

# CLX Medical, Inc.

(OTC BB: CLXN)

29970 Technology Drive, Suite 203, Murrieta, CA 92563

Telephone: (951) 677-6735 / Facsimile: (951) 677-6573

investors@clxmedical.com

www.clxmedical.com

## August 2008 Newsletter

### CLX Medical, Inc. Announces Planned Acquisition of the ThyroTest(R) Rapid Screening Device

#### CLX Will Acquire Worldwide Exclusive Sales and Marketing Rights to Thyrotest(R) Device and Will Enter Into a Co-Development Deal for 2 Additional Products

**C** LX Investment Company, Inc., which is focused on the launch and distribution of unique medical diagnostic testing products, has announced that the company has entered into a letter of intent with ThyroTec, LLC to acquire ThyroTest®, a rapid thyroid stimulating hormone (TSH) screening device used for the detection of hypothyroidism in adults, a common thyroid disease. CLX will now proceed toward a definitive agreement for the acquisition of ThyroTest, which would be positioned in a wholly owned subsidiary of CLX Medical.

The last phase of CLX's analysis and research process on the ThyroTest® product includes an in-depth analysis of competitive strengths and is part of an ongoing study of the product by a clinical laboratory affiliated with a major U.S. university. Data from the study is expected to be made available in the near term.



In addition to the acquisition of ThyroTest®, CLX Medical expects to enter into a co-development deal with ThyroTec, LLC to secure worldwide sales and marketing rights for 2 additional products in the medical diagnostic testing market.

"Our analysis of the potential market for ThyroTest indicates that it is much larger than the current estimated instance of hypothyroidism in the U.S.," stated Vera Leonard, chief executive officer of CLX Medical. "The wide range of symptoms, most of them very common in today's society, opens what we view to be a significant opportunity for a screening device like ThyroTest® that is CLIA waived and therefore allowed to be used in a wide variety of testing venues. We also believe that ThyroTest® is significantly superior to competitive products, and our marketing strategy for the product will include providing data that supports this contention."

Ms. Leonard provided additional follow-up information on ThyroTest®, as well as the opportunity presented by this product and the acquisition in a Q&A interview beginning on page 2 of this newsletter.

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### About the Company

**CLX Medical, Inc. holds a 51% equity interest in Zonda, Inc., which has developed several rapid point of care tests for medical and non-medical markets, including a rapid test for Chlamydia. CLX recently announced a letter of intent to acquire ThyroTest®, a rapid thyroid stimulating hormone (TSH) screening device used for the detection of hypothyroidism in adults, a common thyroid disease. CLX Medical is focused on the successful worldwide distribution of these and any additional products it may acquire or license.**

For more information, please visit the CLX website at [www.clxmedical.com](http://www.clxmedical.com) and the Zonda website at [www.zondaincusa.com](http://www.zondaincusa.com).

## Greetings from the CEO



*The following Q&A with Ms. Vera Leonard, CEO of CLX Medical, Inc., pertains to the planned acquisition of ThyroTest®, a rapid thyroid stimulating hormone (TSH) screening device used for the detection of hypothyroidism in adults, a common thyroid disease. FDA clearance and CLIA waived status have already been achieved for the ThyroTest® product. The Q&A was conducted on August 13, 2008 and will serve as the CEO Greeting for this month's corporate newsletter.*

**Q. CLX Medical just announced its planned acquisition of ThyroTest. Why did you target this device to be the next product that CLX would bring under management?**

A. One of the things we look for in targeting an acquisition is a product that addresses a large market opportunity. The next item on the check list is whether or not that market is currently being served. When we uncover an opportunity that meets both of those criteria we move to the next step; how close is the product to being marketable, that is, what regulatory hurdles does it still have in front of it? The ThyroTest product is a rare find in that it addresses a huge, underserved market and already has all the regulatory hurdles behind it by having the FDA clearance and CLIA waived status. In our opinion the product is available because it was never given a focused sales and marketing effort. The existing market, the potential for growth and the level of performance ThyroTest offers make a compelling case for this acquisition.

**Q. How common are hypothyroidism and the symptoms that might indicate the condition?**

A. That's a good question, and I think what you are really asking is: what is the market potential for a test that can help diagnose hypothyroidism? I'll answer it two ways. First, hypothyroidism is much more common than most people realize. Because the risk increases with age, the symptoms are often dismissed as just "getting older." There are currently about 13 million individuals in the US that are currently diagnosed as hypothyroid. Estimates are that there are at least another 13 million that are undiagnosed. Those are important statistics but they do not describe the market for ThyroTest.

In large part, the market for ThyroTest is defined by its symptoms. Those symptoms include, gaining weight inappropriately, inability to lose weight with diet & exercise, feeling cold when others feel hot, feeling fatigued or lethargic, irregular menstrual cycles, infertility, depression, mood swings, and increased forgetfulness.

Because the number of symptoms is so vast and thyroid disorders can negatively impact so many human body organs, ThyroTest can make a real difference in several therapeutic areas creating a significant sales opportunity. Just looking at the symptoms I have mentioned; (and by the way, these are not all of the symptoms), you see that the product has usefulness to Obstetricians & Gynecologists, Infertility Specialists, Psychiatrists, Internists, Endocrinologists, Cardiologists, as well as Family Practitioners. This is the opportunity presented by helping a doctor identify the cause of a patient's existing symptoms.

Hypothyroidism is generally associated with aging; therefore the number of individuals suffering from hypothyroidism is expected

to grow with the aging of the population. Experts estimate the US market growth to be in the range of 5-10% per year for the foreseeable future.

In addition, the American Thyroid Association recommends that every person be screened for hypothyroidism at age 35 and every five years thereafter. That's a huge market by anybody's count.

**Q. What is the strategy for U.S. and worldwide distribution for ThyroTest?**

A. In the U.S., working with our key consulting group, American Health Partners, we will launch the product through select national and regional medical-surgical distributors. That product launch will be accompanied by ads in appropriate medical and industry journals, trade show attendance and targeted advertising campaigns.

Immediately upon close of the acquisition we will apply for a CE certificate that will allow us to market the product through our existing group of European distributors as we work with our Master Distributor to identify and engage additional distributors. Of course, already having FDA clearance and CLIA waiver will make acquiring CE certification much easier and, we hope, much faster.

We will add other countries to our distribution strategy once we have a solid base of business operating in the U.S. and Europe.

**Q. What advantages are there to having the CLIA Waived status for the ThyroTest product?**

A. Having CLIA waiver is huge! In order for doctors to screen individuals for hypothyroidism, or to conduct an in-office work-up of patients presenting with symptoms he or she must have a product that meets four criteria. It must be reliable, it must be cost effective, it must be able to give a rapid result, and it must be available. Irrespective of any of its other qualities, unless the device has CLIA waived status it is not available for use in most doctors' offices. In that case, the doctor's only option is to send the specimen out to a non-waived lab for testing. This is an expensive option for the patient so most doctors only use it when overt symptoms are present.

If the only option available to the doctor is a lab test, the cost of testing prohibits being able to screen for hypothyroidism. Additionally, when a doctor sends a test out to the lab, the doctor is not paid for the test, the lab is. So having a CLIA waived test generates revenue for the practice where sending it out does not, as well as keeping the cost of testing low enough that doctors can conduct screening in the office.

Based on our most recent information there are 107,000 doctor offices with CLIA waived licenses.

**Q. CLX Medical recently announced that it had targeted LETI Laboratories to serve as European master distributor for its subsidiary products. Will this company distribute ThyroTest in Europe?**

A. Yes. We expect to work with LETI for ex-US distribution of all our products. There are several benefits to this plan. It streamlines our inventory management logistics tremendously. It simplifies our worldwide receivables process and will allow us to more easily

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### Forward-Looking Statements

All statements included in this release, including statements regarding potential future plans and objectives of CLX Medical are forward-looking statements. Such statements are necessarily subject to risks and uncertainties, some of which are significant in scope and nature beyond CLX Medical's control. There can be no assurance that such statements will prove accurate. Actual results and future events could differ materially from those anticipated in such statements depending on many factors. Historical results are not necessarily indicative of future performance.

# CLX Medical Announces LETI Laboratories as Master Distributor for Subsidiary Products Into the European Market

## Successful meetings at recent AACC event pave the way for anticipated Letter of Intent

CLX Medical has reached an agreement with LETI Laboratories, a Barcelona-based biopharmaceutical company that operates with exclusive distributors in countries across Europe, to serve as the sole importer of CLX's subsidiary products into the European market.

As Master Distributor for CLX products, LETI Laboratories will provide product support and product packaging control; coordinate sales to other European distributors; distribute the company's products in Spain and Portugal; act as the registered EU representative for CE marked products; serve as the one point of entry for CLX products into Europe; and assist with the development and implementation of pricing structures.

In meetings held at the American Association for Clinical Chemistry (AACC) Annual Meeting and Clinical Lab Expo held in late July 2008, representatives of CLX Medical and LETI Laboratories agreed to terms that will be included in a Letter of Intent between the two companies.



Laboratorios LETI, S.L. is an independent, family-owned, biopharmaceutical company dedicated to medicinal research. The company, founded in 1909, is based in

Barcelona and its industrial plant and allergy research laboratory are located in Tres Cantos (Madrid). It has subsidiaries in Germany and Portugal and operates with exclusive distributors in different European countries, South America and Africa.

Additional information on LETI Laboratories can be found at [http://www.leti.com/eng/lab\\_perfil.asp](http://www.leti.com/eng/lab_perfil.asp).

Some of the initial work that will be undertaken by LETI on behalf of CLX's subsidiary products includes market research and a plan for distribution in the European market.

"We are extremely pleased to announce LETI Laboratories as our targeted master distributor for the European market and look forward to the Letter of Intent, which we expect to be executed very shortly," commented Vera Leonard, chief executive officer of CLX Medical.

"LETI is a highly capable and well established company and has significant expertise in the European market. Our association is expected to provide a number of distinct advantages for CLX as we pursue widespread distribution for our subsidiary products and additional medical diagnostic tests that we may choose to acquire or license.

"LETI will be an excellent partner for CLX as we seek to expand distribution of our products in the European market," Ms. Leonard added.

## CEO Greeting: Q&A with Vera Leonard

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forecast demand for our contract manufacturers as we gain more insight into ordering patterns throughout Europe. Importantly we are building a relationship with a strong, knowledgeable partner who can help us develop and manage our ex-U.S. business. The individuals we work with within LETI are experts in diagnostic products from a scientific as well as a marketing perspective. They understand the European and worldwide markets and are excited about the unique products we are bringing them. Still, successful relationships come down to the people involved. Are our values compatible, are we equally committed to mutual benefit? We believe we have found that right kind of relationship with LETI.

LETI Laboratories is a well established company and highly regarded in the diagnostics industry. In addition to their operations in Europe; they have operations in Latin America, South Africa and other areas that will likely be of interest to us as we expand our marketing efforts.

### Q. What does the competitive landscape look like for ThyroTest?

A. While there are other rapid products that test for thyroid function, we believe that ThyroTest offers significant opportunity to establish a dominant position in this market. Beyond product performance, which, of course is very important, competitive advantage can also be established through a strong marketing and distribution strategy. In-office screening for hypothyroidism is a young market, fairly early in its development. We certainly expect to see others enter the market as its value becomes more widely recognized. Our strategy is to establish ThyroTest as the market leader and maintain its position as the product of choice in a rapidly growing worldwide market.

### Q. How do you expect to finance the acquisition of ThyroTest and marketing for the product post-acquisition?

A. We have negotiated a good purchase price and process with ThyroTec, the company that owns ThyroTest. We are currently preparing a convertible preferred private placement offer through which qualified investors can benefit especially well from this acquisition. The private placement memorandum will be available for distribution in the next few days. Through this vehicle we expect to raise enough financing to complete the acquisition and fund at least 12 months of operating costs going forward.

### Q. It has been a year since you joined Zonda and 8 months since joining CLX. How would you characterize this first year?

A. The first words that come to mind are challenge, potential and patience. The patience part has been one of the biggest challenges. As you may remember, shortly after I joined Zonda in August 2007, we were notified that some of our European distributors were using product labeling that had not been added to the technical file required for sales in the European Union.

So, my first official act was to halt sales and take action to avoid a mandatory product recall. The process required pulling in all the labeling and artwork in use throughout the European market,

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# CEO Greeting: Q&A with Vera Leonard

## CEO addresses acquisition of ThyroTest, strategy for launch of product in U.S. and internationally, highlights of the last 12 months of operations and company's next steps

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acquiring professional translations of all the product information, getting it through the approval process, and one-by-one, allowing distributors to resume sales of HandiLab products. Of course this took a few months to accomplish but it gave me an opportunity to meet with each of our distributors and quickly understand where opportunities for improving our European distribution strategy lay.

It also helped me formulate a plan to become owners of our own European Union certification rather than relying on our contract manufacturer for that regulatory clearance. This is where "patience" comes in. We realized that while the products have a pretty good track record, and demand was increasing, we needed to go back and get some foundational issues in place. Specifically, we needed to establish a quality system that meets ISO standards. This would be required in order to achieve FDA clearance for any of our products as well as to become the certified CE holder for European sales. We researched regulatory consultant services and contracted with Safis Solutions in Indianapolis, IN to help us with all our regulatory processes including the establishment of a quality system.

I am pleased to say that we have completed all the Standard Operating Procedures (SOPs), and internal systems required. What remains is to conduct a mock audit, address any deficiencies the mock audit uncovers, and then schedule an official audit by an accredited Notified Body that will grant the CE certificates. This has been, and still is, a huge project but one we believe is critical for regulatory clearances as well as market position as a quality company.

Our next big decision came when we had an opportunity to improve the readability of the HandiLab products through an adjustment to the volume of reagents used in the device. We were getting feedback that sometimes the volume of reagent in the reading chamber would wash out the end-result color making the result difficult to interpret. We worked with various adjustments to the reagent volume and were able to identify one that gave consistent results without interfering with the clarity of the end-result. We immediately ordered three lots of the devices and started looking for a virology lab to confirm the performance at the new level and perfect the protocol we would use for FDA clinicals that we want to start as soon as possible.

Well, you know the issue we encountered in that process. What you may not know is that the concept of the HandiLab Chlamydia technology is unique in that it does not test for the presence of the chlamydia organism; it tests for the presence of an enzyme that the human body produces only in the presence of the chlamydia organism. This makes the lab approach to validation very different from any standard validation procedure.

Rather than ordering several strains of chlamydia and testing them on the device, the lab must order the organisms, grow them on human tissue cells and then test for the presence of the target enzyme. A validation process like this depends on quite a few variables. You must use the right strain of organisms, they must be viable enough to grow dependably on human tissue cells and they must grow to an adequate concentration in order to produce enough target enzyme to be detected by the device. The more variables a process has, the less likely it will succeed the first time. We are working closely with the lab through management of each of the variables so that we can confirm the performance of the new-fill device and perfect the protocol we will use in the FDA clinicals.

So, as a quick review, in this first year we have:

- Cleaned up all product labeling and translations worldwide to comply with European Union requirements
- Begun the process to acquire a CE certification under our name so we can better manage our ex-US distribution and regulatory compliance
- Established a quality system required for all regulatory clearances
- Completed a product improvement that will enhance ease-of-use and address identified customer needs
- Identified and hired a first-quality regulatory consultant firm to guide us through all these crucial processes
- Initiated validation studies to confirm the performance of the new device design and prepare for FDA clinicals
- Identified and negotiated an agreement and detailed process with a Clinical Research Organization to conduct and manage the FDA clinicals on the HandiLab Chlamydia product
- Issued a Request for Proposal to selected European distributors to establish a Master Distributor for our ex-US business
- Selected and negotiated the terms of a Master Distributor agreement with LETI Laboratories in Barcelona Spain
- Identified the ThyroTest device as a potential product for acquisition
- Negotiated an acquisition plan
- Conducted due diligence on ThyroTest including an in-depth evaluation in the clinical laboratory – results are looking great! We will provide the data soon

The next steps to complete over the coming weeks include:

- Releasing the preferred placement memorandum
- Raising the financing for the acquisition and operating expenses
- Finalizing the chlamydia validation studies
- Releasing the results of the ThyroTest evaluation
- Completing the ThyroTest acquisition and preparing for the product launch
- Finalizing the Master Distribution Agreement and prepare for re-launch of products to European distributors
- Successful completion of the quality system audits

Some of the projects we expect to accomplish after the first of the year include:

- Apply for CE certification for both HandiLab and ThyroTest
- Begin FDA clinical trials for HandiLab Chlamydia
- And last – but definitely not least – generate revenue!!

Our stockholders have been incredibly patient and supportive of us. We certainly intend to repay that trust with strong products, good business practices and an excellent return on investment. As all of this is achieved, we are committed to keeping shareholders informed on our progress, including in future issues of our corporate newsletter.

Best regards,

Vera Leonard,  
Chief Executive Officer  
CLX Medical, Inc. and Zonda, Incorporated

# CLX Medical Reports Changes to Articles of Incorporation in Preparation for Execution of Acquisition Strategy

CLX has filed a Schedule 14C Information Statement with the SEC reporting majority shareholder approval on proposals that effect the capital structure of the company. The changes were initiated by the company's Board of Directors in order to properly position CLX to execute an acquisition strategy over the next several months.

The information statement reported to stockholders of CLX Medical that a special meeting of shareholders was held on July 25, 2008 at the company's corporate offices. At that meeting, principal shareholders, who collectively represented 64% of the common stock outstanding as of the meeting date, were either present or voted in absentia.

The two proposals to amend the company's Articles of Incorporation considered at the special meeting were: 1) to consider and vote upon a proposal to increase the number of shares of capital stock that the company is authorized to issue to 5,000,000,000; and 2) to consider and vote upon a proposal to effect a reverse split of the company's common stock at a ratio of up to one-for-two thousand during the twelve month period following the date of the special meeting of shareholders. All of the principal shareholders represented at the meeting voted in favor of the proposals. Accordingly, no proxies will be solicited regarding the proposals.

In the 14C, it is reported that the CLX Board believes that the increase in the number of authorized shares is in the best interest of the company in that it will provide available shares which could be issued for various corporate purposes, including acquisitions, stock dividends, stock splits, stock options, convertible debt, and equity financings. The filing also expresses the Board's belief that a future reverse split may increase the trading price of the common stock generating greater investor interest, thereby enhancing the marketability of the common stock to the financial community. In addition, the resulting reduction in the number of issued and outstanding shares of common stock, together with the increase in the number of authorized shares of capital stock, will provide the company with additional authorized but unissued shares which could also be utilized for various corporate purposes, including acquisitions or mergers, stock dividends, stock splits, stock options, convertible debt, and equity financings.

CLX recently announced that it has entered into a letter of intent with ThyroTec, LLC to acquire ThyroTest®, a rapid thyroid stimulating hormone screening device used for the detection of hypothyroidism in adults. CLX will now proceed toward a definitive agreement for the acquisition of ThyroTest, which would be positioned in a wholly owned subsidiary of CLX.

CLX is considering additional potential acquisitions in the medical diagnostic testing market segment, and these amendments are expected to provide the company with sufficient flexibility to execute its acquisition strategy.

Robert McCoy, chairman of CLX, said, "We are confident that with flexibility provided by passage of the proposals contained in the 14C, CLX is poised to successfully execute an acquisition strategy designed to significantly enhance the future potential of the company. While we continue to devote the appropriate amount of time and resources to the development of Zonda's chlamydia test, CLX is concurrently pursuing the acquisition of additional medical diagnostic testing products that the CLX management team believes have the best worldwide market potential. The proposals approved will provide the framework to allow this acquisition strategy to be implemented."

# ThyroTest Announced as Planned Acquisition Target for CLX Medical

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ThyroTest® is FDA cleared and has also achieved CLIA waived status, so the test can be administered in the more than 100,000 CLIA waived doctor's offices in the U.S., as well as in any non-waived laboratory. The simple rapid diagnostic test is a qualitative measurement that allows physicians to screen adult patients for hypothyroidism in approximately ten minutes with a whole blood sample.

Hypothyroidism develops when the thyroid gland does not produce enough thyroid hormone to properly regulate the body's metabolism. A lack of thyroid hormone affects many body systems. The incidence of hypothyroidism tends to increase with age, with older people, especially women, at highest risk. Common symptoms of hypothyroidism include weight gain, fatigue, mood swings, weakness, dry and coarse skin and hair, hair loss, depression, decreased libido, trouble swallowing, increased cholesterol, heavy or irregular periods or trouble getting pregnant.

Approximately 120 million thyroid-related lab tests are performed in the United States each year. At an estimated average cost of \$40 per test, the U.S. market is currently valued at nearly \$5 billion. Approximately 45 million of those tests are conducted in order to diagnose thyroid dysfunction. CLX believes that ThyroTest® is an appropriate, cost-effective first-step for those 45 million diagnostic TSH tests. This current U.S. market opportunity is amplified by the CLIA waived status, which makes the opportunity to meet American Thyroid Association recommendations for screening every individual at age 35 and every five years thereafter a reality.

## CLX Appears at AACC Annual Meeting and Clinical Lab Expo in Washington, DC

CLX Medical recently updated shareholders on its successful attendance at the American Association for Clinical Chemistry (AACC) Annual Meeting and Clinical Lab Expo held July 27-31, 2008 in Washington, DC.



Among the more significant accomplishments achieved by CLX Medical management at the event was reaching an agreement with LETI Laboratories of Barcelona, Spain to serve as the sole importer of CLX's subsidiary products into the European market. (See article on page 3 of this newsletter). In the meetings with LETI, a marketing strategy for European sales was established.

CLX Medical also met with the current owner and the manufacturer of ThyroTest, and the two companies have reached agreement on acquisition terms and on a timeline for definitive agreement and the close of the acquisition (See article on page 1).

The AACC event was held from July 27-31 at the Walter E. Washington Convention Center in Washington, DC. AACC's Clinical Lab Expo, the largest gathering of laboratory industry companies in the world, was anticipated to include 1,800 booths and 650 exhibitors. The Expo allows visitors to see and speak to world-leading companies about the latest developments in laboratory medicine. More information on the event can be found at <http://www.aacc.org>.