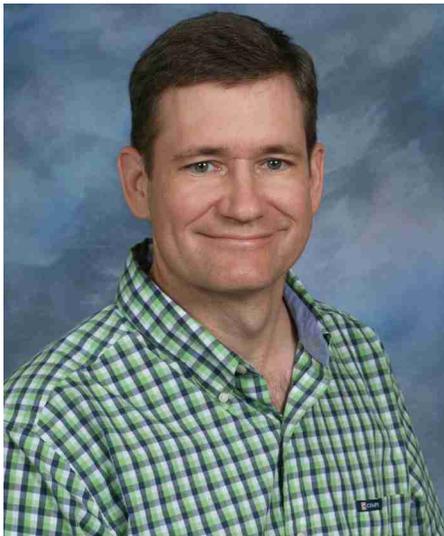




Now in First in Man trials for their Nonsurgical Treatment to Repair Intervertebral Disc, Orthoepuotics, L.P. is offering a better Solution for Degenerative Disc Disease and Similar Problems with Soft Tissues that dramatically reduces the Cost for Care

**Healthcare
Soft Tissue Repair**

**Orthoepuotics, L.P.
1501 Bull Lea Rd., Suite 103
Lexington, KY 40511
512-818-8468
www.orthoepuotics.com**



**Tom Hedman
CEO**

BIO:

Thomas Hedman, Ph.D., is the founder and current CEO of Orthoepuotics, L.P. and an officer for several other medical technology startups. He is also an Associate Research Professor at the University of Kentucky with a focus on translational research and technology commercialization. The treatment strategy pioneered by Dr. Hedman involves direct chemical modification of collagenous soft tissues to treat mechanical and nutritional deficiencies. His research team has shown that this approach can

revolutionize the care for a wide variety of soft tissue disorders while also dramatically reducing treatment costs. Dr. Hedman has more than 65 peer-reviewed publications. He holds more than 30 issued or pending US and international patents and has received research funding from the NIH, the Arthritis Society of Canada, the Kentucky SBIR-STTR Matching Funds Program, angel investors, and numerous orthopaedic medical device companies.

About Orthoepuotics, L.P.:

Orthoepuotics, L.P. was founded in May 2004 to further develop and commercialize revolutionary nonsurgical solutions for common orthopaedic problems. Orthoepuotic's current focus involves a path-breaking, nonsurgical treatment to repair the intervertebral disc, dramatically reducing disc degradation and spinal joint instability.

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

CEOCFO: Mr. Hedman, what was the vision when the company was started and where are you today?

Dr. Hedman: When we started, our focus was primarily on providing an injectable, non-surgical means of treating degenerative disk disease and low back pain. We were trying to avoid the expenses and the poor performance of current surgical modalities of treating intervertebral disc, and we came up with a better plan, a way of modifying the spinal disk tissue such that we were able to repair the disk and restore the mechanical prop-

erties. We found along the way that we were also in a big way benefiting the disk's nutritional requirements by doubling the transport of nutrients into the disk and waste products out of the disk.

CEOCFO: What is happening at Orthoepuotics today?

Dr. Hedman: We have determined that this is a very effective means of treating many avascular soft tissues. There seems to be a common theme with avascular soft tissues degrading, being very difficult to treat with conventional methods as well as with any sort of biological approach because of the nutrient deficiency inherent in these tissues. We have found that we are able to immediately, via chemical cross-linking, modify the mechanical behavior of these tissues and restore their functionality. At the same time, we are able to improve that nutritional condition so that there is perhaps a chance that a biological approach would be effective and long lasting. We have found that there are numerous other applications that fit this technology very well including similar tissue in the knee meniscus and we are looking at applications in areas such as the soft palate, tendons, ligaments and the like.

CEOCFO: What are the protocols that you would be replacing?

Dr. Hedman: In the spine, we have done a study of the instability in a spinal joint that is created by a discectomy procedure that is very common, perhaps the most common surgical procedure, to decompress neural tissue in the spine. There is unfortunately a destabilization of the joint

that occurs. We found that we were able to restore the stability of the joint with our treatment post discectomy. We also feel that this is the right approach for early-stage degenerative disk disease where the degradation of the disk is at that point minimal, but there is the likelihood of decades of increasing problems at that particular spinal joint with the wear-and-tear of life. We would be able to go in, improve the disk functionality and avoid the degradation and the accompanying pain that would result from chronic low back pain.

CEOCFO: Do most people catch the problem early enough today to have your treatment be of value?

Dr. Hedman: On the other end of the spectrum, we believe that this treatment, because it has shown itself to provide dramatic stability to an otherwise unstable joint, and is able to reduce disk bulge and prevent ongoing disk bulge and tearing, also has a place with later-stage disease. Therefore, we are not bound to the early-stage situation. We feel like this treatment provides in a sense a “flexible fusion”, or a flexible stabilization of the joints where we constrain the aberrant motion and preserve the motion that is necessary to keep that joint and all of its surrounding tissues healthy. We do believe there is also a place for this technology in later-stage disease. Early-stage disease may not be caught by the clinician. However, when it is detected early in the progression of degenerative disk disease, because we are not burning any bridges-- we are not doing surgery, we are doing a simple procedure that could deal with the problem right then, but it is also going at the core issue of the mechanical insufficiency of the joint-- we feel like it would be the right approach in early-stage disease.

CEOCFO: Where are you in the development process?

Dr. Hedman: We spent a great amount of time testing this very revolutionary approach, so we have had to answer every question that came up, from toxicity to different applications to quantifying things like disk bulge

and increase of nutritional flow to the disk and so on. After years of testing and some NIH grants supporting us, we are now beginning FIM trials, the First in Man clinical trials. We haven't yet injected this into humans for the first time and before we do that, we want to perfect our injection techniques, translate what we can do very well in the laboratory into the clinic and then start with the small human study. On the other applications, they are in various stages of development. In treatment of horse tendons and ligaments, we are producing product and close to product sales sometime next year.

CEOCFO: Has the medical community paid attention?

Dr. Hedman: I think the clinical community is familiar with this technology in that we have presented it at numerous national and international spine conferences. The large medical

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device companies are generally aware of this technology but like to see that first clinical data before they are willing to get interested and to potentially get on board or acquire the technology. The enthusiasm for say biologic approaches to the disk has been much greater and maybe one hundred times as much money and man hours spent looking for a biological solutions to what we think is a very biologically challenged tissue. We feel that we have a better approach that perhaps is not as glamorous of an approach, but if it works, it works. We have had a very positive response from the clinical community and the scientific community with numerous peer review publications, and others have followed suit and have peer reviewed publications. It needs to grow, but I think we have positive attention from all the different involved groups.

CEOCFO: How far will your current funding take Orthopeutics?

Dr. Hedman: We have conducted our research and grown our companies in very much of a boot-strapping model, so we have raised smaller chunks of money and reached milestone after milestone based on the smaller amounts of money that we raised. Our next step is to fund these First in Man clinical trials, which is all the money that we are looking for at this point. It is something in the realm of \$500,000 to complete our First in Man clinical trials and carry our ongoing expenses. At that point, we will do what we have done before and will make a best case decision in terms of what we are able to self-fund versus whether we need to acquire additional monies.

CEOCFO: What surprised you most as you developed the product?

Dr. Hedman: On the technical side, there have been a number of questions as well as intuition about how this would work and we have been pleasantly surprised. For instance, when we first thought of increasing the cross-linking in collagenous matrix of a disk, we assumed wrongly that there would probably be a decrease in the nutrient flow going through the matrix. We were pleasantly surprised to find that the cross-linking pulled fibers together in a sense and increased the throughput of water and macromolecular particles or larger particles through the matrix. That was one technical improvement that we did not expect. There have been a couple of those. When I started this my vision was that we would do everything here in the US, we would show proof of concept, show the potential for this technology and then be able to do our clinical trials here in the US. Along the way, the industry has changed paths and certainly early clinical trials are usually done offshore and then very often clinical trials come back here. Much of the technology development and even the early marketing is directed offshore, which presents new challenges to an entrepreneur who is starting with a small reach as a startup and needing to navigate the changing trends in the industry to con-

tinue the advancement of technology development. That has been a bit of a surprise to us and we have accommodated.

CEOCFO: Why should the business and investment community pay attention to Orthopeutics?

Dr. Heman: I think the main factor is today's medical reimbursement envi-

ronment. Having a better technology alone is probably not good enough. What Orthopeutics is able to provide is a better solution for degenerative disc disease and similar problems with soft tissues that dramatically reduces the cost for care. Our solution is far less expensive than any emerging biologic solution and we provide an immediate impact. The time to the

treatment effect is a matter of minutes and hours, not weeks and months. I think the ability to provide a less expensive treatment modality is what is needed with our current ballooning healthcare costs in this country and abroad.



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