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Chembio Diagnostics Inc. (CEMI-OTC)

CEMI: Q3 In-Line. Suitors Knocking on CEMI's Door.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (10/05/10)	$0.36
Six- Month Target Price	**$0.92**

OUTLOOK

Chembio's DPP HIV 1/2 screen oral fluid rapid diagnostic test was approved in Brazil in late June 2010. This test is worth at least $10MM in revenue to Chembio over the next 5 years. The test should also launch in the in the U.S. in early 2012. Several other DPP tests with multi-million $ potential are also expected to launch in the U.S. in the next 18 months. Long-term revenue and EPS growth should significantly accelerate following the U.S. launch. Management approached by and still in talks with multiple potential acquirers.

We are maintaining our Outperform rating on Chembio. Our near-term price target is $0.92.

SUMMARY DATA

52-Week High	**$0.37**
52-Week Low	**$0.19**
One-Year Return (%)	**-10.81**
Beta	**-0.05**
Average Daily Volume (sh)	**181,535**
Shares Outstanding (mil)	**62**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**14**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**31.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2010 Estimate	**33.0**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Products**
Zacks Rank in Industry	**19 of 66**

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	$2.55 A	$3.37 A	$4.36 A	$3.55 A	$13.83 A
2010	$2.78 A	$3.75 A	$4.51 A	$5.34 E	$15.97 E
2011					$19.11 E
2012					$28.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.01 A	$0.00 A	$0.00 A	$0.00 A	$0.00 A
2010	$0.00 A	$0.01 A	$0.00 A	$0.00 E	$0.01 E
2011					$0.00 E
2012					$0.03 E

Zacks Projected EPS Growth Rate - Next 5 Years % **28.5**

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WHAT'S NEW…

Third Quarter Financial Results…

Chembio reported financial results for the third quarter on November 4, 2010. Revenue of $4.51 million was about 4% better than our $4.34 million estimate. The $170k difference was mostly a result of recognizing a $225k milestone from FIOCRUZ related to the approval of for the DPP HIV confirmatory test in Brazil one quarter earlier than we had anticipated, partially offset by a $75k milestone from Bio-Rad that we modeled but has been pushed back (we now model this in Q4). Revenue from product sales was $3.79 million which was just about dead-on with our $3.83 million estimate.

EPS was $0.00, in-line with our estimate. Net income came in at $168k versus our $52k figure. R&D was up considerably as a result of ramping the U.S. DPP HIV trials. This however, was largely offset from an impressively strong product gross margin as a result of economies of scale from higher production volumes coupled with the fruits of recent manufacturing efficiency initiatives. While R&D expense will remain elevated through the duration of the U.S. DPP clinical trials, we also expect Chembio to continue to benefit from wider gross margins.

Management's business update was highlighted by the disclosure that they have had discussions with two potential acquirers of the company. Further disclosure in the 10-Q and on the call was very limited other than noting that Chembio expensed $190k in consulting fees during the quarter related to a potential sale and that discussions have continued into the fourth quarter. While we have no specific insight, in our opinion the most likely potential suitors are ALR, BIO, OSUR and TRIB, all of which would have reason to be interested in CEMI and the resources to acquire the company. Our take is that management is likely to be unwilling to sell anywhere near the current valuation. The recent influx of cash makes CEMI much more self-sufficient and, in our opinion, gives CEMI management significantly more negotiating leverage than prior to being awarded the QTDP federal grant.

The update to development timelines remained mostly unchanged from our prior expectations. Noteworthy was that DPP HIV clinical trials are approximately 25% complete (compared to 10% complete at end of Q2) and should conclude in Q1 2011 – also at which time a PMA regulatory filing is expected to be made. At Q2 Chembio was still hoping to get the trials through and file prior to year-end 2010, although it was clear (as we noted in our last update) due to financial constraints that a delay was not unlikely. With roughly $2.8 million in cash on hand (pro forma for receipt of the $1.47 million grant), the company should now have ample funds to hit this new target-date and is no longer considering any additional financing. Assuming no further delays we think the product could launch during the first quarter 2012.

The company also provided product sales and total revenue guidance for the fourth quarter and full-year. Product sales are expected to increase by at least 50% from the same period in 2009 with full-year total revenue expected to be up by at least 15% from 2009. The company also noted that they expect U.S. HIV sales to Alere to increase by at least 15% in 2011 due to high customer satisfaction with Chembio's lateral flow products as well as increased compliance with CDC testing recommendations.

We look for full-year revenue and EPS of $15.97 million and $0.01. We are maintaining our Outperform rating on Chembio and $0.92 price target.

Federal Grant Comes Through

In July 2010 Chembio submitted applications for grants under the Qualifying Therapeutic Discovery Projects provision of the new healthcare reform act. The grants are geared toward helping small biotech companies complete development programs of products that have the potential to result in new treatments, new therapies and life-saving cures – this includes diagnostic products. Awarded grants reimburse 50% of eligible expenses incurred from eligible projects during the years 2009 and 2010. Eligible expenses are those directly related to the qualifying project (i.e. – largely R&D related). Recipients of the grants were selected by the treasury department on October 29th based on one or more of the following criteria:

- The project's potential to result in new therapies for areas of unmet need or to prevent, detect, or treat chronic or acute diseases or conditions
- The project's potential to reduce long-term healthcare costs or advance the goal of curing cancer within 30 years

- The project's potential to advance U.S. competitiveness in biotechnology while creating and sustaining high-paying jobs in the U.S.

On November 1st Chembio was notified that it had been awarded $1.46 million under the program for six of its DPP technology based project including those for the diagnosis of HIV, hep-C and syphilis. Chembio will receive immediate payment of $620k representing the company's qualifying expenditures made in 2009 and will receive the balance ($846k) at the end of January 2011, which represents qualifying expenditures already made or to be made in 2010.

The grant award is of significant importance for two reasons. First and foremost we believe it will provide Chembio with enough cash to complete clinical trials of the DPP HIV test for which management has ballparked the cost at $2 million. Operating cash along with additional milestone payments and other R&D grant money should afford Chembio the financial resources it needs to get the DPP HIV test through clinicals without tapping additional financing. This is a huge positive and likely all but eliminates any lingering risk of dilution from a secondary equity offering.

We also believe there is a chance Chembio can complete clinical trials for the DPP influenza and syphilis tests with internal funds or with supplementing with incremental bank financing. Our view is that the worst case scenario is that these trials, which are expected to cost another $1 million, may be pushed back slightly (~ 6 months) in order for Chembio to fund them with operating cash. The flu and syphilis tests hold less potential, especially in the near-term, relative to the HIV test so a slight delay in getting clinicals through for these are of little concern.

The recent grant is also of importance in that it helps validate the DPP technology as showing a reasonable chance of performing as hoped (i.e. – "detecting acute diseases and conditions") and/or "reducing the long-term growth of health care costs in the U.S." There was a likely a tremendous response from companies applying for these grants and with the total awarded a relatively meager $1 billion, we think the almost $1.5 million granted to Chembio is telling of the potential that the DPP technology holds. In fact management noted on the third quarter call that Chembio received the largest single award among all companies domiciled in New York State.

DPP HIV 1/2 Confirmatory Test Approved in Brazil…

On September 23, 2010 Chembio announced that FIOCRUZ had received approval from Brazilian regulators for its DPP HIV 1/2 confirmation test. The 5-band multiplex test has the ability to detect five strains of HIV and can be used with whole blood, serum or plasma. The approval triggered a $225k milestone from FIOCRUZ to Chembio (recorded in Q3) relating to the technology transfer arrangement for the DPP products.

BUSINESS

Medford, NY based Chembio Diagnostics, Inc. develops, manufactures and markets rapid point-of-care diagnostics tests (POCT) for the detection of infectious diseases, primarily HIV. The majority of revenues are currently derived from the Company's three lateral flow rapid tests that detect HIV through use of blood sampling. Two of these tests gained FDA approval in 2006 and are distributed by Inverness Medical Innovations, Inc. in the U.S. under the Clearview brand name. The lateral flow tests are also marketed internationally in Brazil, Mexico and Africa through various other distributors. The Company has recently begun pursuing CE Marking in order to sell the diagnostic tests in Europe. The U.S. market accounted for approximately 42% of product sales in 2009, with sales to Africa and South America accounting for 27% and 20%, respectively.

New Opportunities for Growth

Chembio is currently developing a rapid diagnostic test for the detection of HIV antibodies in oral fluid samples (i.e. saliva) which affords patients a more convenient and less invasive sampling method (relative to blood sampling) without sacrificing accuracy. Also in various stages of development or in the regulatory approval process are assays for syphilis, hepatitis C and influenza. The tests are developed on the Company's proprietary Dual Path Platform (DPP) which we believe offers significant advantages to competitors' currently marketed blood and oral fluid rapid tests which use lateral flow technology. The large and rapidly growing U.S. POCT market offers tremendous opportunity for the DPP infectious disease tests and for Chembio to significantly grow revenue and earnings. We believe the Company is uniquely positioned to capitalize on the rapid macro shift in diagnostic testing away from the clinical lab setting and into POC. The Company's strategy is to fund their U.S. DPP clinical and regulatory activities through domestic and international sales of their existing lateral flow products as well as income from research and development contracts and grants. Four products developed on the DPP technology, including two rapid HIV tests, are expected to begin to launch in Brazil in the coming weeks which will also provide a significant source of cash flow to help finance the U.S. development and commercialization of the DPP portfolio. Two of the four products are still awaiting Brazilian regulatory approval. The HIV 1/2 screen and HIV confirmatory tests were approved by Brazilian regulators in late June and late September of this year, respectively. We expect revenue from these tests to begin during the fourth quarter 2010, for which we modeled $500k. We model the DPP HIV 1/2 screen test, which we view as the Company's bread-and-butter product, to launch in the U.S. in the first quarter 2012 (slight delay from prior Q4 2011 expectation). Based on very compelling trial data to-date and the added benefits of the oral fluid DPP technology, we expect the DPP HIV assay to be well received and quickly command significant share of the lucrative and high-growth U.S. rapid HIV testing market. The assay will compete with the only other rapid HIV oral fluid test in the U.S. market, OraSure's OraQuick ADVANCE HIV 1/2 product which we estimate commands as much as 50% market share. Following the U.S. launch, we also expect Chembio to look to capitalize on the high-growth over-the-counter market HIV testing market, which we estimate could be worth as much as $80 million annually. Chembio also has several other high-potential assays being developed on the DPP platform that could launch in the U.S. and Europe over the next 24 months.

PRODUCTS

Lateral Flow Tests

Chembio's lateral flow HIV portfolio consists of three rapid tests for the detection of HIV antibodies which are used in the POCT segment. The three tests differ mostly only in the method of sample collection and test procedure, flexibility with different sample types, and cost to manufacture. The tests are qualitative positive/negative tests and offer results within approximately 15 minutes. The tests offer certain advantages over competing products such as higher sensitivity/specificity, longer shelf life, ease of use and interpretation, and lower cost. Chembio launched their **HIV 1/2 STAT-PAK** and **SURE CHECK HIV 1/2** lateral flow tests in 2004 and in 2006 signed a distribution agreement with Inverness, whereby Inverness has exclusive U.S. marketing rights to the products through 2016. Inverness launched the products in 2007 and markets them under the Clearview HIV 1/2 STAT-PAK (HIV STAT-PAK) and Clearview Complete HIV 1/2 (SURE CHECK HIV 1/2) brand names. These two products are FDA approved and CLIA-waived (Clinical Laboratory Improvement Act) and used in the point-of-care setting such as hospital emergency rooms, public health clinics and physician offices. STAT-PAK, along with Chembio's dipstick product, is sold outside the U.S. as well as through international distributors. Chembio is also seeking CE Marking for the STAT-PAK and SURE CHECK products to enable sale throughout Europe. The Company believes that they will be able to meet the CE Marking requirements, has determined an initial budget and is now in discussions with

organizations in Europe about obtaining blood donor samples in order to progress with testing. We note however, that while the U.S. market offers significant demand for POCT HIV tests, Europe, with its lower HIV prevalence and heavier reliance on clinical lab testing (as opposed to the POCT setting), is a much less attractive market for Chembio's rapid HIV tests. We, therefore, do not expect a significant contribution from European sales if and when Chembio gains CE Marking and believe the Company will continue to largely focus on growing U.S. market share of the their lateral flow and (later) DPP products.

Chembio's third lateral flow HIV test, **HIV 1/2 STAT-PAK Dipstick**, has not been approved by the FDA and is a more moderately priced product sold exclusively outside the U.S., primarily in less developed countries with high testing needs and which have testing programs that are largely financed by donors such as the President's Emergency Plan for AIDS Relief (PEPFAR) and The Global Fund.

In addition to the HIV tests, Chembio also manufactures and markets lateral flow tests for Chagas Disease, sickle cell anemia, and a niche line of tuberculosis tests for certain animals. Revenue from these tests is captured under "other product sales" on the Company's income statement accounts for approximately 7% - 9% of total revenue.



HIV 1/2 STAT-PAK Dipstick



HIV 1/2 STAT-PAK



SURE CHECK HIV 1/2

While Chembio's core focus for growth is on the U.S. market, international sales remain a large contributor to total revenue. In 2009 approximately 54% of international product sales were made to countries in Africa (primarily Ethiopia and Nigeria), 39% to Brazil and the remainder split approximately evenly between countries in Asia, Europe and the Middle East. International sales of the lateral flow HIV tests accounted for 64% of total revenue in 2008 and while international sales fell 22% to $5.56 million in 2009, their contribution still accounted for 45% of all product sales and 40% of total Company sales last year. We note however, that the average selling price outside the U.S., especially to disadvantaged countries such as Ethiopia and Nigeria, is significantly lower than that domestically. The result is international profit margins can be up to 75% less than margins for Chembio's HIV tests sold in the U.S.

International markets also present challenges other than lower profit contribution. As many of the international markets with the greatest demand for rapid HIV tests are often those with the least economic resources, funds to procure testing kits are not always available and donor-provided gifting levels can change rapidly. Extending credit to cash-strapped customers can also prove problematic, potentially resulting in payments being delayed or altogether defaulted upon. Government bureaucracy and unforeseen changes in regulations and testing protocol are other challenges that Chembio can face when selling into less developed countries. The result of all this means sales and order demand to and from many of the international markets that Chembio deals in can be highly inconsistent from period to period. An example of this is Chembio's international HIV sales falling 22% in 2009, largely as a result of the Nigerian Ministry of Health changing the designation on Chembio's lateral flow HIV tests from one of the two tests used a parallel testing algorithm (where each patient is tested with two rapid tests from different manufacturers) to a confirmatory test (in which only positive results are confirmed with a second test).

Meanwhile domestic sales grew to $5.24 million in 2009, up 148% from 2008, benefitting from customers switching from more expensive competing products, overall growth in the HIV POCT market and Inverness ramping up its sales efforts. Certain benefits of Chembio's lateral flow HIV products such as high sensitivity/specificity and long shelf life have also helped the Company grow U.S. market share in the HIV POCT testing space. We expect domestic sales growth to continue to benefit from further brand awareness, customer loyalty and growing compliance of the CDC routine testing recommendations.

With sale prices significantly higher in the U.S., gross margins benefit as sales to the U.S. market increase as a percent of total product sales. Product gross margins, which came in at 30.5% in 2008 grew to 35.6% in 2009 as a

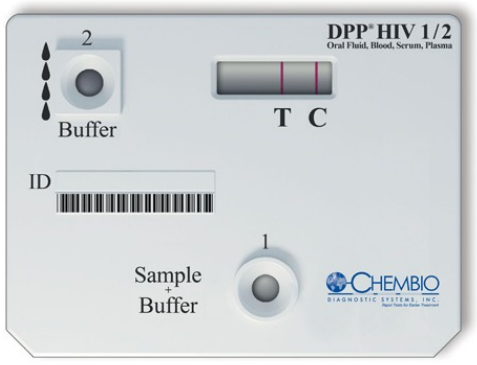
result of U.S. lateral flow HIV sales increasing from just 20% of total product sales in 2008 to 42% of product sales in 2009. Launch of the DPP products in Brazil will partially dilute the gross margin contribution from high-profit U.S. sales of the lateral flow HIV products. However, gross margin should again strengthen following the launch of the DPP products in the U.S., which we expect to begin with the DPP syphilis test near the middle or third quarter of 2011. Chembio is also implementing new automated assembly equipment which is designed to take costs out of the manufacturing process which, along with economies of scale from higher production volumes, should also benefit margins in the years to come. We expect the DPP HIV products to command higher selling prices than the lateral flow tests, which should dually benefit product margins following the launch of the DPP HIV tests in the U.S.

Dual Path Platform (DPP) Technology

Chembio is using its patented DPP technology to develop its next generation of rapid point-of-care infectious disease tests, including assays for HIV 1/2, syphilis, influenza and hepatitis C. The DPP tests offer advantages over many of the currently marketed lateral flow tests including multiplexing capability, increased analytical and clinical sensitivity, and sharper, more distinct visual results. The DPP tests are also adjustable to multiple sample types including blood, serum, feces and oral fluid with no sacrifice in sensitivity. The 24-month shelf life is also a significant benefit, especially as compared to the 12-month shelf life of OraSure's competing HIV oral fluid test (although we note that OraSure is currently seeking to extend the shelf life of their product). We also expect the DPP HIV 1/2 assay to sell for about 25% less than OraSure's competing product. And unlike lateral flow tests, the DPP assays use separate test strips for the samples and buffer materials, with the sample applied directly to the test site and immobilized while the single buffer material is free to migrate to the test zone without the sample. This has significant advantages including decreasing the interaction time (especially with samples such as blood and saliva which migrate slowly in lateral flow tests), thereby increasing the speed of results and it also eliminates potential aggregation issues with the agents, thereby allowing for increased multiplexing capabilities and greater reliability, sensitivity and specificity.

DPP HIV 1&2

Chembio has completed development of their point-of-care **DPP test for HIV 1&2** for use with oral fluids as well as blood samples. The test combines the advantages of DPP with the convenience of oral fluid samples without sacrificing accuracy. Oral fluid is a fast and easy method of sampling and offers substantial advantages over blood sampling. Oral fluid sampling can be done by non-medical personnel and is often preferred by patients over blood sampling which requires a finger-prick. In addition, in certain public health clinics, due to safety concerns, some personnel choose not to handle blood specimens and oral fluid provides a preferred alternative. The DPP test also allows test samples to be stored in a buffer solution, thereby allowing for retesting without the need for additional sample collection. We expect Chembio to seek OTC approval for their DPP HIV test following FDA clearance to market the test in the professional setting. Oral fluid sampling would be an enormous benefit in targeting the OTC market, where a less-invasive (i.e. no need to draw blood) testing method is highly preferable.



DPP HIV 1/2 Screen Assay (oral fluid or blood)

Chembio has teamed up with **Oswaldo Cruz Foundation (FIOCRUZ)**, an affiliate of the Brazilian Ministry of Health, to market the DPP HIV 1/2 test in Brazil, specifically for the Brazilian public health market. Chembio has a long standing relationship with FIOCRUZ, which continues to market some of the Company's lateral flow tests (and which Chembio currently receives royalties from) through a 2004 technology transfer agreement.

The newer technology transfer agreements with FIOCRUZ, which cover the DPP HIV 1/2 test, along with DPP tests for leptospirosis, canine leishmaniasis and a 5-band multiplex confirmation test for HIV 1/2 (discussed below), dictates that FIOCRUZ is responsible for submitting for and gaining regulatory of these DPP tests. All but the leptospirosis have been submitted for approval to Brazilian regulators. Regulatory approval was delayed from management's initial expectations but FIOCRUZ finally received Brazilian regulatory approval of the HIV 1/2 test on June 30, 2010 and the DPP HIV 1/2 confirmatory test on September 23, 2010. We expect approval of the leishmaniasis to come by the end of 2010 or early 2011. We expect to see sales contribution from both newly approved products during Q4 2010 (we model $500k) and estimate sales of all four of the DPP products covered under the recent FIOCRUZ technology transfer agreements to total approximately $2.8 million annually for the next several years (see terms of the technology transfer agreements below for more detail).

And while international sales of the DPP products are important, especially as a source of cash to help fund the U.S. clinical trials and regulatory activities, the domestic market is where we believe the bulk of the opportunity exists for the DPP HIV products. Unlike emerging markets where price is often the overriding determinate of demand for a particular product, demand in the U.S. is heavily influenced by convenience of administration, ease of interpretation of test results and specificity/sensitivity of the test. Therefore, we believe Chembio's DPP HIV 1/2 oral fluid test, which has demonstrated a very high level of specificity and sensitivity compared to FDA approved blood and oral fluid tests in internal studies and international clinical trials, has the potential to quickly capture a significant portion of the U.S. market for professional HIV tests. Assuming eventual FDA approval, we also expect Chembio will look to develop their oral fluid HIV test for the U.S. over-the-counter market, which we estimate to be worth as much as $80 million. With little competition for rapid oral fluid HIV tests anywhere in the world, we believe the DPP HIV 1/2 product could quickly take share of currently marketed rapid blood and oral HIV tests and result in sales ramping very rapidly.

During the fourth quarter 2009 the FDA granted approval to Chembio's clinical testing protocol. Our expectations are that the clinical trials, which commenced during the second quarter 2010 (and were ~ 25% complete through Q3), will conclude during Q1 2011. This is a slight delay from prior expectations (Q4 2010) and is a result of financial resource constraints. Following the $1.47 million cash infusion from the QTDP grants, we believe Chembio will now be able to hit this updated target date.

We also expect a PMA filing in Q1 2011, supported by data from these clinical trials, along with data from internal and field studies (for which the testing protocol was not submitted for FDA review). We note that one of the international trials that we detail below was used to gain approval of the DPP HIV 1/2 assay such that is now eligible for procurement with PEPFAR funds. Based on the published trial data to date, we believe eventual FDA approval of the DPP HIV 1/2 test is likely. Our current expectations are for FDA approval of the DPP HIV 1/2 assay to be granted and U.S. launch to occur in the first quarter 2012 (delay from Q4 2011).

Trial Data To-Date – DPP HIV 1/2

Chembio has completed several internal studies that show the DPP HIV 1/2 test has sensitivity and specificity from oral and blood samples that are comparable to FDA licensed diagnostic tests which are often used in professional clinical labs. The Company has also run one small and two larger field studies that further demonstrate the accuracy of the assay. We detail several of these tests below:

- **Reactivity with Seroconversion Panels study (versus Western Blot and EIA tests)**
  Seroconversion is the process of developing detectable antibodies in an HIV positive patient. Prior to seroconversion HIV antibody tests can provide false negatives (patient is HIV positive but antibodies are not yet detectable by the assay). The DPP HIV 1/2 assay was tested against 27 different seroconversion panels. Each panel consisted of sequential collections from a single individual who seroconverted. Samples were confirmed using Western Blot (WB) and two FDA licensed EIA tests. As shown in the table, the DPP HIV 1/2 assay is similar to currently licensed assays in detecting seroconversion. The table presents the days elapsed from the date of the initial bleed to the first positive sample. This was an internal test.

Panel ID	Collection Time points (days)	DPP HIV 1/2 1st Pos. Sample	EIA 1 1st Pos. Sample	EIA 2 1st Pos. Sample	WB 1st Pos. Sample
PRB-904	0,21,49,92,99	92	92	92	92
PRB-910	0,14,26,28,32,35,40	26	26	26	26
PRB-914	0,4,7,25,31	0	0	4	4
PRB-916	0,4,9,15,30,35	30	30	30	30
PRB-917	0,53,57,65,67	65	65	NR	65 (IND)
PRB-919	0,9,11	9	9	11	11
PRB-922	0,4,7,11	0	0	NR	11
PRB-924	0,2,8,10,26,33,35,40	35	33	35	40 (IND)
PRB-925	0,10,18,22,44,49	44	44	44	44 (IND)
PRB-926	0,2,7,9,27,32	27	27	27	27
PRB-927	0,28,33,35,40	33	28	40	35
PRB-928	0,111,120,125,130	111	111	120	120
PRB-929	0,4,14,18,21,25,28	28	25	28	28
PRB-930	0,3,7,10	10	10	NR	10 (IND)
PRB-933	0,21,27	27	21	27	27
PRB-934	0,7,11	7	7	11	7
PRB-937	0,7,9,14,16,21	NR	21	NR	NR
PRB-939	0,2,7,9,14,16,21,23,103	103	103	103	103
PRB-944	0,2,7,9,14,16	16	14	16	16
PRB-950	0,18,21,28	NR	28	NR	28 (NR)
PRB-951	0,2,8,11,15, 19	NR	19	NR	NR
PRB-952	0,7,10,14,17,21	17	17	NR	17
PRB-953	0,3,7,10	NR	10	10	NR
PRB-955	0,3,7,12,14	NR	14	NR	0 (IND)
PRB-957	0,7,9,14,16,23,28	28	28	28	28 (IND)
PRB-958	0,2,7,9,15,17	NR	15	15	NR
PRB-959	0,7,9,14,19,21,26	14	14	14	14

SOURCE: Chembio, DPP HIV 1/2 Screen Assay product insert
NR = non-reactive
IND = indeterminate

- **Reactivity with Seroconversion Panels study (versus Rapid tests and Western Blot)**

The DPP HIV 1/2 assay was tested against four different seroconversion panels. Each panel consisted of sequential collections from a single individual who seroconverted. Samples were confirmed using Western Blot (WB) and two FDA licensed rapid tests. As shown in the table, the DPP HIV 1/2 assay is similar or better than currently licensed rapid test assays in detecting seroconversion. The table presents the days elapsed from the date of the initial bleed to the first positive sample. This was an internal test.

Panel ID	Collection Time points (days)	DPP HIV 1/2 1st Pos. Sample	Rapid Test 1 1st Pos. Sample	Rapid Test 2 1st Pos. Sample	WB 1st Pos. Sample
9075	0,2,22,32,35	32	32	32	32
9077	0,29,50,52,57,59,71	52	52	52	57
9079	0,48,50,56,72,74,79	56	79	79	56
9081	0,24,26,31	24	24	24	24

SOURCE: Chembio, DPP HIV 1/2 Screen Assay product insert

- **Sensitivity study (serum sample)**

The sensitivity of DPP HIV 1/2 to detect infection with HIV-1 was evaluated using 1,966 serum specimens from individuals known to be infected with HIV-1 and from individuals at high risk for infection with HIV-1. 1,128 serum specimens were identified as positive for infection with HIV-1 using a FDA licensed enzyme immunoassay (EIA), licensed Western Blot (WB) and/or FDA approved NAT assay. Of these, 1,128 tested reactive on the DPP HIV 1/2

assay. The calculated sensitivity of the DPP HIV 1/2 assay in these studies was 100% (1,128/1,128 = 100% with 95% CI = 99.7% - 100%). This was an internal test.

Study Population	Samples	DPP HIV 1/2 Screen Assay Reactive	Licensed EIA Repeatably Reactive	True Positive
Known Positive	1,090	1,086	1,086	1,086
High Risk	876	42	45	42
Total	1,966	1,128	1,131	1,128

SOURCE: Chembio, DPP HIV 1/2 Screen Assay product insert

- **Sensitivity study (oral sample)**
  The sensitivity of the DPP HIV 1/2 assay to detect infection with HIV-1 was evaluated using 99 oral fluid specimens from individuals known to be infected with HIV-1. 97 oral fluid specimens were identified as positive for infection with HIV-1 using a FDA licensed assay and licensed Western Blot (WB). Of these, 97 tested reactive on the DPP HIV 1/2 test. The calculated relative sensitivity of the DPP HIV 1/2 assay in these studies as compared to Western Blot was 100% (97/97). This was an internal test.

Study Population	Samples	DPP HIV 1/2 Screen Assay Reactive	Licensed Rapid Test	Western Blot Positive [3]
Known Positive	99 [1]	97	98 [2]	97

SOURCE: Chembio, DPP HIV 1/2 Screen Assay product insert
1 two samples resulted in indeterminate Western Blot patterns, these samples were excluded in the sensitivity calculations
2 one sample was reactive and Western Blot Indeterminate
3 confirmation performed by licensed HIV-1 Western Blot

- **Specificity (serum sample)**

The specificity of the DPP HIV1/2 assay was evaluated by testing serum specimens representing low risk and high risk populations for infection with HIV-1. The results are summarized in the table. Based on these studies, the specificity of the DPP HIV1/2 assay was calculated to be 99.9% (1506/1507 = 99.9% with 95% CI = 99.6% - 99.9%). This was an internal test.

Study Population	Samples	DPP HIV 1/2 Screen Assay Nonreactive	Licensed EIA Nonreactive	True Negative
Low Risk	675	671	670	672
High Risk	876	835	831	835
Total	1,551	1,506	1,501	1,507

SOURCE: Chembio, DPP HIV 1/2 Screen Assay product insert

- Relative to the five internal tests detailed above, we note that the protocol of the studies were not submitted for FDA review and also caution that the conclusions reached may not be as informative as that gained from clinical field trials. Clinical field trials, especially those with inclusion of patients domiciled in developed markets such as the U.S., may provide a more comprehensive measure of the specificity (as there is a much lower prevalence of HIV in developed markets) and sensitivity (as known positives selected are more likely to be undergoing HIV therapy and thereby are more likely to have lower levels of detectable antibodies) of the product. Despite this, we believe the aforementioned studies, along with the trial data from international field studies which is presented below, provides sound support in favor of the premise that the DPP HIV 1/2 assay, with the use of serum as well as oral samples, is at least on-par (and in many cases potentially superior) in sensitivity and specificity relative to FDA approved immunoassays and rapid tests. This combined with the other significant advantages of the DPP technology relative to the other rapid HIV tests currently on the market bodes very well for the DPP HIV 1/2 test. We also mention that in October 2010 Chembio was awarded a $1.46 million federal grant under the Qualifying Therapeutic Discovery Projects (QTDP) program. The award recognizes six of Chembio's DPP tests including those for HIV, HCV and syphilis as having the "potential to result in new therapies for areas of unmet need or to prevent, detect, or treat chronic

or acute diseases or conditions." There was a likely a tremendous response from companies applying for these grants and with the total awarded a relatively meager $1 billion, we think the almost $1.5 million granted to Chembio (the largest award under this grant to any company in New York State) is indicative of the ultimate potential that the technology holds.

Chembio recently completed two international field studies of the DPP HIV 1/2 assay using oral fluid samples; a 645-patient study sponsored by Chembio and conducted through the National Hospital in Abuja, Nigeria and a 1,674-patient study sponsored by the U.S. Centers for Disease Control Global AIDS Program (CDC-GAP) which was conducted in Mozambique. The Mozambique study was undertaken on behalf of the U.S. Agency for International Development (USAID) and was used for the purpose of gaining approval of the DPP HIV 1/2 assay for use under PEPFAR (U.S. President's Emergency Plan for AIDS Relief). The DPP HIV 1/2 assay is now on the USAID List of approved HIV/AIDS rapid test kits for use with oral fluid and blood samples and can now be procured with funds from PEPFAR.

Abuja, Nigeria Study

The DPP HIV 1/2 assay was evaluated in a prospective clinical study at the National Hospital of Abuja, Nigeria during the fall of 2009. A total of 645 patients were recruited for the study; 215 individuals known to be infected with HIV, 202 individuals at high risk for HIV infection and 228 individuals from a low risk population. The calculated sensitivity of the DPP HIV 1/2 assay was 100% for oral fluid and fingerstick whole blood. The calculated specificity of the DPP HIV 1/2 assay was 100% for oral fluid and 99.5% for fingerstick whole blood. Samples were confirmed using Western Blot.

Abuja, Nigeria Study: Oral Fluid/Blood Samples n = 645

	Oral Fluid n = 645	Fingerstick Blood n = 645
True Positive	223	221
False Positive	0	2
True Negative	422	422
False Negative	0	0
Sensitivity	100% (95% CI = 98.3% - 100%)	100% (95% CI = 98.3% - 100%)
Specificity	100% (95% CI = 99.1% - 100%)	99.5% (95% CI = 98.3% - 99.9%)

SOURCE: Chembio Diagnostics, Inc.

CDC-GAP Mozambique Study

The DPP HIV 1/2 assay was evaluated in a clinical study sponsored by the U.S. Centers for Disease Control Global AIDS Program (CDC-GAP) in Mozambique. The study was used for the purpose of gaining approval of the DPP HIV 1/2 assay for use under PEPFAR, funds from which the assay is now eligible for procurement. The study tested 1,676 patients using four different tests; Chembio's DPP HIV assay using oral samples, OraSure Technologies' OraQuick ADVANCE test using oral samples, Inverness's Determine test using blood samples and Trinity Biotech's UniGold test using blood samples. The three competing tests are all leaders in their respective markets. The DPP HIV 1/2 assay using oral samples was shown to have 100% sensitivity and 99.8% specificity, which, when taken together, exceeded all of the other three tests. This is especially noteworthy as it not only suggests that oral fluid can produce results at least as accurate (and perhaps more so) as those with blood (measured by two of the highest sensitivity/specificity tests currently on the market), but also implies that the DPP HIV 1/2 assay may provide a more sensitive testing measure (i.e. lower rate of false negatives) than the current leading rapid oral fluid HIV test on the market.

CDC-GAP Mozambique Study: Oral Fluid (Chembio/OraSure)/Blood (Inverness/Trinity) n = 1,676

	DPP HIV 1/2 Oral Sample n = 1,676	OraQuick (OraSure) Oral Sample n = 1,676	Determine (Inverness) Blood Sample n = 1,676	UniGold (Trinity) Blood Sample n = 1,676
True Positive	517	516	517	512
False Positive	2	2	8	0
True Negative	1,157	1,157	1,151	1,159
False Negative	0	1	0	5
Sensitivity (95% CI)	100.0%	99.8%	100.0%	99.0%
Specificity (95% CI)	99.8%	99.8%	99.3%	100.0%

SOURCE: Chembio Diagnostics, Inc.

U.S. Clinical Trials – DPP HIV 1/2

U.S. clinical trials commenced during the second quarter 2010. Chembio has set up five testing locations throughout the U.S. to accommodate the trials. The trials are expected to enroll approximately 3,000 patients among three cohorts; those known to be infected with HIV, those at high risk of infection (i.e. intravenous drug users or patients presenting with symptoms of sexually transmitted disease) and those at low risk of infection. The trials are powered to evaluate the performance of the DPP HIV 1/2 assay with oral fluid, whole blood, serum and plasma. The primary endpoint is the detection of HIV-1 antibodies in whole blood, venous whole blood (with EDTA or heparin coagulant – to prevent clotting). Secondary outcome measures are to provide a qualitative screen for the detection of antibodies to HIV-1 compared to an FDA approved HIV 1/2 enzyme immunoassay, with sensitivity and specificity equal to or greater than 98% at the lower 95% confidence interval boundary.

We expect Chembio to use data from these U.S. clinical trials, along with the aforementioned internal studies and international clinical trials to support a Pre-Marketing Approval (PMA) application during Q1 2011. Our current expectations are for the DPP HIV 1/2 product to receive FDA approval and launch in the U.S. during Q1 2012. Chembio does not currently have definitive plans in place relative to marketing the product, although we believe the Company may be considering hiring both a small in-house sales force to target a portion of the U.S. market and utilizing a distributor for the remainder of the market. Based on very compelling trial data to-date and the added benefits of the oral fluid DPP technology, we expect the DPP HIV assay to be well received and quickly command significant share of the high-growth $80MM+ annual U.S. rapid HIV testing market. The assay will compete with the only other rapid HIV oral fluid test in the U.S. market, OraSure's OraQuick ADVANCE HIV 1/2 product which we estimate commands as much as 50% market share.

Chembio will also likely be seeking CE Marking for the DPP HIV 1/2 assay, for which the timeline for approval and launch is expected to be similar to that of the U.S. We reiterate, however, that the market for rapid HIV tests in Europe is only a fraction of what it is in the U.S. due to a lower prevalence of HIV infection and a greater reliance on clinical lab testing in Europe. Despite the greater convenience and superior analytical and clinical sensitivity of the DPP products, we remain ambivalent of the opportunity for Chembio's oral HIV tests in Europe.

CONTRACTS/GRANTS/LICENSES

Over the last several years Chembio has entered into numerous research and development contracts with several public and private organizations and has been the beneficiary of grants from various government entities. The Company has also entered into several licensing and technology transfer agreements with FIOCRUZ covering several of its lateral flow and DPP products. Revenue from the R&D contracts and grants has been meaningful (~ 10% of revenue in 2009) and on the rise ($466k 2007, $694k 2008, $1,340k 2009). However, given the relatively short term nature of the contracts and little foresight in regards to being awarded further business, the level of future income from these sources can be difficult to predict. Contribution margin from this part of Chembio's business also appears (CEMI does break out revenue attributable to R&D contracts/grants but does not break out the associated costs) to be highly profitable. Nonetheless we view this as an ancillary business and a quasi-funding mechanism for Chembio to help support development and commercialization of its "core" business, rapid HIV diagnostic tests.

NIH Grant for Leptospirosis test

In June 2009, the Company received a $3 million, three-year phase II grant from the United States National Institutes of Health (NIH) to develop and commercialize a rapid diagnostic test for leptospirosis. There is no effective prevention for human leptospirosis, a life-threatening emerging zoonotic disease, whose global burden is estimated to be as high as 500,000 cases annually. Untreated leptospirosis often progresses to multi-organ failure and/or pulmonary hemorrhage.

The test is being developed using the DPP technology. Development of the test is in collaboration with the Division of Infectious Diseases, Weill Medical College, Cornell University and FIOCRUZ. Chembio submits invoices as related expenses are incurred. Chembio's expenses are netted from revenue associated with the grant, the result of which (net revenue) runs through the "R&D contracts and grants" line on the income statement. We estimate that Chembio will realize approximately $1.8 million in net revenue from the grant, of which roughly $800k has been collected through the end of the third quarter 2010. The remainder we expect to be realized approximately evenly over the next seven quarters (~ $150k per quarter).

Battelle/CDC Influenza Immunity test

In December 2009, Chembio entered into a $900k milestone-based development agreement for the development and initial supply of a multiplex, rapid POC influenza immunity test using the DPP technology with Battelle Memorial Institute which has a contract with the United States CDC. Chembio received about $773k from this agreement through the third quarter 2010. We expect further milestone payments will be made throughout the next several months and believe the project will be completed and the final milestone payment received around December 2010.

Bio-Rad agreement

In April 2008 Chembio announced an agreement with Bio-Rad Laboratories for the development of a new 6-band multiplex product using the DPP technology. In December 2008 Chembio granted Bio-Rad a limited exclusive license to the DPP technology for development of a product within a defined field of application. The product has yet to be disclosed. Bio-Rad will have exclusive rights to market the product and in June 2010 exercised its option to manufacture the product. Bio-Rad paid Chembio an initial license fee of $340k which was received in the first quarter 2009 and which had been carried as deferred revenue. Bio-Rad completed the development phase of the product in June which allowed Chembio to recognize this license fee as revenue in the second quarter. By exercising its option to manufacture the product, Bio-Rad is obligated to make payments up to $275k to Chembio structured as: $125k due 30 days from option exercise date (which was paid in Q2 2010), $75k due when Bio-Rad makes the test available for clinical evaluation (we model this in Q4 2010) and $75k due one year after the test is made available for clinical evaluation. The option exercise also dictates that Bio-Rad will pay Chembio 7% sales royalties.

Our current timeline is for the test to be made available for clinical evaluations in the fourth quarter of this year. We also believe the test could receive CE Marking around the middle of 2011 and possibly FDA approval by the end of that same year.

Our expectations are that this product will be relatively small. We believe Chembio's motivation for the agreement with Bio-Rad has more to do with validation of the DPP technology than it does with the moderate amount of income that Chembio is likely to receive from it. Therefore, the recent news that development has been completed and that progress is being made towards commercialization is likely worth more to Chembio than are these milestone payments (and eventually royalties) from Bio-Rad. We also note that Brazilian regulatory approval of Chembio's DPP HIV 5-band confirmatory test which came in late September 2010 may provide additional encouragement relative to the validity of Chembio's multiplex platform.

NIH Grant for Tuberculosis

Tuberculosis infection is widespread in developing countries and is often fatal if left untreated. Diagnosis is also difficult and slow, with the most reliable method being sputum cultures which can take 4 – 12 weeks for results. Quicker tests suffer from a lack of sensitivity. This has created a need for a faster and more reliable test for tuberculosis.

Chembio is working with the NIH on a DPP serological test for tuberculosis. Work was completed on the Phase I grant in May 2010 which showed the test achieved the minimum sensitivity goal of 75% - 80%. Chembio subsequently filed a request to the NIH for $2.7 million (over 3 years) in Phase II funding for further development of the test and bring it through to filing for regulatory approval. Chembio believes that, based on feedback from evaluation of their application, there is "substantial likelihood of Phase II funding being awarded beginning in 2011."

FIOCRUZ Technology Transfer agreements

In 2008 Chembio signed four technology transfer agreements with FIOCRUZ in Brazil covering tests developed on the DPP technology for leptospirosis, canine leishmaniasis, HIV 1/2 screen assay with oral fluid samples, and a 5-band multiplex POC confirmation test for HIV 1&2 (the HIV confirmation test can detect five strains of HIV). These agreements are structured similarly to Chembio's "2004 Technology Transfer" arrangement with FIOCRUZ which covered HIV tests developed under the lateral flow technology. Under the recent agreements, the tests will be marketed in Brazil by FIOCURZ under that company's Bio-Manguinhos label. Chembio is responsible for development of the products while FIOCRUZ is responsible for costs and activities associated with submitting for and gaining regulatory approval of the products in Brazil. FIOCRUZ will pay Chembio technology transfer fees totaling approximately $1 million upon Brazilian regulators granting approval to each of the four products. Chembio will receive technology transfer fees in the approximate amounts of $400k for the HIV 1/2 screen assay (received by Chembio in Q2 2010), $225k for the HIV 1&2 multiplex confirmation test (recognized in Q3 2010), $305k for the leishmaniasis test and $100k for the leptospirosis test. The products will be initially manufactured by Chembio and FIOCRUZ is required to purchase a minimum amount (~ $12 million) before full rights to the technology and the products are transferred over to FIOCRUZ. During this period it is expected that FIOCRUZ will initiate manufacture of the products. Following the completion of the transfer arrangements, FIOCRUZ will pay Chembio royalties equal

to 4% of sales of the products over the following five year period (Chembio continues to receive minimal royalties from the "2004 Technology Transfer" agreement). We expect revenue from these recent technology transfer agreements to total approximately $2.8 million annually over roughly the next five years, followed by five years of royalty income of approximately $110k/year.

Chembio completed development of all of the products and recently received Brazilian regulatory approval of the HIV 1/2 and HIV 1/2 confirmatory tests. The DPP HIV tests should begin generating revenue for Chembio during Q4 2010. The leishmaniasis test has been submitted and is still awaiting approval, which we expect to come by the end of 2010 or Q1 2011. This will trigger an additional $305k in technology transfer fees to Chembio. The leptospirosis test is expected to be submitted for approval by the end of 2010.

Other R&D Contracts
Chembio continues to seek additional opportunities to leverage its research and development technology and resources. In April 2009 the Company entered into a services agreement with the Infectious Disease Research Institute to develop products for visceral leishmaniasis and leprosy. Visceral leishmaniasis, which is transmitted to humans through the bite of infected sand flies, is a serious, potentially lethal, systemic parasitic illness that has caused epidemics in India, Southeast Asia, Africa and Latin America. Chembio received $250k related to the project and will be eligible to receive another $75k payment over the next six months upon the attainment of certain development milestones. The Company will be eligible to receive a further $75k milestone payment during the second year.
Chembio also submitted additional grant applications in the first quarter 2010.

PIPELINE

While Chembio's HIV 1/2 screening assay is clearly the product that holds the most promise, the Company has several other DPP assays under development which we believe also have the potential to significantly accelerate Chembio's revenue and earnings growth. The most noteworthy of these pipeline products are DPP tests for syphilis, hepatitis C, influenza A/B antigen and a hepatitis C/HIV combination test.

Syphilis test
Chembio's Syphilis Screen & Confirm test is being developed through a Cooperative Research & Development Agreement with the CDC and upon approval will be the world's first rapid, POC combination screening and confirmation test for syphilis. Based on the market size and significantly added convenience and clinical importance of a POC test for syphilis, we believe Chembio's DPP syphilis assay could easily have multi-million dollar potential. The test combines two markers on a single test strip which will enable a clinician to differentiate active (non-treponemal test) versus past (treponemal test) syphilis infection from a single finger-stick whole blood sample. Results will be available within twenty minutes, enabling treatment decisions to be made at the point-of-care.

Chembio, in collaboration with the CDC performed studies of the DPP syphilis test, which showed a sensitivity and specificity between 90.5% - 93.5% and 92% - 100%, respectively. The retrospective studies, each of which included over 400 patients, used Treponema pallidum passive particle agglutin (TP-PA) and rapid plasma regain (RPR) tests, standard lab treponemal and non-treponamel tests, as the confirmatory tests. An international multi-phase field study which commenced in 2009 and is sponsored by the World Health Organization (WHO) is ongoing. The FDA has approved Chembio's U.S. trial protocol, which will be used to support a 510(k) application. Chembio has recently had some delays in validating lots for clinical trials which we think may push back commencement of the trials to the fourth quarter 2010 or early 2011(from prior expectations of a Q3 start). Chembio is now shooting for a 510(k) filing in Q2 2011 (~2 – 3 month delay from our prior expectations). We now look for the launch to happen towards the back half of 2011. While it is too early to predict whether the DPP syphilis assay will eventually gain FDA clearance, we believe the earlier CDC trial data and a significant unmet need for an accurate and robust POC syphilis test substantially increases the odds in favor of FDA approval. A major problem with clinical lab tests is that results may not be available for days or weeks after the testing was performed, requiring patients that tested positive to return to the physician for treatment. Many of these patients fail to return to the doctor's office or clinic due to inconvenience or other factors and forego treatment. Conversely, test results from Chembio's DPP POC assay are available within twenty minutes, allowing an infected patient to receive initial treatment immediately. Therefore an accurate POC syphilis test could substantially aid in the fight against future spread of the virus. We believe this will add significant support for Chembio's application for FDA clearance.

According to the CDC there were approximately 46,000 reported cases of syphilis in the United States in 2008, an increase of over 13% from 2007. However, it is estimated that only about 20% of infected cases are reported, which means there could be as many as 250,000 or more individuals with the virus in the U.S. The number of people infected with the virus has grown by almost 40% from 2004 to 2008 (latest available data) and is expected to continue to rise. The number of new cases increased by 18% from 2007 to 2008. Worldwide the CDC estimates approximately 12 million people are infected. We estimate the size of the U.S. market for this test to be between $20 million and $40 million, which is about 20% of the total syphilis testing market. Chembio's POC syphilis test, if approved, would likely be first to market and allow it to quickly grab significant share of this market. Chembio also expects to seek CE Marking for DPP Syphilis Screen & Confirm.

Hepatitis C and Hepatitis C/HIV Oral Fluid combination tests
Chembio has developed prototypes of a DPP Hepatitis C (HCV) and a separate DPP HCV/HIV 1/2 oral fluid test. The test will compete with OraSure's product, which gained FDA approval in July 2010 for use with venous whole blood samples and is currently the only rapid HCV test on the market. OraSure filed for FDA approval of the test for use with fingerstick whole blood in July 2010 but has delayed filing the test for use with oral fluid. The oral fluid delay was a result of FDA comments concerning the lower sensitivity of the fingerstick whole blood and oral fluid versus the venous whole blood test. OraSure noted in their Q2 10-Q that they believe it is likely additional clinical data will be required to support the oral fluid application - which they currently expect to continue to pursue.

Chembio's prototypes are being evaluated in a study organized by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the CDC. Chembio received some preliminary data from this during the second quarter – indications from management on the Q2 call was that they were pleased with what they have seen so far. The expectation is that the data will be published by the CDC within the next few months. Assuming the data is positive, we believe FDA clinical trials could begin in late 2010 or early 2011 with a regulatory filing by the second half of 2011. The HCV and HCV/HIV combo tests will require a PMA submissions which likely means FDA approval would not happen before the second half of 2012.

The HCV population offers another attractive opportunity for POC testing in our opinion. With approximately 3.2 million people infected and 17,000 new cases per year (as of 2007 according to CDC estimates), the U.S. market could offer an opportunity of 2 million to 3 million tests/year. At roughly $15 per test, this equates to a market opportunity between $30 million and $40 million annually. Similar to the current protocol with syphilis testing, the patient must return to the clinic to receive treatment after waiting for test results. A POC test with results available in just minutes can significantly reduce time to treatment, thereby resulting in reduced adverse effects of the virus (i.e. – liver damage) and improved patient outcomes. While OraSure's OraQuick Rapid HCV Antibody Test (currently approved only with venous whole blood), which was also recently approved in Europe, has the first-to-market advantage, we believe the size of the market and high unmet need for a POC HCV test could mean another multi-million dollar opportunity for Chembio. We note, however, that we view the DPP HCV test as somewhat of a wildcard at this point. With no trial data currently available and an eventual requisite PMA approval process, the likelihood of eventual FDA approval is difficult to predict. In addition, the FDA regulatory process can be long and drawn out, which could potentially delay an eventual launch.

Influenza A/B antigen test
Chembio is also working on development of a multiplex test for the detection of flu A/B antigen. A prototype of the DPP test was tested against currently marketed competitive products in an independent lab. Results showed Chembio's test performed competitively and indicated that there was a significant opportunity for the DPP flu test. The test would be Chembio's first antigen detection test on the DPP platform. We expect Chembio to complete development of the test during 2010 and make a 510(k) filing in the first half of 2011. This could put the DPP flu A/B test on the U.S. market later in 2011. We also look for Chembio to seek CE Mark for the assay.

The POC influenza testing market is very large but crowded with a number of competing products already on the market. However, we see an opportunity for Chembio's product if it can show higher sensitivity/specificity relative to competing products. And as we discussed earlier the DPP technology offers advantages over lateral flow products, which should provide an advantage over similarly priced products. Chembio can also leverage its antigen detection technology in developing products outside the serological antibody detection areas. We estimate the POC flu A/B testing market at between $100 million and $200 million annually. Despite several companies with competing products which can make market share gains difficult and margins slim, the size of the market, coupled with a growth rate which we estimate at 20%, the market remains very attractive.

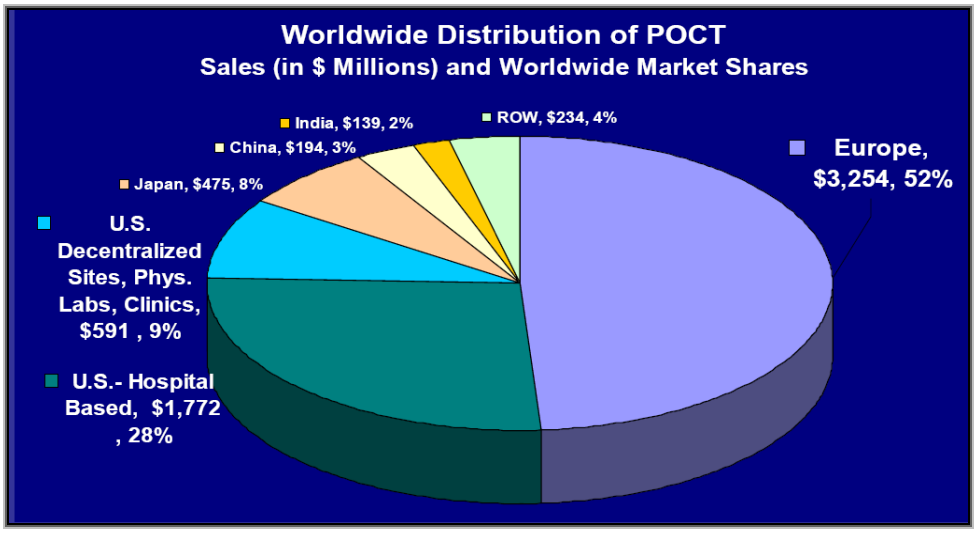
Chembio has yet to announce their plans for marketing the syphilis, HIV, HCV or flu assays but has noted that they will be sold under the Chembio DPP brand name.

PIPELINE CHART		
PRODUCT	**REGULATORY STATUS**	**EXPECTED LAUNCH**
DPP HIV (FIOCRUZ)	APPROVED	Q4 2010
Multiplex DPP HIV confirmation (FIOCRUZ)	APPROVED	Q4 2010
Leishmania (FIOCRUZ)	Submitted for approval in Brazil (thru FIOCRUZ)	Q1 2011
Leptospirosis (FIOCRUZ)	Regulatory submittal Q4 2010?	Q1 2011
DPP HIV (EM ex-FIOCRUZ)	Approved - awaiting launch	?
DPP Syphilis (Europe)	Development completed. Expect data from int'l trials soon.	2H 2011
DPP Syphilis (U.S.)	Development completed. Clinical trials about to commence. 510(k) filing expected Q1 2011	2H 2011
DPP Influenza	Expected 510(k) filing 1H 2011	2011?
DPP HIV U.S./ Europe	Ongoing clinical trials. Expect to submit PMA in Q1 2011.	Q1 2012
HCV, HCV/ HIV 1/ 2 combo	Clincal trials begin late-2010/ early-2011? PMA submission late-2011?	2012?

MARKET DYNAMICS

U.S. POCT Market Experiencing Rapid Growth

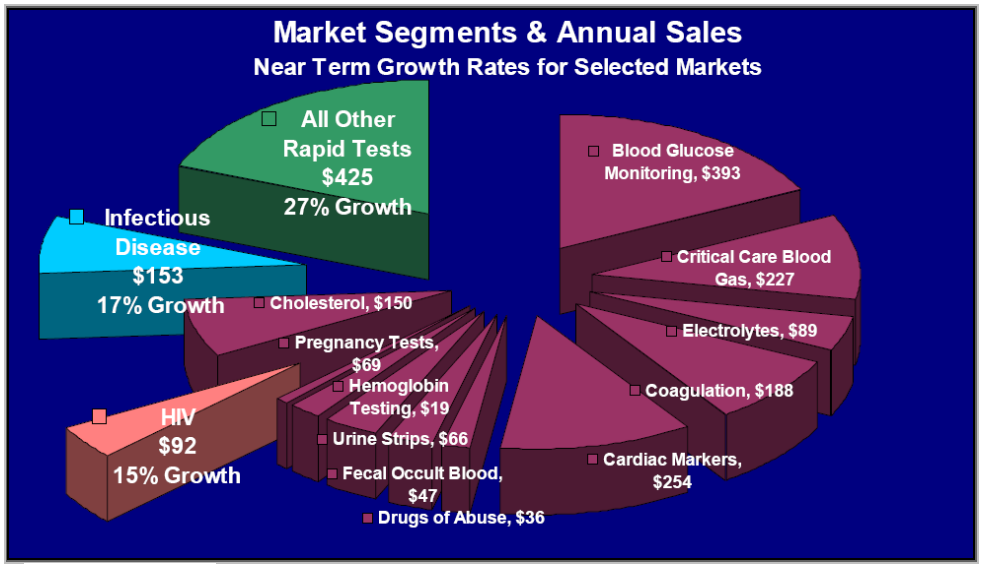
The point-of-care testing market is the fastest growing segment of the in-vitro diagnostics market and is expected to grow at an annual rate of almost 11% through 2013 according to market analysis company, Business Insights. The majority of this growth will come from the U.S. and European markets which dominate the global POCT testing segment. Manufacturers of POCT products are benefitting from healthcare providers shifting more testing from central labs to POC. Higher healthcare costs, lower reimbursement rates, improved accuracy and the demand for and clinical advantages of immediate testing results will likely continue this trend indefinitely. POCT offers certain significant advantages over central lab testing such as lower cost, simpler testing procedures, ease of interpretation, improved therapeutic intervention and the elimination of the need for patients to return for a follow-up visit. And while these have always been benefits of POCT, in the past clinical lab testing had benefitted from greater sensitivity and specificity which had deterred a greater reliance on POCT. The recent advent of new technologies in POCT has significantly narrowed the gap between the quality of results seen from the professional labs versus POC which has been a major impetus for the macro shift towards a greater use of POCT. We believe Chembio's DPP platform, which in the limited internal studies has shown sensitivity and specificity on par with or better than conventional professional HIV tests, is the next generation of high quality POC diagnostic tests and will benefit as healthcare providers shift towards a greater reliance on POCT. While international markets such as Europe and Africa will remain important contributors to revenue and cash flow, Chembio's "core" strategy is to target the U.S. POCT market, which accounts for roughly 37% of the global POCT market and is experiencing significantly greater rates of growth.



Chembio Diagnostics, Inc.

And while the POCT as a whole is expected to grow at a respectable low double-digit annual rate over the next several years, certain segments of this market are projected to grow even significantly faster. HIV and infectious

disease diagnostics are especially benefitting from healthcare providers shifting testing from the professional labs to POC, largely as a result of the recently improved sensitivity and specificity of certain POC tests. This along with new recommended testing guidelines and the rise in new infectious disease strains will be catalysts to growth of the HIV and infectious disease testing in the POC setting. Quality and accuracy of results will also be major drivers growth of this segment of the POCT market, benefitting those manufacturers with next generation technology and higher quality tests. We believe Chembio, which has already recently experienced rapid growth of its lateral flow products in the U.S., will be a direct beneficiary of this as the Company rolls out its products developed on the DPP platform. HIV and infectious disease POC diagnostic testing is forecasted to grow at annual rates of 15% and 17%, respectively, over the next several years. DPP assays such as the HIV 1/2, HCV/HIV 1/2, and flu A/B antigen products which combine greater ease of administration and interpretation with potentially industry leading sensitivity and specificity should be among the greatest beneficiaries of the shift towards greater reliance on POC testing.



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U.S. OTC Market Highly Attractive

We expect Chembio will look to bring their DPP HIV oral fluid product into the highly profitable over-the-counter (OTC) market following PMA approval. Prior to this we believe the Company may even bring the Sure Check (Clearview Complete) whole blood device to the OTC market. The segment offers high margins as products that are sold in bulk to the professional segment are packaged individually to the OTC market. The OTC portion of the POCT segment, which is currently dominated by glucose monitoring and pregnancy testing, is expected to experience a considerable expansion in breadth and depth over the next several years. The burden of rising healthcare costs, public overhaul of the healthcare system, more knowledgeable patient population and significant improvements in diagnostic testing kits are all catalysts to what we expect to be significant growth in the OTC portion of the POC testing space. OTC testing offers a lower cost and quicker alternative to a physician office visit and can increase compliance of recommended testing guidelines. With the enormous increase in information resources via the internet over the last decade people are more knowledgeable about health related issues which has also benefitted the growth in this “do-it-yourself” segment.

Key to tapping and creating demand in the OTC market will be developing additional diagnostic tests such as the DPP HIV oral fluid test which combines high accuracy with ease of administration and interpretation. We believe Chembio’s DPP technology is ideal for the OTC setting as it directly targets these specific attributes. Less invasive oral fluid sampling with the DPP HIV 1/2 assay will be especially attractive to the OTC user, as will the easy to read and interpret “yes, no” visual test results. With separate test strips, an OTC user (i.e. non-professional) of the DPP assays is less likely to encounter problems with samples and buffer material coming into contact with each other, as can be a concern with lateral flow assays. We also believe the DPP HIV 1/2 assay would benefit from the low compliance with CDC HIV testing recommendations which has been a major detriment to slowing spread of the disease. Some individuals at high risk of infection for HIV may be more prone to seek OTC testing as opposed to professional diagnostic testing due to the stigma associated with HIV. As a result, patients are much more likely to comply with these testing recommendations when they are not required to visit a doctor and can instead administer an accurate and easy to use test at home.

European POCT Market Remains Challenging
The majority of the growth in the POC segment in Europe is coming from blood glucose and cardiac marker testing as well as coagulation monitoring. Infectious disease testing in Europe in the POC setting, while not growing at nearly the same rate as in the U.S., has also recently shown signs of increased demand. With an increasing number of flu strains and greater desire for quicker and more accurate testing, we expect the DPP flu A/B product to be well received in Europe. Although, we note that certain markets in Europe such as France, forbid doctors from carrying out POC testing in the physicians' office which will somewhat constrain overall growth of POCT in Europe.

With its lower incidence of HIV and continued heavy reliance on professional labs for much of the HIV diagnostic testing, Europe is a much less attractive market for Chembio's HIV testing products. Despite the added convenience of oral sampling and potentially superior accuracy, we do not expect the European market to offer nearly the same opportunities as the U.S. market for the DPP HIV assays.

Africa Near-Term Opportunity May Be Limited
Chembio also expects to introduce the DPP HIV 1/2 assay in Africa, although we believe the near-term opportunity for the product may be somewhat limited in that market and initial sales will be delayed as the assay has yet to be selected on any national testing protocols. As sales to Africa are funded by donors such as PEPFAR and The Global Fund, price and accuracy are typically the overriding factors that determine demand, with ease of administration and interpretation of test results of significantly lower importance. Trinity Biotech's UniGold HIV blood sample test is a high quality product with sensitivity and specificity ranked the best among about two dozen currently marketed rapid HIV tests according to published CDC rankings. UniGold HIV and Inverness' Determine rapid HIV blood test, another highly accurate assay, command significant share of the African market. With a lower cost to manufacture and high specificity/sensitivity, these blood tests will be difficult for the DPP HIV 1/2 test to compete against, at least in the near-term.

With the African market so highly price-sensitive, the added convenience of oral fluid sampling with the DPP tests, which are attractive features in developed markets, may not spark additional demand in more economically constrained regions such as Nigeria and Ethiopia. The DPP product will also cost more to manufacture than competitor's blood tests as well as Chembio's exported lateral flow HIV tests and with little ability to raise prices in Africa, Chembio's already thin margins on international product sales would suffer even more.

Despite what we expect will be a somewhat limited near-term opportunity for Chembio's oral HIV test in African markets, we believe demand may grow over time if testing compliance increases as a result of the added convenience of oral sampling. As compliance with recommended HIV testing guidelines continues to be a major impediment to stopping the spread of HIV/AIDS in certain parts of Africa, we expect there will be added demand for a product that will prompt a greater percentage of the population of heavily HIV infected areas to get tested for the virus. While there are currently several rapid blood-sampling HIV tests sold to the African market, OraSure's OraQuick lateral flow test is the only oral fluid test available. Based on the advantages of the DPP technology relative to lateral flow and the superior results demonstrated in the (limited) trial data to date, we believe the DPP HIV 1/2 assay would compete very strongly against OraSure's product. This may provide some wiggle room to adjust pricing and potentially increase margins, making the African market a more attractive opportunity in the longer-term.

CASH POSITION

As of September 30, 2010 Chembio had $1,335k in cash and equivalents. The Company is conservatively capitalized with little debt (~ $239k bank debt) and no preferred stock outstanding. Cash from operations was $214k ($991k ex-changes in working capital) through the first nine months of the year (+$236k through 12 months ending 12/31/2009).

Cash balance will also benefit from the $1.47 million from the QTDP grant ($620k immediately + $846 in Q1 2011) as well as approximately $550k from milestones and contracts which we expect Chembio to receive during Q4 2010. Additional cash flow could come from the NIH tuberculosis grant, if awarded, beginning in early 2011.

Despite our expectations of a spike in research and development and regulatory activities related to commercialization of the DPP pipeline along with $875k due to Bio-Rad in December 2010 (related to a February 2008 sub-license agreement), we now believe that operating cash along with the QTDP grant money will allow Chembio to forego any additional outside financing.

In June Chembio took a $250k term loan (5 year term) and $250 revolver with HSBC bank in order to increase working capital flexibility. Through the third quarter the revolver remained untapped.

OUTLOOK

Chembio's strategy will be to finance their U.S. DPP business (i.e. their "core" business) with domestic and international sales of its legacy lateral flow products as well as R&D contracts and international licensing of the DPP technology. We expect sales of the lateral flow products, which have grown from $8.8 million in 2007 to $12.4 million in 2009, to continue to provide a significant source of cash which will be funneled back into product development and commercialization of the DPP product portfolio. The recent technology transfer agreements with FIOCRUZ began providing income (from technology transfer fees and product sales) to Chembio following the approval of the HIV 1/2 test in late June. We model the HIV ½ and multiplex HIV confirmation tests to generate $500k in product revenue through the end of 2010. We estimate revenue generated from the DPP FIOCRUZ agreements to be approximately $2.7 million in 2011, which will grow modestly from this base over the next several years. This will provide a substantial source of additional cash for Chembio to use to help finance U.S. commercialization and initial marketing of the DPP products.

Based on the compelling data from the various internal studies and field trials which demonstrate very high sensitivity and specificity of the oral fluid DPP HIV 1/2 assay, we believe eventual FDA approval is likely. We also do not anticipate any hurdles in obtaining CLIA waiver for the assay, which has been developed as a more user-friendly and easier to interpret test than the Company's FDA-approved and CLIA waivered lateral flow HIV tests. With the necessary funding now in place we do not anticipate any further delays and believe clinical trials for the DPP HIV 1/2 assay will conclude during Q1 2011 – followed immediately by a PMA filing. If all goes well the product will be on the market by early 2012. We also expect the DPP syphilis assay to launch during 2011. Sales of the assays should ramp rapidly immediately following launch. The DPP flu A/B and DPP HCV assays could potentially gain FDA approval and launch in 2011, although we have much less visibility on these timelines. We think the DPP product portfolio could generate almost $9 million in sales from the U.S. and European markets alone in 2012, which we think grows to approximately $18 million in 2013 as sales gain traction from maturation of the marketing and distribution platforms for the products.

In the meantime R&D expenses will materially increase as a result of clinical trials and regulatory activities associated with bringing the U.S. DPP products to market. We expect this to weigh on operating income but the several development milestones and additional revenue expected from sales through FIOCRUZ should allow Chembio to post modest positive income in 2010. Through 2011 R&D expenses will remain elevated from the DPP trials which will again impact the bottom line, although we again forecast moderate positive income for the full-year. We also assume that Chembio hires a direct sales force to market the DPP products in the U.S., although management has yet to determine their plans relative to this. An in-house sales force, along with higher selling prices of the DPP products and U.S. sales growing as a percent of total sales should result in significant gross margin improvement over the next several years. The gross margin improvement will be partially offset be a corresponding increase in sales and marketing expenses but we expect the net result to be continuous operating margin growth for the foreseeable future.

We project revenue to grow from $15.97 million in FY2010 to $19.1 million in 2011, benefitting from a full-year contribution of DPP FIOCRUZ sales as well as a moderate contribution from the U.S. launch of the syphilis assay. We also expect lateral flow sales to Alere to remain robust during 2011 (we model +17%). We think total revenue grows to $28.0 million in 2012 and $38.4 million in 2013. Chembio will likely also be looking to bring the HIV DPP product to the OTC market. An eventual OTC launch would add significantly to the already robust long-term revenue and earnings growth prospects for the Company. We look for 2010 EPS of $0.01, up from $0.00 in 2009 and for this to show continuous improvement for the foreseeable future, benefitting from significant growth in revenue and continuous improvement in operating margin. Based on our model we forecast EPS of $0.06 in 2013.

RECOMMENDATION/VALUATION

Management has shown great resiliency in growing both the domestic and international sides of the business. Revenue grew at a CAGR of 33% from 2004 to 2009 and Chembio ended the most recent fiscal year with $309k in net income, marking 2009 as the first profitable year in Company history. 2010 is shaping up to be another profitable year. Management has also done an excellent job in finding ways to take costs out of the business but at the same time reinvesting in newer technologies and higher growth opportunities. We view this as the beginning of the next significant phase of growth for the Company as it begins to transition away from the lateral flow assays and into what we believe will quickly become the leading oral fluid rapid HIV test in the U.S.

Several Catalysts To Propel Future Growth…
Chembio is poised to deliver on several highly significant milestones over the next 18 months which we expect to be the catalysts to tripling revenue over the next four years from the $13.8MM posted in 2009. The first major milestone was achieved with the late June approval of the DPP HIV 1/2 test in Brazil. This was followed in late September with the Brazilian approval of the DPP HIV 1/2 multiplex confirmatory test. The DPP leishmaniasis and leptospirosis tests could launch later this year or early next.

Based on the compelling data from the various internal studies and field trials of the oral fluid DPP HIV 1/2 assay, we believe eventual FDA approval is likely. The data suggests the assay may have greater sensitivity and specificity than OraSure's OraQuick ADVANCE HIV 1/2 oral fluid test as well as leading blood sample assays. Clinical trials are underway, and although delayed, should finally conclude in early 2011. Our current expectations are that both the DPP HIV 1/2 and DPP syphilis assays will be on the market by Q1 2012. We believe Chembio will have a huge opportunity to take significant market share from OraSure's HIV oral fluid sampling product, which generates approximately $40 million in domestic revenue. We expect the DPP assay to sell for about 25% less than OraSure's product and combined with other significant advantages of the DPP technology, we forecast sales to ramp very quickly upon FDA approval.

We also see significant opportunity for the DPP syphilis test. Based on the market size and significantly added convenience and clinical importance of a POC test for syphilis, we believe Chembio's DPP syphilis assay could easily have multi-million dollar potential.

The OTC market for the DPP HIV product is enormous and, due to the huge margins offered in this segment, is one which can be exponentially profitable for Chembio. We expect Chembio to seek OTC approval for this product following FDA approval to market it in the professional setting. In the meantime, Chembio may pursue OTC approval of its Sure Check assay, which is already FDA-approved and CLIA waived for the professional market. Sure Check's easy to use barrel format would likely be ideal for the OTC market.

Finally, Chembio should also benefit from the macro-shift that is underway by healthcare providers shifting more testing from central labs to the POC setting. Higher healthcare costs, lower reimbursement rates, improved accuracy and the demand for and clinical advantages of immediate testing results will likely continue this trend indefinitely.

Near-term Expectations…
In the meantime and in the near-term, Chembio should receive approximately $505k in milestones, contracts and grants in Q4 2010 – this is on top of the $1.47 million in QTDP grant money. Chembio will begin generating revenue from the DPP HIV and HIV confirmatory tests during Q4 as well. We expect combined domestic and international sales of the lateral flow products to come in about 9% higher in 2010 compared to 2009 as a result of a resurgence in sales in both Africa and the U.S. during Q3 and expected during Q4. We model total revenue to grow 15.4% in 2010 and despite the spike in R&D expenses, Chembio should generate positive net income for the full year (we model $878k).

The revelation at Q3 quarter-end that Chembio has been in discussions with (and continues to do so) two potential suitors makes things even more interesting. We believe management is unlikely to consider a buyout anywhere near the current valuation but we think several companies (including ALR, BIO, OSUR and TRIB) would all have reason to make a play for the company.

Longer-term, we project revenue to grow from $15.97 million in FY2010 to $19.1 million in 2011. We think this grows to $28.0 million in 2012 and $38.4 million in 2013. Our model does not currently incorporate a launch of the

DPP products into the OTC market prior to 2013, although we expect an eventual OTC introduction to add significantly to the already robust long-term revenue and earnings growth prospects for the Company. We look for 2010 EPS of $0.01, up from $0.00 in 2009 and for this to show continuous improvement for the foreseeable future, benefitting from significant growth in revenue and continuous improvement in operating margin. Based on our model we forecast EPS of $0.06 in 2013.

Valuation

We are maintaining our Outperform rating of Chembio Diagnostics with an Outperform rating. Based on the potential for the DPP product portfolio to significantly ramp long-term revenue, cash flow and earnings we feel the Company is grossly undervalued. Average valuation for competitors in the rapid diagnostic testing space is 2.2x estimated 2011 revenue. Given that we estimate Chembio's revenue growth rate will only begin to show significant acceleration beginning in late-2011 (following the DPP HIV and syphilis launch) and vastly outpace that of its competitors for the foreseeable future afterwards, we believe Chembio's shares should trade at a significant premium. Our near-term price target of $0.92 is based on 3x our estimated 2011 revenue of $19.1 million.

KEY MANAGEMENT AND DIRECTOR PROFILES

Lawrence A. Siebert
President and Director

Mr. Siebert has been Chairman of Chembio Diagnostic Systems, Inc. since 1992 and its President since mid-2002. Mr. Siebert's background is in private equity and venture capital investing. From 1982 to 1991, he was associated with Stanwich Partners, Inc, which during that period financed and invested in middle market manufacturing and distribution companies. From 1992 to 1999, he was an investment consultant and business broker with Siebert Capital Corp. and Siebert Associates LLC, and was a principal investor in a privately held test and measurement company which was sold in 2002. Mr. Siebert received a JD from Case Western Reserve University School of Law in 1981 and a BA with Distinction in Economics from the University of Connecticut in 1978.

Richard J. Larkin
Chief Financial Officer

Mr. Larkin oversees Chembio's financial activities and information systems. He has been Chief Financial Officer of Chembio Diagnostic Systems, Inc. since September 2003. Prior to joining Chembio Diagnostic Systems Inc., Mr. Larkin served as CFO at Visual Technology Group from May 2000 to September 2003. He led their consultancy program providing hands-on expertise in all aspects of financial service, including initial assessment of client financial reporting requirements within an Enterprise Resource Planning (Manufacturing) environment. Prior to joining VTG, he served as CFO at Protex International Corporation from May 1987 to January 2000. Mr. Larkin holds a BBA in Accounting from Dowling College and is a member of the American Institute of Certified Public Accountants.

Javan Esfandiari
Senior VP, Research & Development

In 1993 Mr. Esfandiari co-founded, and became a co-owner of Sinovus Biotech AB where he served as Director of Research and Development for lateral flow technology until Chembio Diagnostic Systems, Inc. acquired Sinovus Biotech AB in 2000. From 1993 to 1997, Mr. Esfandiari was Director of Research and Development with On-Site Biotech/National Veterinary Institute, Uppsala, Sweden, which was collaborating with Sinovus Biotech AB on development of veterinary products using lateral flow technology. Mr. Esfandiari received his B.Sc. in Clinical Chemistry and his M. Sc. in Molecular Biology from Lund University, Sweden.

Richard Bruce
VP, Operations

Mr. Bruce has been VP of Operations since April 2000. In this capacity, he directs Chembio's production, maintenance, inventory, shipping and receiving, and warehouse operations. From 1998 to 2000, Mr. Bruce was a senior manager at V.I. Technologies. From 1993 to 1998, he held various management positions at Biomerieux. Mr. Bruce held director level positions at American Home Products from 1984 to 1993. Mr. Bruce has over 25 years of operations management experience with Fortune 500 *in vitro* diagnostic and blood fractionation companies. Mr. Bruce received his BS in Management from National Louis University in 1997.

Tom Ippolito
VP, Regulatory Affairs, QA & QC

Mr. Ippolito joined Chembio in June 2005. He has over 20 years experience with *in vitro* diagnostics for infectious diseases, protein therapeutics, vaccine development, Process Development, Regulatory Affairs and Quality Management. Over the years, Mr. Ippolito has held Vice President level positions at Biospecific Technologies, Corp., Director level positions in Quality Assurance, Quality Control, Process Development and Regulatory Affairs at United Biomedical, Inc. Mr. Ippolito is also the Course Director "drug development process" and "FDA regulations", a BioScience Certificate program at New York State University of Stony Brook.

Gary Meller, MD MBA
Director

Dr. Meller was elected to Chembio's Board of Directors on March 15, 2005. Since 2001, he has been the president of CommSense Inc., a healthcare business development company. CommSense Inc. works with clients in Europe, Asia, North America, and the Middle East regarding medical information technology, medical records, pharmaceutical product development and financing, health services operations and strategy, and new product and new market development. From 1999 until 2001 Dr. Meller was the executive vice president, North America, of NextEd Ltd., a leading internet educational services company in the Asia Pacific region. He is also a member of the Advisory Board of Crestview Capital Master LLC, which was the lead investor in Chembio's series B preferred stock private placement. Dr. Meller is a graduate of the University of New Mexico School of Medicine and has an MBA from the Harvard Business School.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2009 A	Q1A	Q2A	Q3A	Q4E	2010 E	2011 E	2012 E	2013 E
Product sales	**$12,372**	**$2,215**	**$2,336**	**$3,787**	**$4,785**	**$13,121**	**$17,270**	**$26,310**	**$36,660**
% of total revenue	*89.4%*	*79.6%*	*62.3%*	*84.1%*	*89.7%*	*82.2%*	*90.6%*	*93.9%*	*95.5%*
YOY Growth	*19.5%*	*-2.4%*	*-23.5%*	*-3.5%*	*53.0%*	*6.1%*	*31.6%*	*52.3%*	*39.3%*
License & royalty income	**$122**	**$0**	**$340**	**$62**	**$0**	**$0**	**$15**	**$125**	**$185**
% of total revenue	*2.1%*	*0.0%*	*9.1%*	*1.4%*	*0.0%*	*0.0%*	*0.1%*	*0.4%*	*0.5%*
R&D contracts, grants, milestones	**$1,340**	**$569**	**$1,074**	**$657**	**$550**	**$2,849**	**$1,780**	**$1,580**	**$1,530**
% of total revenue	*9.7%*	*20.4%*	*28.6%*	*14.6%*	*10.3%*	*17.8%*	*9.3%*	*5.6%*	*4.0%*
Total Revenues	$13,834.5	$2,783.4	$3,749.4	$4,505.0	$5,335.0	$15,970.0	$19,065.0	$28,015.0	$38,375.0
YOY Growth	*25.2%*	*9.3%*	*11.1%*	*3.2%*	*50.2%*	*15.4%*	*19.4%*	*46.9%*	*37.0%*
Cost of Revenues	$7,974	$1,477	$1,654	$2,297	$2,919	$8,347	$9,844	$13,944	$17,230
Gross Income	$5,861	$1,306	$2,095	$2,209	$2,416	$7,623	$9,221	$14,071	$21,145
Gross Margin	*42.4%*	*46.9%*	*55.9%*	*49.0%*	*45.3%*	*47.7%*	*48.4%*	*50.2%*	*55.1%*
Product Margin	*35.6%*	*33.3%*	*29.2%*	*39.4%*	*39.0%*	*36.4%*	*43.0%*	*47.0%*	*53.0%*
Research & Development	$2,884	$801	$792	$1,230	$1,375	$4,197	$5,800	$4,450	$3,600
% R&D	*20.8%*	*28.8%*	*21.1%*	*27.3%*	*25.8%*	*26.3%*	*30.4%*	*15.9%*	*9.4%*
Selling General & Admin	$2,659	$662	$680	$802	$790	$2,934	$3,320	$7,004	$12,280
% SG&A	*19.2%*	*23.8%*	*18.1%*	*17.8%*	*14.8%*	*18.4%*	*18.0%*	*25.0%*	*32.0%*
Operating Income	$318	($156)	$623	$177	$251	$895	$101	$2,617	$5,265
Operating Margin	*2.3%*	*-5.6%*	*16.6%*	*3.9%*	*4.7%*	*5.6%*	*0.5%*	*9.3%*	*13.7%*
Other income (expense)	($7)	$0	$0	($4)	$0	($4)	$0	$0	$0
Interest income, net	($2)	($1)	($1)	($5)	($5)	($13)	($16)	$25	$50
Pre-Tax Income	$309	($157)	$622	$168	$246	$878	$85	$2,642	$5,315
Taxes	$0	$0	$0	$0	$0	$0	$7	$317	$904
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*8.0%*	*12.0%*	*17.0%*
Net Income	$309	($157)	$622	$168	$246	$878	$78	$2,325	$4,411
YOY Growth	*-115.9%*	*NA*	*NA*	*-45.5%*	*NA*	*NA*	*NA*	*2869.5%*	*89.7%*
Net Margin	*2.2%*	*-5.7%*	*16.6%*	*3.7%*	*4.6%*	*5.5%*	*0.4%*	*8.3%*	*11.5%*
EPS	$0.00	($0.00)	$0.01	$0.00	$0.00	$0.01	$0.00	$0.03	$0.06
YOY Growth	*113.0%*	*NA*	*NA*	*-41.7%*	*NA*	*NA*	*NA*	*2869.5%*	*89.7%*
Weighted Avg. Shares O/S	75,042	61,986	70,614	70,547	70,600	68,437	71,000	71,000	71,000

Brian Marckx, CFA

BALANCE SHEET

Chembio Diagnostics, Inc.

	September 30, 2010	December 31, 2009
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,335,983	$ 1,068,235
Accounts receivable, net of allowance for doubtful accounts	2,634,956	1,776,327
Inventories	1,883,441	1,555,903
Prepaid expenses and other current assets	190,515	266,637
TOTAL CURRENT ASSETS	6,044,895	4,667,102
FIXED ASSETS, net of accumulated depreciation	828,320	580,213
OTHER ASSETS:		
License agreements, net of current portion	625,000	700,000
Deposits on manufacturing equipment	28,800	338,375
Deposits and other assets	36,226	29,560
TOTAL ASSETS	$ 7,563,241	$ 6,315,250
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 2,416,672	$ 1,906,163
Current portion of loan payable	55,470	9,600
Deferred research and development revenue	81,673	360,833
License fee payable	875,000	875,000
Current portion of obligations under capital leases	23,865	21,536
TOTAL CURRENT LIABILITIES	3,452,680	3,173,132
OTHER LIABILITIES:		
Loan payable - net of current portion	200,071	14,931
License fee payable - net of current portion	-	-
Obligations under capital leases - net of current portion	21,071	39,273
TOTAL LIABILITIES	3,673,822	3,227,336
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - $.01 par value; 100,000,000 shares authorized	621,382	619,799
Additional paid-in capital	39,620,376	39,453,522
Accumulated deficit	(36,352,839)	(36,985,407)
TOTAL STOCKHOLDERS' EQUITY	3,889,419	3,087,914
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 7,563,241	$ 6,315,250

Chembio Diagnostics, Inc.

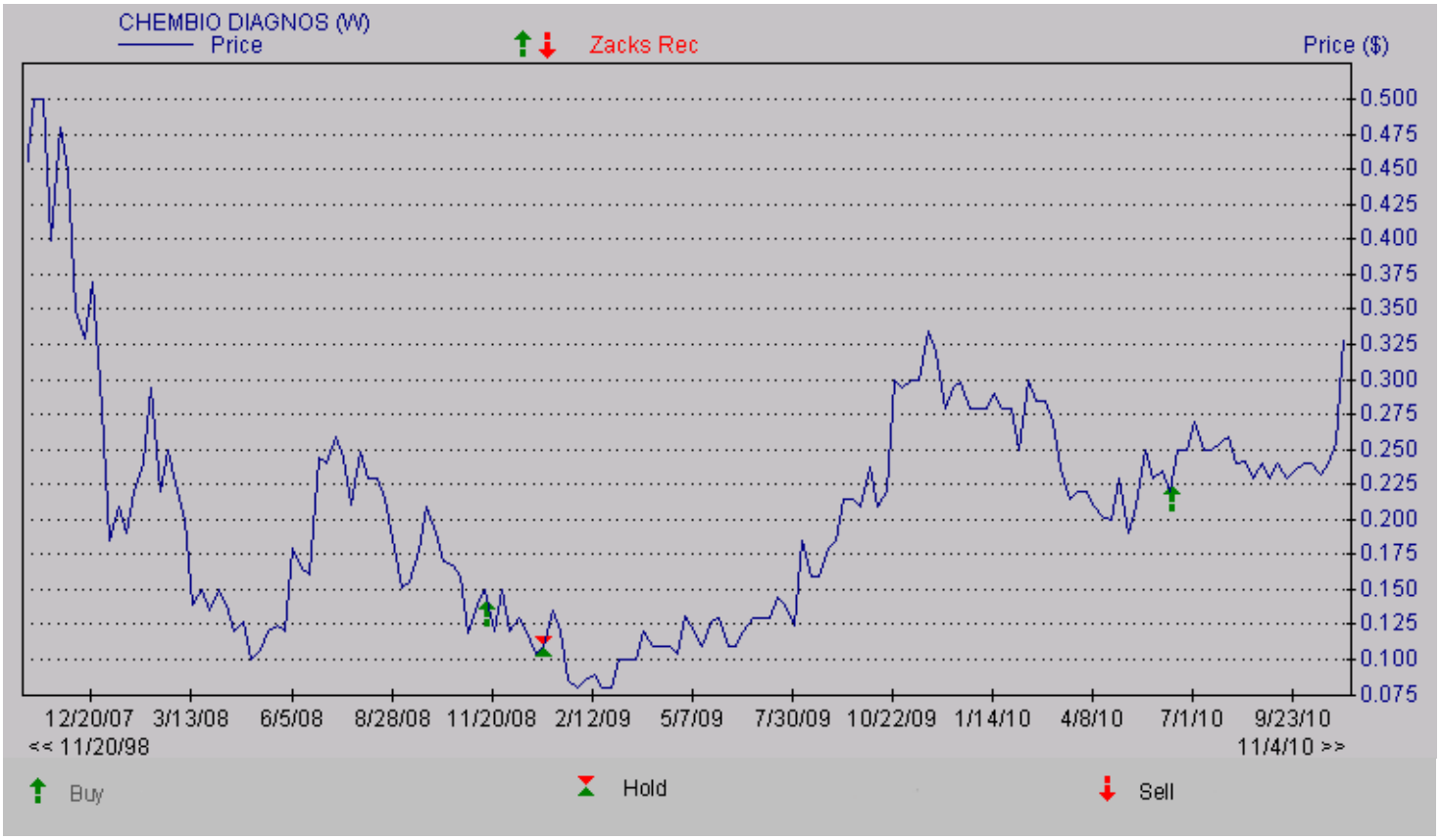
CASH FLOW STATEMENT

Chembio Diagnostics, Inc.

		Nie Months September 30, 2010	2009
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS:			
CASH FLOWS FROM OPERATING ACTIVITIES:			
Cash received from customers	$	10,179,232	9,959,812
Cash paid to suppliers and employees		(9,964,407)	(9,010,860)
Interest received		1,110	7,083
Interest paid		(2,204)	(8,210)
Net cash provided by (used in) operating activities		(213,731)	947,825
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale of fixed assets		-	13,750
Acquisition of and deposits on fixed assets		(188,193)	(310,035)
Net cash used in investing activities		(188,193)	(296,285)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from option exercises		27,073	-
Proceeds from loan		250,000	29,228
Payment of loan obligation		(18,990)	(2,340)
Payment of capital lease obligation		(15,873)	(13,841)
Net cash used in financing activities		242,210	13,047
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		267,748	664,587
Cash and cash equivalents - beginning of the period		1,068,235	1,212,222
Cash and cash equivalents - end of the period	$	1,335,983	1,876,809
RECONCILIATION OF NET LOSS TO NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES:			
Net income	$	632,568	(91,845)
Adjustments:			
Depreciation and amortization		212,838	278,568
Provision for doubtful accounts		-	9,699
Loss on sale of fixed asset		3,923	6,696
Common stock, options and warrants issued as compensation		141,864	140,517
Changes in assets and liabilities:			
Accounts receivable		(858,629)	(335,034)
Inventories		(327,538)	445,053
Prepaid expenses and other assets		76,122	(85,722)
Other assets and deposits		101,234	213,260
Deferred revenue		(279,160)	359,000
Accounts payable and accrued expenses		510,509	(176,057)
Licenses fee payable		-	-
Net cash provided by (used in) operating activities	$	213,731	847,768

Chembio Diagnostics, Inc.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The analysts contributing to this report do not hold any shares of CEMI. Zacks EPS and revenue forecasts are not consensus forecasts. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts' personal views as to the subject securities and issuers. Zacks certifies that no part of the analysts' compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report. Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed herein are subject to change. This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time. Zacks uses the following rating system for the securities it covers. **Outperform**- Zacks expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. **Neutral**- Zacks expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. **Underperform**- Zacks expects the company will under perform the broader U.S. Equity market over the next one to two quarters. The current distribution of Zacks Ratings is as follows on the 1011 companies covered: Outperform- 15.1%, Neutral- 78.7%, Underperform – 5.6%. Data is as of midnight on the business day immediately prior to this publication.