

Q&A with Ms. Vera Leonard,  
Chief Executive Officer of CLX Medical, Inc.  
Conducted: August 13, 2008



*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.*

**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.

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**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 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.

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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, 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.

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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.

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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 Chlamydia and ThyroTest products
- 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 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.

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