Guided Therapy Systems Keeps Options Open on Tissue Regen Device

Scalpel or sound wave to treat musculoskeletal and sporting injuries? Mesa, AZ medical device innovator Guided Therapy Systems, LLC (GTS), claims it has developed a revolutionary method of treating conditions like plantar fasciitis, epicondylitis and tendon injuries that is superior to laser, radio-wave or other energy delivery devices.

Revolutionary because the device, Actisound, introduces intense therapeutic ultrasound (ITU) guided by ultrasound imaging in a device that offers a quicker, safer, cheaper way of noninvasively repairing tissue. Its action enables concentrated energy deposition to occur deep inside skin tissue, which initiates the healing response and stimulates tissue growth, all without breaking the skin.

This novel therapy is set to enter a lucrative market. To give an idea of the potential territory at stake, Meddevice-tracker’s report U.S. Markets For Sports Medicine Products https://www.meddevicetracker.com/ViewReport.cfm?ReportID=25 notes that of the 200 million adults who participate in non-work-related sports or recreational activities in the US, nearly 5 million receive medical treatment for sports injuries including sprains/strains, dislocations/fractures, knee injuries, shoulder injuries, and muscle/tendon tears every year.

In 2013, combined sales of sports medicine products in the US totalled approximately $13.0 billion, of which conservative care products accounted for 81% of sales. Combined US sales of sports medicine devices are expected to increase at a compound annual rate of 3.5%, reaching nearly $15.5 billion in the year 2018.

GTS’ Actisound, developed over a period of more than two decades by serial innovator, engineer and entrepreneur Dr Michael Slayton, PHD, is set to become a major solution in tissue repair, firstly in the private sector and later in the public sector, upon being reimbursed.

IN VIVO: How disruptive is the technology that you are developing for soft tissue repair?

Michael Slayton: That’s difficult to say, as very disruptive technologies do not come along very often. What we’re trying to do is repair soft tissue. We’re not trying to get something into the body—not yet anyway—we simply help the restorative or rejuvenative mechanism of the tissue. The Actisound intense therapeutic ultrasound (ITU) device noninvasively creates small incisions/lesions—small zones of thermal injury—that restart and enhance the production of endogenous growth factors in connective...
tissue. In short, the immune system responds faster and well when there is an area that is repairable.

It works by encouraging natural soft tissue repair cascade and peaks inflammation. Next, the fibroblasts migrate into the targeted area, leading to the formation of collagen. Then there is maturation and a remodelling phase in which the new collagen converts into fibers, and formation of collagen fiber cross-linkage in the final stage of the repair process. The final stage is the formation of new musculo-skeletal tissue and the repair of the damaged organ. The idea is we try to repair things that don’t need open surgery, and if we do things right, it’s curative not a palliation.

IV: How far have you progressed with trials of the technology?

MS: We have been involved in three trials to date, two of which are fairly complete. We selected plantar fasciitis (PF) and epicondylitis, as they are prevalent conditions.

The first trial, at the University of Arizona, was in PF, which affects 10% of the US population. It was double blinded and sham-controlled. We recruited 50 people and have already published the results of what from our point of view was a very successful trial under principal investigator Dr Daniel Latt, Orthopedic Surgeon and Professor at the University of Arizona Medical School. We used chronic patients (we did not involve people with acute injuries) who had had PF for 12-18 months: it was hurting a lot and/or they couldn’t walk. The disease becomes chronic as there’s not enough blood supply going through the MS tissues—it’s poorly perfused. We had an over-80% repair rate within 12 weeks post-treatment—an over-80% repair rate is statistically significant and is testament to a disruptive device.

The second trial is in 30 people with epicondylitis (tennis elbow). We are working toward completing it at The CORE Institute, Phoenix, Arizona. It was conducted to explore the success of ITU technology on lateral epicondylitis, which affects up to 3% of the population, and chronic problems in tennis players can occur in 40% of cases. The efficacy rate—in what is a much smaller muscular structure—is about the same as we saw in the PF trial: 83% of the first 18 patients reported improvements in elbow pain when ITU technology was applied. They also showed significant improvement in daily function.

IV: What setting are you targeting for use of the device?

MS: Our primary market is orthopedic surgery. We plan to introduce Actisound into the professional setting—for the most part the non-hospital setting. The primary market is orthopedic surgeons and podiatrists; the secondary market is GPs and secondary providers. At the top of the pyramid are the people who feel comfortable and know what they’re doing. There are no user/skill issues to worry about. It is a relatively simple device. It doesn’t have to be “idiot-proof”, but we’ve built in precautions and a safety valve such that the damage that could be created is minimized to a point where it’s not a regular concern at all. Basically it’s a turn on/off device, which the user moves up and down the damaged area.

IV: What size is the market you are addressing?

MS: A market study (by J&J) reveals a market that’s very large—over 18,000 potential users/practitioners in the US alone. Normally, double the US market to get an approximation of the worldwide market. If we get 5-10% penetration—which is a moderate goal—we’ll be in pretty good shape. The most valued commodity for any physician is their time, and that’s the simplicity of using this device: the procedure takes just a few minutes.”

We are now starting a third trial, in 30 people, at University Foot and Ankle Institute in Los Angeles which is also in PF. We are doing this one in order to get the numbers up for the regulatory submission. We want to avoid any uncertainty there. Regulatory submissions have become pivotal; it’s no longer enough to make some-thing that works, but FDA usually looks favorably on well-designed trials that have more than 50-100 people and a good safety profile. The trial schedule is six months, and there will be a further month to gather the data together—so it will be completed within this year.
strength training, or advice about staying off the leg. After a few months, it usually eases up, but it may or may not heal. The problems start when it doesn’t heal. Tenotomy is then usually brought into play—a minimally-invasive technique of using needles to create a lesion. For the most part it works. The alternative is shockwave therapy, but that is marginal and works in, say, only 30-40% of cases. It’s not bad, but then again it’s not very good. After you’ve exhausted all of those options, the patient basically has to face that they’re living with a chronic injury.

ITU can penetrate safely through tissue and delivers precisely targeted heating while sparing intervening tissue, unlike lasers, microwaves or radio frequency. ITU technology is a cost-effective, fast and relatively pain-free treatments that leads to reduced pain and inflammation within 2-3 days and soft tissue injury repair within 12 weeks.

Actisound is being tested on ligaments, tendons and muscle, and apart from PF and lateral epicondylitis, initial indications include Achilles tendon and patella tendon injury.

**IV: What is the regulatory plan for the device?**

**MS:** We may be a US-based company, but we’re not starting with FDA. We’re starting with the CE mark. We have several CE-marked products. We also have extensive FDA experience, but FDA changed dramatically last year: the straightforward path for substantial equivalence has been made less easy —now you have to file an IDE, and the FDA needs to confirm the protocol.

**IV: How will you move Actisound into the market?**

**MS:** There are two ways to get into the market. The first can be likened to ‘selling your soul’—basically going to a major company and giving them the product and the regulatory package. They sometimes move you to one side, to take greater control, do some of their own work on it over a couple of years and if there’s enough movement, it hits the market big time.

The second route is to go with SMEs, which generally don’t have time to sit on a product. If it’s too big for them to handle, they might get bought out. The majors want the success, but they also want the risk to be taken out even if they have to pay a premium. Our goal is simple: to get to the market and make the product available. In my experience, if something works, it usually finds its way to patients.

We’re preparing to go ahead with the device this year. Depending on what we hear from customers, we’ll go one way or the other—either direct sales or via a partner. That will be a matter of tactical approach.

**IV: To public sector reimbursement, is that in the plan yet?**

**MS:** The device is not very expensive, and reimbursement is not a major factor at this point, but it would be up ahead if we were to go with a company the size of a Stryker or DePuy—which is quite possible. The strategics, with their dedicated departments, have more ‘oomph’ than we would as far as reimbursement is concerned. Reimbursement tends to become a big part of a selling strategy when capital-intensive and extensive procedures are involved. In those cases, without reimbursement, you can’t move. Fortunately we’re more dynamic than that, and reimbursement for us is important, but not critical.

**IV: What category of partners are you looking for as you move towards market launch?**

**MS:** Not necessarily just distributors. We have several strategies “on the leash” at this point. They say: finish it; give us the package and we’ll go from there. But we don’t want to be dependent on somebody giving us a letter of intent and then saying they need six months to figure things out.

If we had the alternative of a small company that combines manufacturing with a distributorship in, say, Ireland or the Czech Republic, we’d go with that. You have to keep a range of options or basically you become subservient to whomever.

As to manufacturing, we can manufacture in the US ourselves at present, as the volumes are not yet huge. But I’ve convinced that eventually we’ll go for manufacturing in Europe if we start with Europe—about that there is no question in my mind.

Ideally, we would opt for a technically astute partner—regardless of size (within reason)—whom we can rely on. And we are only at the first clinical applications. Just looking at musculo-skeletal, there is jumper’s knee, shoulder tears etc. There are so many things we can fix that it simply boggles the mind. And later, we’ll have drug delivery too. I want this treatment to become pervasive.

**IV: You have experience in Germany: will that be the starting point in Europe?**

**MS:** We have several relationships in Germany—and I also worked for Dornier in the past—so it’s not an
unknown territory. But the borders are blurred in Europe, and it’s not as geographically well-defined as it used to be. Germany is not necessarily the answer for the whole of Europe—it is part of Europe. We would not be focused on Germany to the exclusion of France and the UK, say. We also have contacts in the Czech Republic, France, the UK and other countries. If we were to opt for the distributor route, it’s an arrangement that usually covers several countries. We might also consider going the “big” route, and teaming up with US tax inversion companies that are now headquartered in Europe—and maybe use one or two of them for Europe. We’ve already started to talk to small/medium-sized companies in the $50-100m sales range—and even those up to $200 million. We are trying to see who has right level of hunger that matches our expectations. At the risk of sounding trite, you have only one chance to make the first impression.

“By the time a product has been approved, you’d have had a couple of thousand users vouching for how good it is.”

IV: Why has such a compelling technology taken this long to get to the market?

MS: For us, we must finish the clinicals, start the pre-production runs (which are already underway), and we need to start the submission. It has to take its course—and we want to do it right. We’re talking about more sophisticated technology, with drug delivery potential that combines medication and energy sources, so it has to sit on a base of good solid clinical practice, and that’s what we’re going for.

We’re investing heavily into this, and as we said, we’ve been doing this for the better part of 22 years. But as to investment, we’ve learned our lesson by now. We used to do deals with VCs, but we no longer want to be dependent on outside sources of any kind. We’re in a position to invest ourselves, so we do, and that gives us a control over timings. It gives us a bit more control over what we own rather than always having to look over our shoulders.

As to our sales model, I don’t see any departure from the traditional model. And looking at price, we’ll review the results, clinical possibilities, and the patient population. The price is defined by the cost of goods, and will probably be set at what the market can bear. A broad guess would be in the $25,000 to $35,000 range.

We see Actisound as an affordable, effective, and logical patient-centric technology. We don’t have a competitor at this point—there is no effective noninvasive alternative on the market that allows doctors directly to treat soft tissue injuries without breaking the skin—but that does not concern me. I simply want people to know about the innovation we’ve developed for the musculoskeletal space, and athletic sector in particular, and I want them to consider adopting it. I want people to know about this technology that we’ve been working on for so many years. We’re a small company that has done some interesting things, and this latest one is very worthwhile, as far as I’m concerned.