CHEMBIO DIAGNOSTICS, INC.
Form 10-K
March 03, 2011

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, 2010

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 __ No X

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. [ ]

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 [ ] (Do not check if a smaller reporting company)	Smaller reporting company [X]

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 $3,550,000.

As of March 1, 2011, the registrant had 62,240,483 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 ter 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, 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."

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 antibodies. Three of these products 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 distributed by Alere, Inc., formerly Inverness Medical Innovations, Inc. ("Alere"), in the United States. Our fourth rapid HIV test, which we more recently developed on our patented Dual Path Platform (DPP®) and does not require in-licensing, detects antibodies to HIV in oral fluid samples as well as in all blood matrices. We anticipate launching this product under Chembio's brand in 2012.

Our new product pipeline 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 worldwide. With the DPP® proprietary platform, we can participate in the point-of-care market segment of the nearly $40 billion global in-vitro diagnostic market that is estimated to be $6-8 billion with an overall growth rate of 7% per annum. POCTs, by providing prompt and early diagnosis, can reduce patient stays, lower overall costs, improve therapeutic interventions and improve patient

outcomes as a result of prompt and early diagnosis. They 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 Influenza and HIV for example), the utility of a rapid point–of-care test has been well established, and large markets have been established for these kinds of tests globally. We have focused our product development activity within these areas as they tend to have the higher growth rates within the point-of-care segment.

PRODUCTS

Lateral Flow Rapid HIV Tests

All three of our lateral flow rapid HIV 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 (for example directly 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 which 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 as Clearview Complete HIV 1/2 (the barrel format) and Clearview HIV 1/2 STAT PAK® (the cassette format), and by Chembio in all other markets as 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.

Our third lateral flow HIV test, 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; an adhesive backing is provided as a more cost-effective and compact "housing" on which to run the test.

Regulatory Status: 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. A Clinical Laboratory Improvement Act (hereinafter "CLIA"; see Governmental Regulations) waiver was granted by the FDA for the HIV 1/2 STAT-PAK in November 2006 and for the two Alere Clearview® brands in October 2007. Our HIV 1/2 STAT-PAK Dipstick, though not FDA-approved, qualifies under FDA export regulations to sell, subject to any required approval by the importing country, to customers outside the United States.

All three of our lateral flow HIV tests have qualified for procurement under the President's Emergency Plan for AIDS Relief ("PEPFAR"). The STAT PAK (both the cassette and dipstick versions) are also qualified for the second largest global program, known as the Global Fund (see Glossary), through qualification with the WHO bulk procurement scheme.

DPP® HIV Test

We have completed development of and are now commercializing our DPP® HIV 1&2 Assay. As in the case of our lateral flow HIV tests, the DPP® HIV test is also a qualitative "yes/no" test for the detection of antibodies to HIV 1 & 2, delivers visual results within approximately 15 minutes, is simple to use, has a shelf life of 24 months, and does not require refrigeration. However this product, which is our first product incorporating our patented DPP® technology, can be used with oral fluid samples, as well as 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 tested for multiple conditions. Most importantly, clinical and laboratory studies conducted over the last couple of years have shown this product to have improved performance compared with all of the current FDA-approved CLIA-waived rapid tests, even including our own.

Regulatory Status: In the first half of 2010 we commenced clinical studies with this product in the United States pursuant to an investigational device exemption and in support of an anticipated Pre-Marketing Approval application to the FDA. During the first quarter of 2011 we submitted the first module of such PMA application, and we anticipate submitting the final module later this year. We believe that approval of our PMA application will be within approximately six months after we submit the final module. Thereupon we would apply for CLIA waiver of this product.

The Company conducted laboratory and field studies with this product in 2007-2009 prior to our commencing the clinical trials in the United States. One of the international clinical studies was conducted by the United States Centers for Disease Control, Global AIDS Program in Mozambique ("CDC GAP"). CDC GAP is responsible for evaluating products seeking to participate in PEPFAR, and CDC GAP had already performed its standard laboratory study in 2009 that resulted in the approval for the use of the product in the U.S. government's international AIDS relief program known as PEPFAR (see Glossary) with blood matrices; the Mozambique study facilitated approval of this product for procurements by PEPFAR for use with oral fluid samples. The other study was sponsored by Chembio and was conducted at the National Hospital in Abuja Nigeria. In both of these studies the DPP® product's

performance equaled or exceeded the sensitivity and specificity of each of the other rapid tests in the study, including the only oral fluid HIV test that is currently FDA-approved. During the first quarter of 2011 we also received additional data from the CDC that further supports the previously reported performance. In order to capitalize on the PEPFAR and WHO approvals, this product still has to be registered and approved for export to a PEPFAR or Global Fund beneficiary country, and to also be one of the tests selected by such country for incorporation in such country's national testing protocol. This is a process we are undertaking in selected markets.

In June 2010 ANVISA (see Glossary) approved the DPP® HIV test in Brazil. We are also seeking to have this product approved by WHO pursuant to its bulk procurement scheme as such approval is necessary to pursue certain international donor-funded markets.

PARTNERS INVOLVED IN MARKETING OUR HIV PRODUCTS

On September 29, 2006 we executed marketing and license agreements with Alere. The marketing agreements (one for each of the two FDA approved products) provide Alere with a 10-year exclusive right (i.e. until September 2016) to market our rapid HIV tests in the United States under Alere's brand. The agreements provide Chembio a non-exclusive license to certain Alere lateral flow patents that may be applicable to our lateral flow products, principally including our lateral flow HIV tests we have continued to market outside the United States. 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).

The agreements with Alere have allowed the Company to participate in the growth of the rapid HIV test market in the United States in an OEM (Original Equipment Manufacturer) capacity. This collaboration has been successful as it has allowed the company to invest in its product development, regulatory and manufacturing activities, and to avoid investing in a United States marketing organization.

We have appointed distributors internationally for our lateral flow HIV tests. Our largest markets for our lateral flow HIV rapid tests outside the United States are certain countries in Africa and Mexico.

Our DPP® HIV test was approved by ANVISA in June 2010. This approval was granted to our Brazilian partner, the Oswaldo Cruz Foundation ("FIOCRUZ"), pursuant to one of six technology transfer, supply and license agreements we have entered with this public health organization since 2004 (See OEM DPP® products).

OTHER LATERAL FLOW RAPID TESTS

The Company entered the rapid test market segment with lateral flow technology and for many years our revenues were almost entirely based on this technology, primarily pregnancy tests before we developed the HIV lateral flow tests. Because of the limited license we entered into with Alere to manufacture and market only certain applications of lateral flow technology, we developed our own patent-protected rapid point-of-care technology platform, DPP®, that does not require a lateral flow license, all of our other products and products under development are based on the DPP®. Revenues from products based on lateral flow technologies other than our HIV tests were 3.9% of sales in 2010, substantially all of which are primarily attributable to our niche product line relating to veterinary tuberculosis and Chagas. We developed the veterinary tuberculosis tests as a result of and development program we did pursuant to a National Institute Health grant. This grant work enabled us to have our facility approved for the manufacture of products regulated by the United States Department of Agriculture. We are pursuing new opportunities in the veterinary diagnostics field in order to leverage this capability together with our development capabilities and proprietary point-of-care platform, DPP®.

OTHER DPP® PRODUCTS

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 entirely involved efforts in developing third party funded OEM research and development contracts and grants. This strategy enabled us to conserve our own capital resources, while at the same time acquire important know-how and experience with the platform while also 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. While we will 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 serve (e.g., veterinary) , we believe that we can also develop our own branded line of products, and we plan to do this in the public health area. This brand will be launched with our DPP® HIV Screening Assay in the United States market in 2012, to be followed by our Syphilis test (See RECENT DEVELOPMENTS AND CHEMBIO'S PLAN OF OPERATIONS FOR THE NEXT TWELVE MONTHS).

Following is a discussion of the OEM DPP® products for which we have completed our development activity pursuant to our OEM contracts with FIOCRUZ, Bio-Rad Laboratories, and the Battelle Memorial Institute. The status of those OEM and Chembio-branded products that are still under development are described in Part II Item 7.

OEM DPP® Products
Oswaldo Cruz Foundation OEM DPP® Agreements

During 2008 we signed four agreements and in 2010 one additional agreement with the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil relating to 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 and has basic research and educational divisions as well as extensive manufacturing facilities that manufacture drugs and vaccines, as well as diagnostic products.

During 2010, two of the products under agreement with FIOCRUZ, the DPP® HIV Screening Assay and the 5-band multiplex point-of-care confirmation test for HIV 1&2, were approved by ANVISA. We believe that FIOCRUZ is seeking to have these products used in a new serial testing algorithm to be deployed by the Ministry of Health in

Brazil; an evaluation concerning this new algorithm is underway. During the fourth quarter of 2010, we shipped $537,500 of DPP® HIV Screening Assays to FIOCRUZ. Under the two agreements we have for the recently approved products, there is a potential for aggregate sales of $13.5 million. 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 other products under agreement with FIOCRUZ are for DPP® products for Leishmaniasis, Leptospirosis and Syphilis. These products are still pending regulatory approval in Brazil and their status is briefly discussed in Part II Item 7.

All of the agreements with FIOCRUZ contemplate a technology transfer license to FIOCRUZ for the manufacture of the subject products over stipulated periods of time. These technology transfers, and the provision by Chembio of the information and training that is required for this to occur, are subject to Chembio receiving orders for a minimum amount of products for manufacture by Chembio; thereafter Chembio may receive royalty payments for a defined period based on product sold by FIOCRUZ to the public health programs in Brazil. During 2010 Chembio received $92,000 of royalties from FIOCRUZ pursuant to the 2004 agreement with FIOCRUZ.

Bio-Rad Laboratories OEM DPP® Agreement- On April 6, 2008, we entered a milestone-based development agreement with Bio-Rad Laboratories N.A., a division of Bio-Rad Laboratories Inc (NYSE:BIO), a leading in-vitro diagnostic and life science company. The agreement with Bio-Rad was for the development of a six-band multiplex product (the specific application is confidential) on our DPP®. Based on achieving the proof of concept for this product during 2008, in January 2009 we entered a limited exclusive license agreement with Bio-Rad related to the field of use for this application, and we continued the development work during all of 2009 and until Bio-Rad confirmed that the product specifications were met in the second quarter of 2010. In June 2010, Bio-Rad exercised its option to have Chembio transfer the manufacturing of this product to Bio-Rad, which process was completed in October 2010. Chembio believes that Bio-Rad is proceeding with the regulatory approvals of this product, with CE Mark likely by the end of 2010, although there can be no assurance of this. We further believe that Bio-Rad has begun discussions with the FDA to discuss this product, its proposed performance claims and the intended clinical protocol to support its regulatory submission.

During 2008 to 2010, Chembio earned approximately $460,000 for product development work rendered to Bio-Rad under this agreement, plus an additional $490,000 in license and other fees related to the manufacturing transfer.

Battelle/CDC DPP® Influenza Immunity Test – In December 2009 Chembio entered into a milestone-based development agreement for the development and initial supply of a multiplex, rapid point-of-care ("POC") influenza immunity test. The agreement contemplated a period of approximately nine months in which the development activity was to be completed. Chembio entered this agreement with Battelle Memorial Institute, which has a master contract with the United States Centers for Disease Control and Prevention ("CDC") to enter into, implement and provide technical oversight of agreements relating to pandemic preparedness on behalf of CDC. The objective of the project was to develop a product that can determine an individual's immunity to seasonal and novel influenza viruses, including novel swine H1N1, either in the field or in an outpatient setting. Development work with respect to the contract development specification is substantially completed and our contract partners are assessing the prototype product and determining potential additional funded development activity.

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 and are visually read. Certain of our new DPP® products will incorporate reader technologies that can help record and report test results and reduce subjectivity of results sometimes found with visually read tests. 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. This format provides 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. Also, because of the usage in DPP® of a separately connected sample strip, the control and delivery of sample material is substantially improved. This 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.

We can also use hand held and desktop readers to objectively measure, quantify, record and report 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.

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 if samples have to be sent out to a laboratory which can take at least several days to process. However, 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.

There are approximately 53,000 new diagnoses of HIV infection in the United States each year, according to the CDC. In time, most of these infections progress to AIDS. The CDC estimates that approximately 1.1 million individuals in the U.S. are living with HIV, with an estimated 250,000 Americans, or more than 25%, unaware that they are infected. It is these 250,000 infected people that account for 54% of all new infections per year. 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 from samples that have to be sent out to a laboratory and that can take at least several days to process. Healthcare officials believe that by making more people aware of their HIV status, it will reduce the number of HIV transmissions.

Rapid HIV testing in the United States has now developed into a 6-7 million test market. This is from zero in 2003 when Orasure received FDA approval for the first rapid HIV test. We believe that the US professional HIV rapid test market (not including the OTC market) has the potential to increase to 15-18 million tests over the next several years, which would represent about 50% of all HIV tests done today in the United States for clinical purposes. Assuming an average price to the manufacturers of $10.00 per test, a total potential market of $180 million U.S. market is inferred.

In 2006, the outlook for HIV testing was given a big boost with the release by the CDC of new guidelines for HIV testing. These new CDC recommendations 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. Adoption of the 2006 CDC recommendations by a number of states continues to have an increasing impact.

In the international market, PEPFAR, the large United States funded international AIDS relief program focused on fifteen countries, was reauthorized in 2008 for up to $48 billion for FY2009-2012 (up from $15 billion in 2004-2008). PEPFAR, and the Global Fund are the largest of the global initiatives that have helped to make life-saving treatments available to those that need them. For example PEPFAR has the goal that by 2013 three million infected individuals will be provided treatment and 12 million new cases will be averted. To achieve these goals more and more people are likely to get tested. As more effective treatments become available at lower costs there is a clearer reason to be tested.

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 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. There is also now an opportunity to participate in the over-the-counter market for HIV tests. This opportunity received important support by the FDA and CDC in November 2009.

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 untreated can cause pelvic inflammatory disease, infertility, ectopic pregnancy and can infect newborns. Treatment cannot be provided without a confirmed diagnosis of an active, previously untreated case of syphilis. Current testing algorithms in the United States require two different tests (called non-treponemal and treponemal markers), each requiring trained personnel in laboratory settings and several days to receive back 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 is a minimum of 3 million tests, which is approximately 20% of the total number syphilis tests performed in the United States today. Unlike HIV testing, where a positive result first requires a confirmatory test, and even then further tests to measure viral load before expensive treatment decisions are made, an individual with a confirmed active case of syphilis can be prescribed antibiotics immediately.

In February 2011 a study was released by the CDC that suggested that the “newest” laboratory screening tests, which are using technologies developed in the 1980s (i.e. Enzyme-linked Immunoassays), are resulting in a large number of suspected false positive test results, which are test results that are not in fact representing active cases of Syphilis. This study involved tests done in high throughput blood screening laboratory settings, and not necessarily clinical settings. Nevertheless we believe that the study suggests that if public health clinicians could have what is effectively the CDC-recommended laboratory testing algorithm in a point-of-care test, this could be an invaluable public health tool in higher risk testing (higher STD prevalence) settings. We believe this is the opportunity we have with this product.

Marketing Strategy

Our marketing strategy is to:

- Support, review and assess the marketing and distribution efforts of our rapid HIV tests by Alere. Alere, which is a leading marketer of point-of-care diagnostic products, has significantly expanded its distribution footprint since we signed our agreement with them, and although we believe that this will enhance opportunities for Alere to market our rapid HIV tests, the product line is a very small one for them notwithstanding the strong growth they have enjoyed with respect to our products.

- Leverage our DPP® intellectual property and regulated 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.

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.

Research and Development

During 2010 and 2009, $4.1 million ($2.6 million, net of Qualified Therapeutic Discovery Project ("QTDP") grants) and $2.9 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 $2.8 million in 2010 and $1.3 million in 2009. 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. Research and development and regulatory activities are explained in detail in Part II Item 7.

Employees

At December 31, 2010, we employed 118 people, including 115 full-time employees. We have entered into employment contracts with our President, Lawrence Siebert, 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 Mr. Siebert provides that Mr. Siebert will serve as the Chief Executive Officer and President of the Company for an additional three-year term through May 11, 2012. The contract with Mr. Esfandiari has a term of three years ending March 2013. We have obtained a key man insurance policy for Mr. Esfandiari.

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.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's implementing regulations to have an approved application), the FDA must approve a Pre-Marketing Application ("PMA") before marketing can begin. PMA's must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a 510(K) pre-market notification. The Company has approved PMAs for the two rapid HIV tests now marketed by Alere Medical as Clearview® Complete HIV 1-2 and Clearview® HIV 1-2 STAT PAK®. FDA approval of our DPP® HIV screening assay for use with oral fluid or blood samples will be pursued by means of a PMA application.

The Clinical Laboratory Improvement Act of 1988 ("CLIA") prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the United States Department of Health and Human Services (via the FDA) applicable to the category of examination or procedure performed. Although a certificate is not required for the Company, it considers the applicability of the requirements of CLIA in the design and development of its products. The statutory definition of "laboratory" is very broad, and many of our customers are considered labs. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products and this is in fact critical to the marketability of a product into the point-of-care diagnostics market. The Company has received a CLIA waiver for each of the two rapid HIV tests now marketed by Alere Medical as Clearview® Complete HIV 1/2 and Clearview® HIV 1/2 STAT PAK®. The CLIA waiver was granted by the FDA for HIV 1/2 STAT-PAK on November 20, 2006 and for the Clearview® Complete HIV 1/2 on October 22, 2007.

In addition, the FDA regulates the export of medical devices that have not been approved for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) complies with the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is prominently labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. However, the Federal Food, Drug and Cosmetic Act does permit the export of devices to any country in the world, if the device complies with the laws of the importing country and has valid marketing authorization in one of several "listed" countries under the theory that these listed countries have sophisticated mechanisms for the review of medical devices for safety and effectiveness.

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval or evaluations by international public health agencies, such as the World Health Organization, in order to sell diagnostic products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for United States governmental approvals. On the other hand, the fact that our HIV diagnostic tests are of value in the AIDS epidemic may lead to some government process being expedited. The extent of potentially adverse governmental regulation affecting Chembio that might arise from future legislative or administrative action cannot be predicted.

One or more of the Company's rapid HIV tests are also approved or pending approval for marketing in several foreign jurisdictions, including but not limited to Brazil, Mexico, and a number of other nations in the developing world.

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 owned intellectual property portfolio around our Dual Path Platform 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 reagents and new hardware platforms for the development and manufacture of rapid diagnostic tests.

The Company has obtained patent coverage on the DPP® product line, including three U.S. patents, and patents in China, Malaysia, Eurasia, Mexico, Singapore, and the U.K. Additional patent applications on the DPP® product line are pending in the U.S., as well as in many foreign countries such as Australia, Brazil, Canada, the European Union, India, Indonesia, Israel, Japan, Korea, and South Africa. Patents have also been filed on extensions to the DPP® product line concept such as 4th generation assays.

The Company has also filed for patents and obtained some patents in the U.S. for other inventions such as its multiple host species veterinary TB test, and patent applications for the other inventions are in various stages from being recently filed and not yet examined, to already examined and allowed but not yet issued. The Company selectively and strategically foreign files its patent applications based on the importance of the invention to the Company.

Trademarks

The Company has filed and obtained trademarks for its products including DPP®, SURE CHECK® and STAT-PAK®. The DPP® trademark is also registered under the European convention (ECT).

Trade Secrets and Know-How

We believe that we have developed a substantial body of trade secrets and know-how relating to the development of lateral flow and DPP® based diagnostic tests, including but not limited to the sourcing and optimization of materials for such tests, and how to maximize sensitivity, speed-to-result, specificity, stability and reproducibility. The Company possesses proprietary know-how to develop tests for multiple conditions using colored latex. Our buffer formulations enable extremely long shelf lives of our rapid HIV tests and we believe that this provides us with an important competitive advantage.

Lateral Flow Technology and Reagent Licenses

As part of our agreements in 2006 with Alere for the marketing of our HIV tests, we were granted non-exclusive licenses to certain lateral flow technology for certain products manufactured and marketed by Chembio including but not limited to our HIV tests. Although we believe our DPP® 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 the best interests of the Company and our stockholders. 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 the Company's lateral flow or DPP® products will not be granted and that licenses to such patents, will be available on reasonable terms, if any. Alere has aggressively enforced its lateral flow intellectual property, although some of the main patents will expire within the next few years.

Regardless, the DPP® technology provides us with our own intellectual property, we believe it provides us with a freedom to operate, and that it also enables tests to be developed with improved sensitivity as compared with comparable tests on lateral flow platforms. The Company has signed and anticipates signing new development projects based upon the DPP® technology that will provide new manufacturing and marketing opportunities. We have filed other patents 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.

The peptides used in our rapid HIV tests are patented by Adaltis Inc. and are licensed to us under a 10-year non-exclusive license agreement dated August 30, 2002. In connection with Adaltis' bankruptcy, during the third quarter of 2009 we bought out all of our remaining obligations under that agree