1 & 2 in oral fluid samples as well as in all blood matrices. We have sold this product in Brazil since 2009 where it was approved by ANVISA, through our agreement with the Oswaldo Cruz Foundation ("FIOCRUZ"), and we received United States FDA regulatory approval for this product on December 19, 2012. We anticipate launching it in the United States under Chembio's brand in 2014.

Our product pipeline, which currently includes a multiplex rapid test for earlier detection of HIV by detecting P-24 antigen as well as antibodies, a test for Hepatitis-C, and a multiplex test that detects HIV and Syphilis specific

antibodies (which we are already selling internationally), is based on this DPP® technology for which we were issued a United States patent in 2007 and for which additional patent protection has issued or is pending in a number of other countries. With the patented DPP® and the lateral flow platform, we participate in the estimated $8-10 billion point-of-care market segment of the estimated nearly $50 billion global in-vitro diagnostic market that has an overall growth rate exceeding 5% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient outcomes. POCTs can also prevent needless hospital admissions, simplify testing procedures, avoid delays from central lab batching, and eliminate the need for return visits.

In the areas of infectious and sexually transmitted diseases (such as HIV and syphilis), the utility of a rapid point–of-care test, particularly in identifying patients unaware of their disease status, has been well established. Large and growing markets have been established for these kinds of tests, initially in high prevalence regions where they are indispensable for large scale prevention and treatment programs. More recently introduced in the United States in 2004, rapid HIV tests now also present a significant segment of the U.S. market for HIV clinical testing, which is still dominated by laboratory tests. We have focused our product development activity within areas where the availability of rapid, point-of-care screening, diagnostic, or confirmatory results can improve health outcomes. More generally we believe there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

PRODUCTS

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV antibody detection tests are qualitative "yes/no" tests for the detection of antibodies to HIV 1 & 2 with visually interpreted results (one line "negative"; two lines "positive") available within approximately 15 minutes. The tests are simple to use, have a shelf life of 24 months, and do not require refrigeration. The tests differ principally only in the method of test procedure, convenience and cost. One of our FDA-approved lateral flow HIV tests incorporates a proprietary plastic "barrel" device that houses the lateral flow strip. This barrel format enables collection of samples directly (usually from a finger-stick whole blood sample) into the barrel's capillary tip. A sealed unitized buffer vial, assembled onto the top of the barrel, is removed and seated into a stand; the seal is then pierced by the barrel's capillary tip, thereby initiating the upward flow of the resulting sample-buffer solution through a filter, up into the vertical device's chamber and onto the lateral flow strip. This results in a unique unitized and closed device system that can reduce the chance of exposure to potentially infectious samples. Our other FDA-approved lateral flow HIV test uses a more conventional rectangular plastic cassette format that houses the lateral flow strip. In this case, a sample is transferred by use of a separately provided transfer device ("loop") into a sample well or port of the cassette that houses the lateral flow strip, which is positioned horizontally or flat.

Both of the above-described products are marketed exclusively in the United States by Alere (see Partners Involved in Marketing Our Products) as Clearview® Complete HIV 1/2 (the barrel format as governed by the Barrel Agreement) and Clearview® HIV 1/2 STAT PAK® (the cassette format as governed by the Cassette Agreement), and in all other markets by Chembio under the names Chembio SURE CHECK® HIV 1/2 and Chembio HIV 1/2 STAT PAK®. Alere has non-exclusive rights to the barrel product outside the United States. In addition to the above-referenced agreements for Alere to market our products, Alere also licensed their lateral flow technology patents to Chembio for our international rapid HIV test sales and certain other Chembio lateral flow product sales. Also this license would extend to sales by Chembio of the cassette and barrel products in the United States should we decide to exercise certain rights now exercisable by us based on Alere's notice to us of their having a Permitted Competing Product (see Partners Involved in Marketing Our Products).

Our third lateral flow HIV test, the HIV 1/2 STAT PAK® Dipstick, is our most cost competitive and compact format. It does not have any plastic housing so that 30 test strips can be packaged into a small vial that is ideal for transporting into remote settings. The test procedure is similar to the cassette format except that a user-applied adhesive backing is provided as a more cost-effective and compact "surface" on which to run the test.

Regulatory Status of the lateral flow HIV tests

The FDA approved our Pre-Market Applications (hereinafter "PMA"; see "Governmental Regulations" and Glossary) in April 2006 for our SURE CHECK HIV 1/2 (and also now Alere Clearview® Complete HIV 1/2) and for our HIV 1/2 STAT-PAK® (now Alere' Clearview® HIV 1/2 STAT-PAK® in the United States only) products. Waivers under the Clinical Laboratory Improvement Act (hereinafter "CLIA"; see Governmental Regulations) were granted by the FDA for these two FDA-approved products in 2006 and 2007, respectively. A CLIA waiver is required in order for

health care providers to administer these tests in the settings where they are most suited and needed, such as public health testing clinics, hospital emergency rooms and physicians' offices. The SURE CHECK® product received a CE Mark in July 2013 and the CE Markings for the HIV 1/2 STAT-PAK® (as well as the DPP® HIV 1/2 Assay described below) are expected in 2014. Our HIV 1/2 STAT-PAK® Dipstick, although not FDA-approved, qualifies under FDA export regulations [See Government Regulation] to sell to customers outside the United States, subject to any required approval by the importing country. CE Mark has not been pursued for this product.

All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). Both the cassette and dipstick versions of the STAT-PAK® are also qualified by the World Health Organization (WHO) for procurements by the second largest global program, known as the Global Fund, as well as other related programs funded by agencies affiliated with the United Nations, such as UNICEF and UNITAIDS (see Glossary), through qualification with the WHO bulk procurement scheme.

DPP® HIV 1/2 Assay

As in the case of our lateral flow HIV tests, our DPP® HIV 1/2 Assay is also a qualitative "yes/no" test for the detection of antibodies to HIV 1& 2, delivers visual results within as little as 15 minutes, is simple to use, has a shelf life of 24 months, and does not require refrigeration. This product, which is our first FDA-approved product incorporating our patented DPP® technology, can be used with oral fluid samples, as well as with all blood matrices. This product also incorporates our patent-pending oral fluid collection and storage system that enables samples to be fully extracted in buffer solution before application to the test device, and also enables the extracted sample to be stored and retested or potentially tested for multiple conditions in future product applications. Clinical and laboratory studies demonstrated the ability of the test to accurately detect the presence of antibodies in individuals down to two years of age. Studies have also shown this product to have improved performance compared with all of the current FDA-approved CLIA-waived lateral flow rapid tests, even including our own lateral flow tests. FDA-approved label claims include sensitivity/specificity on oral fluid and finger-stick whole blood of 98.9%/99.9% and 99.9%/100% respectively. Oral fluid sensitivity was 100% among HIV-positive patients not taking anti-retroviral medication: Due to the low HIV prevalence in the U.S., clinical trials are performed on known HIV-positive patients, and more and more of these individuals are on more highly active anti-retroviral treatments (known as "HAART") for much longer periods than when we and our competitors Orasure and Trinity performed their clinical trials ten to fifteen years ago. We believe that this fact, combined with our product's superior performance in a direct comparative evaluation that was conducted by the United States CDC Global AIDS Program, together with analytical studies that confirm earlier detection with our DPP® product than our main competitors on well characterized serum samples, all combine to provide us with a significant market opportunity with this product.

Regulatory Status of the DPP® HIV 1/2 Assay

In April 2012 we completed a 3,000 patient clinical study with our DPP® HIV 1/2 Assay in the United States which we had begun in 2010. In June 2012 we submitted the third of three modules required for a modular PMA application to the FDA. On December 19, 2012 we received FDA approval of our Pre-Marketing Approval. During 2013, we completed a 1,000 patient clinical study in order to submit a CLIA waiver application to the FDA, which was submitted at the end of November 2013. In February 2014 we received a letter from the FDA on the current status of review of our CLIA waiver application. The FDA determined that additional information is needed to complete their review of the Company's DPP® HIV 1/2 Assay CLIA waiver application. During the blinded prospective clinical study, a disproportionate number of new infections were found at one clinical site due to the lower than expected prevalence at two other sites. We are currently in discussion with the FDA to finalize the protocol to collect additional data. Upon receiving guidance on our proposed protocol, we anticipate that we will be able to update the timeline of activities for the CLIA waiver of the DPP HIV1/2 Assay.

The DPP® HIV 1/2 Assay product is qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR") for use with all sample matrices, and we are pursuing WHO qualification in order to enable procurement of this product by the Global Fund and United Nations agencies, including programs underwritten by them. We are also pursuing CE Marking, anticipated during 2014, as stated above.

In June 2010, ANVISA approved the DPP® HIV 1/2 Assay that is being marketed in Brazil through our collaboration with the Oswaldo Cruz Foundation, Brazil's leading public health institute (see Oswaldo Cruz Foundation OEM DPP® Agreements).

DPP® HIV-Syphilis Multiplex Test

This product, launched in 2013, allows for the detection of antibodies to both HIV and Syphilis on a single test device within approximately 15 minutes. In certain global/public health settings (see Target Markets) this product may

provide a more convenient and cost effective means of rapid detecting both markers in a single test procedure at the point of care as compared with performing separate rapid tests for each indication. This product takes advantage of the multiplexing feature of DPP® which provides for a more robust reaction between the sample and biomarkers being tested for (HIV and Syphilis antibodies in this case), resulting in a greater ability by the user to visually interpret test results. We launched this product in Mexico in the fourth quarter of 2013 as a unitized product, meaning that each test kit was separately packaged to include each of the other components necessary to run this test, as compared with other configurations where a test kit of 20 or 30 devices is accompanied by one bottle of running buffer. The initial results of this launch have been very positive, and we anticipate good results in Mexico during 2014 from the program. Building on this initial success, we are pursuing commercialization efforts for this product in a number of additional international markets.

Regulatory Status of the DPP® HIV-Syphilis Test

The DPP® HIV-Syphilis multiplex test development was completed in 2013, and commercialization activities commenced in 2013 and are moving well as stated above. Also as mentioned above, a unitized version of this product was approved and launched in Mexico during the fourth quarter of 2013, and the product has been well received. In addition, this product is the first such product to have been approved by the USAID for procurement with U.S. foreign aid program funds (such as PEPFAR). We are pursuing pre-qualification of this product with the World Health Organization (WHO) in order to allow procurement through programs such as the Global Fund. Simultaneously we are pursuing registration of this product in a number of foreign jurisdictions where we believe there is an opportunity for this product.

In 2013, and 2014 year to date, we have made significant efforts on pursuing an FDA submission for this product. However, FDA has advised thus far that performance specifications for this product must be substantially equivalent both in comparison to the traditional algorithm and the "reverse" algorithms that are both now in use in the United States for syphilis testing, as well as meet the requirements for HIV sensitivity and specificity. It is possible to that other pathways to receiving FDA approval may be available by limiting the performance claims and/or the settings in which the tests could be used. We are conducting further studies now, and we are in dialog with the FDA and others, to see whether and how we may be able to meet their requirements without making changes to this product, which would result in further delays.

OTHER DPP® PRODUCTS

Our product pipeline includes a multiplex test that detects P24 HIV antigen as well as HIV 1/2 antibodies, and a rapid test for the detection of Hepatitis-C antibodies. These products are still in a development stage and have not been commercialized in any markets. The Company has a robust research and development department that is involved in a number of ongoing collaborations, some of which are sponsored, with public and private organizations. During 2013 we conduct sponsored research and development activities for two programs sponsored by agencies of the United States government; One is for the development of a 9-band influenza immune status test and the other is for a multiplex febrile illness test that could help identify and differentiate, in remote settings, symptoms that could be attributable to a variety of tropical diseases, including malaria, dengue, and the bubonic plague. We have also continued to conduct research and development activities on a serological test for tuberculosis pursuant to a Phase II SBIRR grant from the National Institutes of Health (NIH). All of these projects are based on our patented DPP® technology.

PARTNERS INVOLVED IN MARKETING OUR PRODUCTS
Alere

On September 29, 2006, we executed marketing and license agreements with Alere. The marketing agreements (the Barrel Agreement and the Cassette Agreement) provide Alere with a 10-year exclusive right (until September 2016) to market our rapid HIV tests in the United States under Alere's brands. The agreements also provide Chembio a non-exclusive license to certain Alere lateral flow patents that may be applicable to our lateral flow products, including for manufacture of the HIV tests in the United States for sales outside the United States and even for sale in the United States should Alere enter the U.S. market with a competitive rapid HIV test product and in such case we choose to market our products directly as provided in the agreements in such event of a competitive rapid HIV test product. Simultaneous with the execution of the agreements, we also settled litigation with StatSure Diagnostics, Inc. (SDS), that had been ongoing relating to the proprietary barrel device which is incorporated into one of our two FDA-approved rapid HIV tests (See Lateral Flow HIV Tests above). SDS, pursuant to the settlement, is a party to the 3-way Barrel Agreement. As a result, until now, it is through the agreements with Alere that we have been participating in the growth of the rapid HIV test market in the United States.

In late July 2013, we received notice from Alere that they intend to commercialize their own rapid HIV test (see Competition), which test had just received FDA approval as a moderate complexity product (i.e. not CLIA-waived though this is being pursued and anticipated during 2014), in the United States. Under the Barrel Agreement and the Cassette Agreement such product is considered to be a Permitted Competing Product (PCP). Each of the two aforementioned agreements provides that, in the case of notice of a PCP, Chembio may make certain elections (jointly with SDS in the case of the Barrel Agreement), or elect to continue each agreement without taking any further action. Under the Cassette Agreement, Chembio may, at any time, terminate such agreement, which termination would become effective 60 days after the date notice was made. Under the Barrel Agreement, Chembio and SDS may jointly issue a non-exclusivity notice, which notice shall be effective immediately. In the event that Chembio (and SDS) makes this election with respect to either (or both) of these products, Chembio could sell that respective (or both) product(s) in the United States market under Chembio/SDS brands and in such case, the lateral flow license that Chembio has from Alere for international sales would be expanded to include sales in the United States, which would require the payment of a royalty to Alere at the time of any sales. See Lateral Flow Technology and Reagent Licenses.

We have appointed distributors internationally for our lateral flow HIV tests. Our largest markets outside the U.S. for our lateral flow HIV rapid tests are certain countries in Africa, Asia, and South America, as well as Mexico. Internationally, most of the demand for our products is based on governmental and non-governmental prevention and treatment efforts. Given this, these programs can and do often result in large orders, but also can result in periods of relatively lower demand, based on the variations associated with this kind of demand.

OEM DPP® Products

Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008-2010 we signed five separate agreements, each of which is titled and constitutes a "Technology Transfer Agreement", with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil. FIOCRUZ includes the Institute of Technology on Immunobiologicals/Bio- Manguinhos, which is the FIOCRUZ unit that produces vaccines and diagnostic kits. FIOCRUZ and Bio-Manguinhos are referred to herein interchangeably. Each of the five agreements relates to a different specific product or group of products based on our DPP® technology. FIOCRUZ is the leading public health organization in Brazil, and it is affiliated with Brazil's Ministry of Health, which is its principal client. It has extensive research, educational and manufacturing facilities for drugs and vaccines, as well as for diagnostic products.

Each of the agreements grants to FIOCRUZ the right, but not the obligation, to earn the right to request a technology transfer to be able to license and manufacture that product on its own. FIOCRUZ is not required to earn this right, but if it desires to do so, then it needs to purchase a stated amount of the product as set forth in the respective agreement for that product.

During 2010 and 2011, all of the initial products contemplated under the five agreements were approved for marketing by the applicable regulatory agencies in Brazil. The agreements between the Company and FIOCRUZ are unique examples of technology transfer collaborations between a private sector rapid test manufacturer and a public health organization. The five products categories for which FIOCRUZ can earn a separate right to request a technology transfer for that product only are: DPP® products for HIV screening, HIV Confirmatory, Leishmaniasis, Leptospirosis and Syphilis. Each technology transfer, and the provision by Chembio of the information and training that is required for this to occur, will occur only if FIOCRUZ purchases from Chembio the amount of that product that is specified in the respective agreement for that product. The actual amount of purchases for each product is totally at the discretion and option of FIOCRUZ and may be more or less than the amount needed to qualify for a technology transfer.

More specifically, the five agreements, although separate and independent of one another, are structurally similar according to the following:

- Each agreement states: "the object of this Agreement is for the Transfer of Technology from Chembio to Bio-Manguinhos, the license by Chembio to Bio-Manguinhos [of] the Chembio Patents applied or granted in Brazil or other Mercosur countries for the term of the patents and the transfer of all the technical information related to the DPP technology and the process to obtain the product by the DPP® technology. This Agreement contemplates the scientific and technological co-operation between Chembio and Bio-Manguinhos for such activities so that Bio-Manguinhos will be able to manufacture the Product in Brazil."
- Each agreement provides that Chembio will supply free of charge to Bio-Manguinhos prototypes of the product to demonstrate performance characteristics that are necessary for evaluation by the Brazilian Ministry of Health and for registration with ANVISA. ANVISA is the Agencia Nacional de Vigliancia Sanitaria, or the National Sanitary Vigilance Agency. The number of prototypes ranges from 15,000 to 45,000 in the various agreements.
- Each agreement provides that the prototypes will be utilized both for a performance study that follows a protocol prepared and approved by Bio-Manguinhos and the Brazilian Ministry of Health, and also will be used for studies in Brazil for the registration procedures at ANVISA. Bio-Manguinhos will then apply to ANVISA to register the product. Within 120 days of the registration of the product with ANVISA, Bio-Manguinhos will make an advance

technology transfer payment to Chembio (the "Advance Payment"), in an amount specified in that particular agreement. All five of the Advance Payments provided for in the agreements were made in 2010 and 2011.

- At such time, if any, that the product for a particular agreement has been successfully registered with ANVISA, then Bio-Manguinhos has the right to qualify for the full technology transfer for that product by purchasing the amount of the product, and at the price, specified in the agreement.
- Bio-Manguinhos is not required to purchase any amount of any product. For each product, it only needs to purchase that product, in the amount specified in the agreement, only if it desires to be able to complete the technology transfer process in order to manufacture and sell that product on its own. Chembio does not have recourse against Bio-Manguinhos if Bio-Manguinhos does not purchase the qualifying purchase amount of any product. In that case, Chembio can only suspend further phases of the technology transfer, attempt to renegotiate the agreement, and/or retain any amounts previously paid by Bio-Manguinhos. Chembio cannot force Bio-Manguinhos to purchase any amount of any product.

- As a result of the terms of these agreements, Bio-Manguinhos has never been required to, and is not now required to, purchase any amount of any of the products.
- As of December 31, 2013 Bio-Manguinhos had earned the status described below with respect to each of the five products:

1. With respect to Chembio's DPP® HIV1/2 Screen test, Bio-Manguinhos had qualified to request the technology transfer. It has requested, and has received, the technology transfer information. Bio-Manguinhos purchased $880,175 of this product in 2011, and $4,990,840 in 2012, all of which applied to the qualifying amount to obtain the right to the technology transfer (the "Qualifying Amount") for this product. In 2013, Bio-Manguinhos made $291,235 of purchases that applied to the Qualifying Amount for this product, and $3,320,010 of purchases in excess of the Qualifying Amount.
2. With respect to Chembio's Canine Leishmania test, Bio-Manguinhos had qualified to request the technology transfer and did so request. Submission of the technology transfer information is in process at this time. Bio-Manguinhos purchased $2,000,817 of this product in 2011 and $99,183 of this product in 2012 that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $1,314,117 in 2012 and $1,736,700 in 2013.
3.
   a. With respect to the three variations of Chembio's DPP® Syphilis test, all of which are covered by a single agreement, Bio-Manguinhos had qualified to request the technology transfer with respect to Trep only, and intends to do so in the near future. Bio-Manguinhos purchased $1,194,250 of this product in 2011 and $165,750 of this product in 2012 that applied to the Qualifying Amount. In addition, Bio-Manguinhos made purchases in excess of the Qualifying Amount equal to $2,817,750 in 2012, and equal to an estimated $646,340 in 2013.
   b. With respect to the two variations of Chembio's Screen & Confirm Test, Bio-Manguinhos had not made any purchases in 2011, 2012, or 2013, and therefore had not qualified to request the technology transfer for either of them. In order to qualify, Bio-Manguinhos would need to purchase an additional $2.2 million of one of these tests, and an additional $2.08 million of the other test.
4. With respect to Chembio's DPP® Confirmatory test, Bio-Manguinhos had not qualified to request the technology transfer. Bio-Manguinhos made purchases of $560,000 of this product in 2011, $819,000 in 2012, and $390,000 in 2013, all of which applied to the Qualifying Amount. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $585,000 of this product.
5. With respect to Chembio's DPP® Leptospirosis test, Bio-Manguinhos had not qualified to request the technology transfer. Bio-Manguinhos made purchases of $135,000 of this product in 2011, and it made -0- purchases in 2012 and $45,000 in 2013. In order to qualify for the technology transfer, Bio-Manguinhos would need to purchase an additional $225,000 of this product.

- As stated above, Bio-Manguinhos is not obligated to make any purchases. After the specified level of sales for a particular product has been achieved, FIOCRUZ may request that the technology for that product be transferred to FIOCRUZ together with an exclusive license to produce and sell that product in a defined territory. The license is to provide that Chembio will receive a royalty on all sales. Chembio does not release the amount of this royalty because it could have an adverse effect on negotiations concerning royalties in potential transactions with other parties.

- All the agreements expire five years after the date of the technology transfer. If terminated earlier by default of FIOCRUZ, FIOCRUZ must stop all activity; if terminated earlier by default of Chembio, or if terminated by natural expiry, FIOCRUZ can continue to produce and commercialize the product without paying royalties."

Other OEM And License Agreements Related to DPP® Technology

In addition to our agreement with FIOCRUZ, we have entered into certain other OEM and License agreements with other parties with respect to certain products that we have developed based on our DPP® technology. In 2008 we entered into a product development and license agreement with Bio-Rad Laboratories, Inc. (Bio-Rad), a leading multinational life sciences company, for the first ever POC test for the confirmation of HIV (reflex test used after

initial screening test(s) are positive). This product utilizes our DPP® technology, capitalizing on its multiplexing advantages, and is much simpler to perform than the legacy confirmatory platform, known as western blot, which requires a substantial amount of technical training and hands-on time and which is more expensive to manufacture and distribute. This product was CE marked and was launched by Bio-Rad in the second quarter of 2013 in Europe under their Geenius® brand; and an FDA submission is underway.

In 2013 we entered into collaboration with Labtest, a private company in Brazil, for the distribution of a number of products in Brazil that would be co-branded with Labtest and Chembio trademarks. Under this agreement, upon request from Labtest, for which there is no requirement, Chembio will sell the appropriate DPP® components to Labtest for further manufacture and assembly in Brazil.

Most recently, in February 2014, Chembio entered into a technology transfer and license agreement with RVR Diagnostics SDN BHD ("RVR"), a privately-held company in Malaysia. The agreement supports Chembio's strategy of establishing a market presence in Asia, in collaboration with RVR as a licensee, distributor, and contract manufacturer. The agreements grant exclusive distribution rights to RVR in certain countries in the region and enable RVR to manufacture Chembio's DPP® HIV 1/2 Assay and DPP® HIV-Syphilis Assay and potentially other products developed by Chembio incorporating its patented DPP® technology.

Our strategy with respect to our DPP® technology has evolved as the Company has evolved. Initially, following the issuance of our DPP® patent in the United States in 2007, our strategy was necessarily limited to developing third-party-funded OEM research and development contracts and grants. This strategy enabled us to conserve capital resources, while at the same time acquiring know-how and experience with the platform and developing third-party references and implicit endorsements of the technology. As our capabilities to develop and manufacture DPP® products expanded, and as our financial position has improved, so have our strategic options expanded and improved. Although we have employed and may continue to employ the strategy of seeking OEM development and manufacturing agreements as a way to participate in markets that we cannot and/or choose not to serve with Chembio-branded products, we believe that we can also develop our own branded line of products, and we plan to do this in the public health area. We plan to launch this brand with our DPP® HIV 1/2 Assay in the United States market in 2014, to be followed by the other products in our pipeline in 2015 and beyond.

Our Rapid Test Technologies

All of our commercially available current products employ either in-licensed lateral flow technology or our own patented Dual Path Platform® (DPP®) technology. Both lateral flow technology and DPP® allow the development of accurate, low cost, easy-to-perform, single-use diagnostic tests for rapid, visual detection of specific antigen-antibody complexes on a test strip. These formats provide a test that is simple (requires neither electricity nor expensive equipment for test execution or reading, nor skilled personnel for test interpretation), rapid (turnaround time approximately 15 minutes), safe (minimizes handling of potentially infected specimens), non-invasive (requires 5-20 micro liters of whole blood easily obtained with a finger prick, or alternatively, serum or plasma,), stable (24 months at room temperature storage in the case of our HIV tests), and highly reproducible.

We believe that products developed using DPP® technology can provide superior diagnostic performance as compared with products that use lateral flow technology. The reason for this is that one of the major differences between the two platforms is that in DPP® samples are allowed to incubate with the target analyte in the test zone before introduction of the labeling reagent/conjugate, whereas in lateral flow, samples are combined with the labeling reagent to form a complex before coming in contact with the target analyte. We believe that this complex can compromise test performance. Also, because of the usage in DPP® of a separately connected sample strip, the control and delivery of sample material is substantially improved. This feature is critical in the development of multiplex tests, as well as tests that involve viscous sample material (such as oral fluid) that can be impeded when forced to combine with labeling reagents before migration on the test strip to the test zone area.

Multiplexing is significantly improved as a result of the design of DPP® and this provides a significant advantage. For example, the HIV confirmatory test we developed for Bio-Rad that is described above employs six different markers related to various epitopes of the HIV antigen. We have a number of other products in development, including those being developed in sponsored development programs, that involve the use of multiple (e.g. eight) test bands. Although all of these products could be visually read, we can also use handheld and desktop readers with our DPP® products to objectively measure, quantify, record and report DPP® test results. Certain of the products we

have and/or are developing incorporate some of these readers, and we are developing other products that may be used with or will require use of a reader. Also, platforms can incorporate labeling reagents that cannot be visually read except by employing a reader, such as fluorescence, though no products are currently utilizing such reagents.

We are pursuing additional capabilities and technologies that will complement our current product portfolio and business strategy. This activity includes pursing development, license or acquisition of diagnostic technologies that complement our existing platforms, proprietary biomarkers that can result in new product applications of our existing platforms, and new platforms that would complement our commercial strategy.

Target Markets

Rapid HIV Tests

A large percentage of individuals that are HIV positive worldwide are unaware of their status. Part of the reason for this is that even those that do get tested in public health settings will often not return or call back for their test results when samples have to be sent out to a laboratory which can take up to several days to process. The increased availability, greater efficacy and reduced costs for anti-retroviral treatments (ARVs) for HIV has increased the demand for testing, as the stigma associated with the disease is lessened, and the ability to resume normal activities is substantially improved, providing a positive message to those potentially infected. The impact that rapid HIV testing has had on prevention efforts has in turn increased the demand for testing, particularly by public health programs worldwide, which have also become more effective in reducing the number of annual new infections in many, but by no means, all high prevalence regions.

Despite less attention to HIV by the media as compared with prior years, there are still approximately 50,000 new diagnoses of HIV infection in the United States each year, according to the CDC. CDC estimates that approximately 1.2 million individuals in the U.S. are living with HIV, with an estimated 250,000 of these U.S. individuals, or more than 20%, unaware that they are infected. It is transmissions from these 250,000 infected people that are reported to account for 54% of all new infections per year. Part of the reason for this is that even those individuals that do get tested in public health settings will often not return or call back for their test results if their blood samples have to be sent out to and tested in a laboratory and then reported back, a process which can take up to several days to complete. Making more people aware of their HIV status at the point-of-care reduces the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into an estimated 7.5 million test market at an average price of $10, or a total of $75 million. Public health programs, currently funded by grants distributed to states by the CDC, account for an estimated 45% of the market, with hospitals (40%) and doctor's offices (15%) comprising the other estimated market segments. Chembio's lateral flow rapid HIV tests, the cassette and barrel, together represent approximately a 25% share of this market. Orasure Technologies, Inc., which was the first FDA-approved rapid HIV test, has lost nearly half its market share, now estimated to be approximately 55%. Trinity Biotech has an estimated 15% market share and Biolytical Laboratories, Medmira and Bio-Rad share the remaining 5%.

We believe that the US professional HIV rapid test market has the potential to increase to 15-18 million tests over the next several years, which would represent 40-50% of all HIV tests done today in the United States for clinical purposes. Assuming an average price to the manufacturers of $8.00 per test, a total potential U.S. market of nearly $120-$145 million is implied.

In 2006, the outlook for HIV testing was given a big boost with the release by the CDC of new recommendations for HIV testing. These new CDC recommendations were/are that an HIV test should be given as a routine test like any other for all patients between 13 and 64 years of age, regardless of risk, with an opt-out screening option and focused testing procedural (pre- and post-test counseling) guidelines. Though not mandatory, gradual adoption in whole or in part of the 2006 CDC recommendations by a number of states continues to have an increasing impact. Finally, in 2013, the United States Preventive Services Task Force ("USPSTF") fully embraced these CDC routine HIV testing recommendations. This USPSTF recommendation, which was given an A grade under their recommendation grading system based on the benefits of this practice and the nearly 600,000 AIDS-related deaths in the United States, requires insurance coverage under the Affordable Care Act (the "ACA") as a preventive screening test without any co-payment required. We expect this to result in an increase in HIV testing in the United States in the coming years, which we believe will include point-of-care HIV testing utilizing the Company's products. Although as stated above currently most public health testing in the United States is funded by grants allocated to high prevalence areas by the CDC, we believe this will shift to an insurance-funded model under the ACA in the years to come, increasing the

amount of testing done in doctor's offices and community health centers.

In the international market, we sell our products directly and through distributors to large screening programs overseen by ministries of health and NGOs, most but not all of which are funded by large bi-lateral and multi-lateral AIDS relief programs, the largest of which is the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Established by President George Bush as a 5-year $15 billion program in 2003, PEPFAR was reauthorized in 2008 and again in 2013. In 2012 PEPFAR directly supported HIV testing and counseling for more than 11 million pregnant women, and testing and counseling for more than 49 million people overall. The U.S. is also the first and largest donor to the Global Fund to Fight AIDS, Tuberculosis and Malaria. To date, the U.S. has provided more than $7 billion to the Fund.

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, the new law doesn't authorize a specific dollar amount for funding. Nevertheless it is widely anticipated that PEPFAR will continue to enjoy strong funding; the FY14 budget has $6 billion for global HIV/AIDS assistance, including $4 billion for PEPFAR.

Chembio, with its four U.S.-manufactured rapid HIV tests, three of which are FDA-approved, is recognized as a reputable and dependable supplier of high quality products that are available at reasonably competitive prices. As a result, certain of our products have been selected in the testing protocols in countries (national algorithms) that are large beneficiaries of PEPFAR and the Global Fund. As mentioned above, these programs can and do often result in large orders, but also can result in periods of relatively lower demand, based on the variations associated with this kind of demand. Also, even though the United States taxpayer is funding the largest share of global AIDS relief, U.S. companies do not receive any preference for these procurements, and therefore must compete with foreign suppliers that manufacture competitive products with lower costs, including those related to quality, regulatory, intellectual property, and costs of manufacturing.

Oral fluid testing is an established alternative to blood testing for diagnostic tests, including HIV tests. It is also often patient preferred, providing a more comfortable, less invasive test. In certain public health clinics, staffs choose not to handle blood specimens; thus, oral sample collection provides a viable alternative. The most well-established market for oral fluid HIV testing is the United States. Given the premium price required for an oral fluid test as compared with blood tests, the higher volume programs will not specify an oral fluid test. However, segments of these programs may want to have an oral fluid testing option, and certain programs that have greater resources may also choose to incorporate oral fluid testing into the testing protocol.

There is also now an over-the-counter market for HIV self-testing in the United States. Orasure Technologies Inc. received FDA approval for an over-the-counter (self-testing) version of its previously professional-market-approved (test performed on an individual by a health care professional) HIV test. The FDA approval was granted in July 2012, and Orasure has been investing heavily in developing this market. Initial results after over a year of marketing are well below expectations. The costs for such over-the-counter approval, including primarily the associated clinical trials, are estimated to be at least $5 million and they may take two to three years to complete, not to mention the cost of distribution. Orasure's initial results are not convincing of a large market, although this possibility remains. In any case, Orasure is likely to spend heavily on this for some time, and if it appears that there is an attractive market, we believe we are very well positioned versus any other competitors.

Rapid Syphilis Tests

Recent data indicate that approximately 70,000-100,000 new cases of syphilis are occurring annually in the U.S. Syphilis can be treated with antibiotics, but if untreated, it can cause pelvic inflammatory disease, infertility, ectopic pregnancy and can infect newborns. Treatment cannot be provided without a confirmed diagnosis of an active case of syphilis. Current testing algorithms in the United States require two different laboratory tests (called non-treponemal and treponemal), as neither test alone has the required specificity to rule out certain other conditions (i.e., other infection or past infection), but in combination they can provide reasonably reliable results. However each requires trained personnel in laboratory settings and can take several days to receive results, in order to confirm an active, previously untreated case.

Development of the POC market for syphilis testing is expected to be comparable to the development of the POC market for HIV testing, as there is a significant public health value to being able to provide results at the point-of-care. There are several ways to assess the market opportunity for this unique rapid test, although we believe the U.S. rapid test market opportunity may exceed 8 million tests, which is approximately 20% of the total number of syphilis tests performed in the United States for clinical use today.

Rapid HIV-Syphilis Test

There are significant risks relating to transmission of Syphilis from a pregnant mother to child, just as there are for transmission of HIV. Therefore we believe there is a significant opportunity to improve prevention efforts in pregnant mother to child transmission testing programs (PMTCT) that are currently not doing any or nearly enough testing for syphilis even though they are testing for HIV. In the United States, we believe there is also a significant need for this product in some of the highest HIV prevalence populations, such as among men that have sex with men (MSM), as data show high degrees of HIV and Syphilis co-infection in this segment of the population.

Marketing Strategy

Our marketing strategy is to:

- Depending on our decision based on Alere's introduction of a PCP:
  - If we remain status quo: Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Alere in the U.S., as well as our distributors worldwide, and to engage in sales and marketing activities that allow us to engage with our target markets and customers. Alere, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint and product portfolio since we signed our agreement with them, and although we believe that this will enhance opportunities for Alere to market our rapid HIV tests, our product line is a very small one for them, notwithstanding the strong growth they have enjoyed with respect to our products. In this case we would not have to bear the expense of establishing our own sales and marketing organization and we would continue to share a substantial portion of the net sales proceeds of the products with Alere as we have been. However, since Alere now has their own product to sell, they are likely to have a greater financial incentive to sell that product depending upon the market acceptance of that product and other factors. Therefore this could have a material and adverse effect on the sales Alere makes of our products.
  - If we decide to make certain elections available to us now such as to assume direct sales by Chembio under Chembio brands of the lateral flow products that we developed and that we manufacture but have been and continue to be marketed by Alere under their brands, then we will need to establish a commercial organization that is capable of assuming the distribution of these products. In this case Chembio would not have to share any portion of the net sales proceeds with Alere, except for the 8.5% lateral flow royalties applicable to the sales of the products, which royalty is only applicable until February 2015 at which time the applicable lateral flow patent of Alere's expires. This will immediately result in higher gross margins than if we continue with the status quo . However this decision will involve our incurring expenditures related to hiring sales representatives, establishing agreements and associated discounts with distributors, incurring advertising and marketing expenditures, warehousing, customer service and technical support. If Alere's new product is indeed successful, our ability to retain a significant share of the market that has been established for our products may be enhanced by our having control of the marketing of our products, rather than having Alere sell our products. We have been developing contingency plans so that we can activate this strategy in a timely manner, including the possibility of ultimately utilizing the same sales force that we would use for U.S. Sales of DPP® HIV 1/2 Assay.
- Leverage our DPP® intellectual property and product development and manufacturing experience to continue creating new collaborations where Chembio can be the exclusive development and manufacturing partner supporting leading marketing organizations.
- Establish strong distribution relationships for our Chembio-branded products in the U.S and abroad, and establish a direct sales and marketing organization that is focused in the public health market segment, and that utilizes distributors for other market segments, primarily the acute care market which, together with public health, are the main market segments for rapid HIV tests in the United States. We believe that creation of a Chembio public health brand and marketing organization is fundamental to the creation of shareholder value over the long term.

During 2013 we increased our commercial activities and efforts in Africa and Europe for our HIV tests by establishing a sales representative in each of these markets. We believe the sales representative in Africa will enable us to be more closely engaged with opportunities to participate in the national testing algorithms that are established and revised from time to time by countries that are beneficiaries of PEPFAR, Global Fund and/or other bilateral or multilateral donor funding. In Europe, where there are a larger percentage of HIV positive people unaware of their status than in the United States, we believe that there is an emerging public health outreach opportunity, and there are relatively few strong competitors that are CE marked. Most recently we have established new sales and marketing positions in the Company to support our efforts to increase brand awareness globally and to lead our direct sales effort in the U.S. market.

Competition

The diagnostics industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing and marketing resources.

Industry competition in general is based on the following:

- Scientific and technological capability;
- Proprietary know-how;
- The ability to develop and market products and processes;

- The ability to obtain FDA or other required regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements, (i.e. FDA's Quality System Regulations) (see Governmental Regulation section);
- The ability to manufacture products cost-effectively;
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

We believe our scientific and technological capabilities and our proprietary know-how relating to our in-licensed lateral flow technology rapid tests and to our proprietary know-how related to our patented dual path platform® technology, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases such as HIV, are very strong.

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 in lateral flow technology and in our Dual Path Platform® (DPP®) technology has been instrumental in our obtaining the collaborations we have and that we continue to pursue. We believe that the patent protection that we have with our Dual Path Platform® (DPP®) enhances our ability to develop more profitable collaborative relationships and to license out the technology. However there are a number of competitive technologies used and/or seeking to be used in point-of-care settings. These technologies may be based on immunoassay principles such as the Company's products or other technologies such as molecular-based technologies.

We plan to introduce our FDA-approved DPP® oral fluid HIV test, which test also can be used with blood samples, in the U.S. market under a Chembio brand. Until it is CLIA-waived, this product will serve a very small market segment. Orasure Technologies manufactures the only other oral fluid HIV test that is FDA-approved, and Orasure has enjoyed this position for approximately 10 years. Orasure has lost a significant share of this market as certain customers have been indifferent to using blood or oral fluid samples, because the blood tests, including those made by Chembio and marketed by Alere, are priced lower and/or are as or more accurate than the performance of Orasure's product on blood samples. Orasure has primarily retained those customers for whom the oral fluid sample feature is a strong preference, and this is an estimated $35 million business for Orasure. Although we believe we can capture a meaningful portion of this Orasure market share, we also anticipate that Orasure will defend this business aggressively.

In 2006 Alere acquired a division from Abbott Diagnostic located in Japan that manufactured and marketed a rapid HIV test product line called Determine®. The Determine® format is was developed for 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 that, 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 is an advantage for the developing world markets it has served. 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 at 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. Since the P24 antigen is known to occur in HIV-positive individuals' blood samples before antibodies do, based on its performance claims, the 4th generation Determine® test is therefore able 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 "4thgeneration" tests, but they are of course neither rapid nor point-of-care.

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. However the 4th generation product that is now FDA-approved was apparently modified as compared to the initial international version of it, and it may perform more satisfactorily. Alere received FDA approval of this modified product in August 2013 and Alere is seeking CLIA-waiver for it. Alere is also aggressively pursuing development of the market for this product in anticipation of receiving CLIA waiver. Although the product can now be sold to moderate complexity certified laboratories, there is very limited supply of the product thus far, and there is no assessment thus far concerning the actual performance of this product in the hands of customers. We believe the price that Alere is charging for this product is substantially higher than our and our competitors' antibody tests, as the antigen claim avails some customers of an additional reimbursement code. Moreover there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and if Alere is able to successfully launch this product, it 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 technology used in the INSTI test, flow-through, is older than lateral flow, and it 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.

Although we have no specific knowledge of any other competitors' products that are a 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 the products developed by our competitors, which could result in a loss of revenues and cash flow.

Research and Development

During 2013 and 2012, $5.8 million and $4.5 million, respectively, were spent on research and development (including regulatory activities). These expenses were in part underwritten by funding from R&D and milestones revenues of $2.0 million in 2013 and $1.3 million in 2012. All of our new product development activities involve employment of our Dual Path Platform® (DPP®) technology. These activities include completing development of certain products and making significant progress toward the development of additional products.

Employees

At December 31, 2013, we employed 206 people. We have entered into employment contracts with our President, Lawrence Siebert, our Chief Operating Officer Sharon Klugewicz and our Senior Vice President of Research and Development, Javan Esfandiari. Due to the specific knowledge and experience of these executives regarding the industry, technology and market, the loss of the services of either one of them would likely have a material adverse effect on the Company. The contract with Ms. Klugewicz, has a term of two years ending May 2015. The contract with Mr. Esfandiari has a term of three years ending March 2016. We have obtained a key man insurance policy for Mr. Esfandiari. The contract with Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company through May 11, 2014, and Mr. Siebert has advised the Company that he intends to retire from the Company on or before that date. Upon Mr. Siebert's announcement in 2013, of his retirement plans, the Company began a search for a new CEO.

Governmental Regulation

The manufacturing and marketing of the Company's existing and proposed diagnostic products are regulated by the United States Food and Drug Administration ("FDA"), United States Department of Agriculture ("USDA"), certain state and local agencies, and/or comparable regulatory bodies in other countries. These regulations govern almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and record keeping. The Company's FDA and USDA regulated products require some form of action by each agency before they can be marketed in the United States, and, after approval or clearance, the Company must continue to comply with other FDA requirements applicable to marketed products, e.g. Quality Systems (for medical devices). Failure to comply with the FDA's requirements can lead to significant penalties, both before and after approval or clearance.

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, in which the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence. FDA clearance of our DPP® Syphilis Screen & Confirm test will be by means of a 510(k) submission.