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# Low-Level Laser Therapy Creating Photochemical Effects to Treat Fat Loss, Onychomycosis, Pain, Toenail Fungus and Plantar Fasciitis

***Steven C. Shanks***
*President*
**ERCHONIA CORPORATION**

**BIO:**
Steven Shanks, the President of Erchonia Corporation; stands at the forefront of medical innovation and the growth of low level laser technology. He has spent the last 20 years advocating and promoting bio-modulation as an alternative modality to invasive procedures and primary treatment. A calculated risk taker, with profound understanding of clinical research, he has devoted his knowledge to researching applications that advance safe, effective and non-invasive medical technology. Even with the numerous FDA issued market clearances to his credit, all awarded based on FDA IRB approved Level 1 clinical trials and the creation of a new product code OLI, Steven Shanks continues to look for opportunities where low level laser as a medical modality can improve healthcare and the quality of life.

**CEOCFO: *What is the idea behind ERCHONIA?***
**Mr. Shanks:** We are a research development company. Our core technology is low-level laser therapy. We conduct research to determine the effect of low level lasers on the body and develop treatment protocols based on the research. From there, we do clinical trials on human subjects, similar to what drug companies do; in order to obtain new indications for use from the FDA.

**CEOCFO: *Would you tell us about laser therapy?***
**Mr. Shanks:** Erchonia promotes low-level therapy or non-thermal laser therapy. Most people are familiar with heat lasers that obliterate tissue. Low-level or non-thermal laser therapy stimulates the tissue without causing damage. The effects on the cells are similar to the basis of a medication. With a drug, you are going to get a biochemical effect and many side effects. With non-thermal lasers, you will obtain a photochemical effect and depending on the wavelength, usually red, green or violet, different photochemical effects will happen. The benefit of non-thermal laser therapy photochemical effects are you can go directly to the site. You can get phenomenal results, and there are no known side effects.

**CEOCFO: *What are some of the areas you are tackling?***
**Mr. Shanks:** We have a number of FDA clearances, each obtained through clinical research. We obtained our first FDA clearance in 2002 on chronic neck and shoulder pain; then in 2004 and 2008 we received post-surgical pain indications from the FDA. Erchonia has seven indications for non-invasive fat reduction that we received from the FDA from 2010 to present day. The most recent indication for use was FDA cleared in June of this year for Onychomycosis or toenail fungus.

**CEOCFO: *Would you tell us about that product?***
**Mr. Shanks:** The Lunula Laser is FDA market cleared to treat toenail fungus. We use two different wavelengths with this laser in order to target the fungus and obtain clear nail growth. To prove efficacy in our clinical trial we measured “clear nail” growth. Erchonia submitted clinical data three times to the FDA and finally received this new indication in June 2016. It took us about seven years of clinical research to get one indication for toenail fungus, but the final results were worth it -- The FDA success criteria was a minimum of 3 millimeters of new clear nail growth at 6 months in 60% of the patients. Our results were an average of 5.18 millimeters of new growth in 67% of the patients in 6 months so we easily obtained the FDA success criteria.

**CEOCFO:** ***Why does low laser treatment work and what do you understand that others may not?***
**Mr. Shanks:** When developing a treatment protocol, whether by a drug or a low-level laser, we focus on the photochemical effect of the body. We have done research at several universities where we identified the photochemical effect three different wavelengths have on mitochondria production, TNF-alpha (Tissue Factor-alpha), which is inflammation into the tissue. We have looked at laser Doppler, where we can get blood to the area. We then apply the cellular effects from each wavelength based on this research; we then select the wavelengths that will result in the desired affect for the condition to be treated. For instance, we just started a clinical trial on Alzheimer's disease based on a completed pilot study. Knowing that I can reduce inflammation and stimulate neuron function with red lasers, we will then mimic the pulsing of what a normal brain operates at (alpha, theta, beta waves, etc.) and that is how we develop protocols. From there we perform research and compare the laser to placebo LED to see if our theory is correct.

**CEOCFO:** ***You mentioned a wide range of medical areas. How do you decide what to look at next?***
**Mr. Shanks:** We consider market, medical need, doctor request and building upon and following what was learned from previous research. At present, fat loss as an indication, is as viable as its application is extremely widespread. It is also a natural progression for the research we have conducted since 1999, when attempting to make liposuction less intrusive. In the fat reduction industry is probably one of the largest markets out there, and it is one where there is a possibility for return on investment. We try to go into those markets where we have the best chance of success.

**"We believe low-level laser is the future of medicine." - Steven C. Shanks**

For medical needs such as brain diseases, even being new to us, we have done pilot studies on Parkinson's disease and Autism. Typically for new a medical area, we conduct pilot studies in order to observe the results and determine viability. Once successful results are obtained, we take those to clinical trial. Application will depend on some of our basic research, what we have looked at in the past and as we get through a pilot study, we will look at what the results are. We will then take those results and go through a process with the FDA called Pre-IDE where we say we figured out what it will take to get FDA clearance for an indication. We work out the protocol with the FDA and from there, we to go to clinical trial.

Erchonia is extremely fortunate. We have many brilliant doctors come to Erchonia with requests to explore a diverse number of research projects. We usually have anywhere from six to eight research projects going on at any time.

**CEOCFO:** ***There are many people in the non-invasive fat loss arena with many claims. Why is the ERCHONIA approach valid?***
**Mr. Shanks:** In non-invasive fat loss, there are two different kinds of science. Everyone has heard of Cool Sculpting by Zeltiq. It is one of the bigger players in the market. It is a publically traded company. Their indications are to affect appearance of fat loss. Affecting appearance is the lowest form of science that you can prove. To get an appearance claim is simple; basically you have someone say they treated one flank and did not treat the other. Then you ask, "Can you tell which one was treated?" This is how success is measured. It is not compared to a placebo which is the gold standard. If you look at the Zeltiq research, it is based on what they say is a 22% fat reduction, but what they do not tell the consumer is that the 22% is a 1.8 millimeter fat reduction off a fat pad according to Dover on their website, which is not much. The clinical trials that we do are Level 1, blinded and controlled. We have a treated group and we have a placebo group. Our fat loss laser can take 3 ½ inches off your waist, hips and thighs with the red laser in two weeks, compared to placebo. Those are reduction claims. We have seven different indications for reduction claims with the FDA for fat loss. My latest device, I took over the counter (OTC). When you look at science, what is the difference between fat loss and affecting appearance? Some of that stuff gets lost in marketing. What people do not understand with the FDA is 90% of all devices, when they get their 510(k) marketing clearance, they have submitted no data. Of the remaining 10% that due submit data, virtually none of it is blinded and controlled. Depending on what the FDA requires, most all of our clinical trials are blinded and controlled. We do the same clinical trials that drug companies perform, but have a smaller sample size. To date, we have reported no side effects.

**CEOCFO:** ***Do providers want an ERCHONIA product? Do they know the company?***
**Mr. Shanks:** We have been in business since 1996. We were the first company to get a low-level laser through the FDA in 2002. Now we have thirteen different indications through blinded and controlled clinical trials. We are a small research development company. We are known in the pain management market, but we are getting more and more known for our research. We have been published in over 20 peer review journals and textbooks.

**CEOCFO:** ***Are all the products something that a provider would use as opposed to something a person could use at home?***
**Mr. Shanks:** Most of our devices are by order of physician through the FDA except our Zerona Z6® device. The Zerona Z6 is over the counter, which does not require a doctor's supervision. We decided to take this device OTC to go after the tanning market which is kind of getting beat up because of the carcinogen effects that the FDA has claimed for tanning. We are working with some of the tanning chains to put our Zerona Z6 in them to give another form of income. We market to Plastic Surgeons, Dermatologists, Physical Therapists, Podiatrists, Chiropractors and Obesity doctors.

**CEOCFO:** ***With the toenail fungus product, would people anticipate this being a first line treatment or might people eventually turn to a provider because they have tried other methods?***
**Mr. Shanks:** Yes. Currently high powered lasers are being used to treat toenail fungus and many of the patients are diabetic and cannot feel their toes. If you apply a hot laser to a diabetic foot, you do not know if you are burning the patient, and there is an increased risk of getting an infected wound. Hot lasers also vaporize tissue, making fungus spores airborne. When you can smell the smoke you are breathing in some of the fungus.

With most of the drugs used to treat this condition, you have to do liver tests, before, during and after treatment. We have a patent on the process of using low-level laser to treat toenail fungus. The results are very good, and there are no known side effects. Additionally, if you used a Laser Doppler, which measures blood flow, directly after the Onychomycosis treatment, you would see the blood being delivered to the foot. Erchonia sees this as a two phase treatment which not only kills the fungus but makes the toenail grow out clearer. The treatment is unique in its application, and it is a different way of looking at toenail fungus treatments. Since we just received the market clearance from the FDA, we are going to start educating doctors on the efficacy and safety of the Lunula Laser for toenail fungus. We think this will be a huge success. We have sold probably over a hundred devices in Europe this year so we think this indication will be a front line treatment.

**CEOCFO:** ***How do you reach potential customers?***
**Mr. Shanks:** We do many of our own trade shows. We are also present at most of the medical conferences, whether they are in dermatology, plastic surgery or podiatry and we have our own general pain management seminars where we reach out to the chiropractic market.

**CEOCFO:** ***Would there be a one-time treatment or an ongoing series of treatments?***
**Mr. Shanks:** Most of them are a series of treatments. Typically for fat reduction, it is six treatments over 2 weeks or you can treat 1 time a week for 6 weeks. The toenail fungus is one treatment a week for four weeks. For plantar fasciitis, it is six treatments over three weeks. For post-surgical pain, we usually just do a pre-treatment, a post-treatment and follow the pain over a month. Laser treatment times are influenced by acute and chronic conditions. Acute treatments like post-surgical pain respond quicker, so there are fewer treatments. Chronic conditions such as toenail fungus, plantar fasciitis and low back pain require more treatments over time and are harder to treat so our clinical trial follow up is much longer.

**CEOCFO:** ***Is the device easy to use in general for the providers?***
**Mr. Shanks:** With the newer laser devices like Zerona Z6 OTC, Verju, Lunula and FX 635, we are using many scanning techniques that are unattended. The doctor positions the laser on the treatment area, then presses a button and the treatment is performed. This saves time and money.

**CEOCFO:** ***Your site indicates ERCHONIA is the world leader in low level laser technology. What is your geographic range, and where do you see growth?***
**Mr. Shanks:** We are in most countries except for China, which we hope will happen later this year. We have sold in Europe, Brazil, Canada, Australia and North America. We are working on several other countries, which have to go through the regulatory process to begin marketing.

**CEOCFO:** ***What is next?***
**Mr. Shanks:** We are getting heavily involved in brain diseases. Currently we are in the process of performing clinical trials for Alzheimer's disease, Autism, post-surgical pain following neck and low back surgery and peripheral neuropathy pain in diabetic patients.

**CEOCFO:** ***How have you maintained the cultural and principles of a small family business?***
**Mr. Shanks:** My business partners are my brothers John, Charlie, Mark and Kevin Tucek. We have been in business for 20 years. This is a family business with many of the employees' last names being Shanks or Tucek. My Dad when he was alive really kept all of us close. It is the only way we know how to do business and work together. It helps that we have each other to rely on when things get tough.

**CEOCFO:** ***Why pay attention to ERCHONIA?***
**Mr. Shanks:** We believe low-level laser is the future of medicine. We feel that we can accomplish as good or better results than pharmaceutical intervention without side effects. That is why we tag ourselves as the world leader in low-lever laser technology. There are 15 indications for low-level laser right now, and ERCHONIA has 13 of them. We have a history of science publications and FDA indications, so people need to start paying more attention to this technology. The problem we face right now is doctors were not taught this in school, and it is really hard for them to wrap their minds around this technology. They don't know how shining a laser that you cannot feel works. In my opinion, this requires lots of cellular research and many Level 1 clinical trials trying to get new FDA indications.

**Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine**

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