

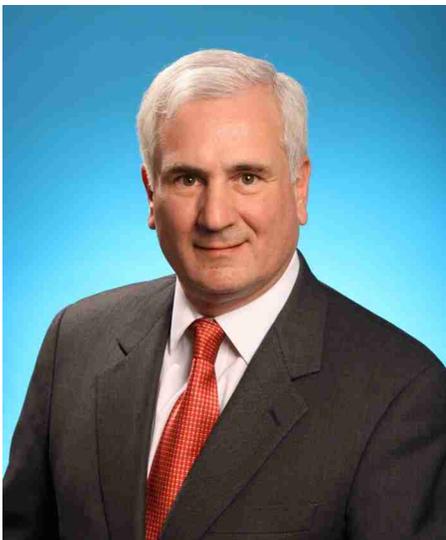
Tonix Pharmaceuticals Holding Corp. is Focused on Developing Innovative Drugs that Address Central Nervous System (CNS) Conditions

Lead Program Targets Fibromyalgia Syndrome, which Affects 5 Million Patients in the US Alone

**Healthcare
CNS Treatments
(TNXP-OTCBB)**

**Tonix Pharmaceuticals
Holding Corp.**

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**Dr. Seth Lederman, M.D.
Co-Founder, Chairman,
President and CEO**

BIO:

Seth Lederman is a physician, scientist, and specialty pharmaceuticals entrepreneur. Prior to founding TONIX, from 2007-2008 Dr. Lederman co-founded and was a managing partner of Konanda Pharma Partners, LLC and Konanda Pharma Fund I, LP. Through Konanda, he co-founded and served as director and chairman of its wholly-owned operating compa-

nies Validus and Fontus Pharmaceuticals Inc., which acquired and market Equetro® (carbamazepine – Extended Release), Marplan® (isocarboxazid) and Rocaltrol® (calcitriol). Equetro is the only carbamazepine product approved by the FDA to treat bipolar disorder. Dr. Lederman also co-founded Vela Pharmaceuticals, to develop innovative drugs to treat disorders of the central nervous system, or CNS.

A member of the faculty of Columbia University’s College of Physicians and Surgeons since 1985, Dr. Lederman maintains an appointment as Associate Professor. His basic and clinical research has resulted in numerous scientific articles and issued patents for drug development technologies.

Dr. Lederman’s fundamental research on the CD40-Ligand (CD154) elucidated the molecular basis of T cell helper function and led to the development of therapeutic candidates for autoimmune diseases and organ transplant rejection in collaboration with Biogen-IDEC and CellTech/UCB.

Company Profile:

Tonix Pharmaceuticals Holding Corp. is a specialty pharmaceutical company focused on developing innovative prescription pharmaceutical products for CNS conditions. Tonix’s core technology improves the quality of sleep in patients with chronic pain syndromes. Tonix’s lead products are designed to be fundamental advances in sleep hygiene and pain management and to be safer and more effective than currently available treatments. Tonix’s products are the result of a program to harvest advances in

science and medicine to search for potential therapeutic solutions among known pharmaceutical agents. Tonix is developing new formulations that have been optimized for new therapeutic uses.

Tonix’s lead product candidate, TNX-102, is a new formulation of cyclobenzaprine in clinical development for the management of fibromyalgia syndrome, or FM. FM is a CNS condition characterized by diffuse musculoskeletal pain, increased pain sensitivity, fatigue and disturbed sleep.

Tonix’s other leading product candidate, TNX-105, is a formulation of cyclobenzaprine to treat symptoms of post-traumatic stress disorder, or PTSD. PTSD is a psychiatric disorder that begins in the aftermath of traumatic experiences. Sleep disturbances, including nightmares and insomnia, are core features of PTSD. PTSD shares several features with FM and some patients suffer from both PTSD and FM.

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

CEOCFO: Dr. Lederman, what led to the formation of Tonix?

Dr. Lederman: Tonix was founded to develop innovative prescription medications that address disorders of the central nervous system, or CNS. Our lead program targets fibromyalgia syndrome, which is a pain syndrome that originates from a disorder of the CNS. Fibromyalgia affects about 5 million patients in the United States.

CEOCFO: Why the decision to look at

CNS disorders and fibromyalgia in particular, what is the unmet need that Tonix understands?

Dr. Lederman: My co-founder, Dr. Donald Landry, and I believe that CNS disorders are some of the most important problems confronting our society. We focus on the relationship between poor sleep and chronic pain. People with chronic pain struggle to get restful sleep. People who cannot sleep develop pain syndromes that originate in their brains. Poor sleep, this type of chronic pain, and the combination of poor sleep and chronic pain are directly or indirectly the most intractable health care problems in the United States. Humans are not equipped to function with the amount and type of sleep that modern life in the US provides. Many people have recognized that we have become a nation of insomniacs. The widespread use of hypnotic sleep drugs is a symptom of these societal problems. The chronic use of the available sleep drugs do not satisfy their craving for restful sleep.

CEOCFO: Will you explain your background to us, the medical, science, entrepreneurial, and how those things tie into Tonix and your mission at the company?

Dr. Lederman: I'm a physician and a problem solver. I trained in internal medicine and rheumatology at Columbia University, became a faculty member, and ran a basic science laboratory. When I started my career in research, the biggest problem was AIDS. At that time, the HIV virus that causes AIDS had not been discovered yet. In the first chapter of my career, I devoted myself to studying AIDS with the goal of inventing treatments or preventive vaccines. In the very first paper that described AIDS, Dr. Andrew Saxon and his team explained the syndrome of AIDS by the loss of "Helper" T cells. Since AIDS was my calling, I began a quest to understand how Helper T cells were lost and to understand "Helper Function". While I made some contributions to understanding how HIV enters Helper T cells, my biggest accomplishment was identify-

ing the molecule on the surface of Helper T cells that is the basis for Helper Function.

The work on Helper Function became the second chapter of my career because it opened the door for my team and others to characterize Helper function. This work not only increased our understanding of how the immune system works, but also led to important potential therapeutics for autoimmune diseases, which are still in development.

In the third and current chapter of my career, I started applying the physician problem-solving tools to develop therapeutics to new areas. I am drawn to decipher CNS problems by their

We are unraveling the connection between chronic pain and disordered sleep in the hope that it will lead to fundamental improvements in treating fibromyalgia and other pain syndromes. Many people are aware that there is a connection between chronic pain and disordered sleep just from common experiences. But medical science has been slow to be able to connect chronic pain and poor sleep. Sometimes an effective medicine is the best way to convince the scientific community. Tonix is developing a medicine that improves the quality of sleep because we believe that improving sleep quality, will decrease the pain and other symptoms in fibromyalgia.

- Dr. Seth Lederman, M.D.

complexity and by the enormous suffering of patients. Fibromyalgia was a compelling problem and one that challenged me directly since I devoted about 11 years to practicing and teaching rheumatology at Columbia. Even though fibromyalgia syndrome is a pain disorder that originates as a disorder in the CNS, traditionally rheumatologists cared for fibromyalgia patients. Given my personal experiences caring for fibromyalgia patients, the syndrome was a natural challenge for me as a drug developer. I should also mention another connection between AIDS and fibromyalgia. When I started work in AIDS, caring for these patients was frustrating because they all died no matter how well we managed their opportunistic infections. With better

treatments for HIV came more compassion for patients because physicians regained the natural satisfaction of having their hard work pay off with healthier patients. Fibromyalgia patients have been frustrating to manage in ways that remind me of the early days of treating AIDS patients. Fibromyalgia patients don't die, but they don't get better. When better treatments are available for fibromyalgia, I believe physicians will regain satisfaction from having their work pay off with healthier patients. When doctors learn how to treat fibromyalgia symptoms in a meaningful way, I hope it will lead to a virtuous cycle in which patients will be treated with more sympathy, compassion and dignity.

CEOCFO: What new ideas does Tonix offer as far as treating fibromyalgia?

Dr. Lederman: We are unraveling the connection between chronic pain and disordered sleep in the hope that it will lead to fundamental improvements in treating fibromyalgia and other pain syndromes. Many people are aware that there is a connection between chronic pain and disordered sleep just from common experiences. But medical science has been slow to be able to connect chronic pain and poor sleep. Sometimes an

effective medicine is the best way to convince the scientific community. Tonix is developing a medicine that improves the quality of sleep because we believe that improving sleep quality, will decrease the pain and other symptoms in fibromyalgia.

CEOCFO: What is the scientific connection?

Dr. Lederman: The connection between chronic pain and poor sleep is just being unraveled. One of the breakthroughs involves our lead compound, and was just published in the December 2011 issue of the Journal of Rheumatology. The lead author and principal investigator of the study is Dr. Harvey Moldofsky. The paper shows that bedtime treatment with an early version of our lead product im-

proves the quality of sleep in fibromyalgia patients. This treatment also improves the pain and other symptoms of fibromyalgia. Finally, the paper also shows a signature of disordered sleep in the brainwaves of patients while they are sleeping. Putting it all together, the paper shows that our bedtime medicine enters the brain, decreases a certain kind of sleep pathology, makes sleep more restful and improves the pain and symptoms of fibromyalgia.

CEO CFO: Where is Tonix in the development process?

Dr. Lederman: We are working now on an improved formulation of our product. The new formulation of our product is designed to be taken by patients at bedtime, improve the quality of their sleep and result in as little hangover as possible.

CEO CFO: Have there been other studies or other people looking at the connection between sleep or is this something that Tonix has figured out that others have not?

Dr. Lederman: The signature of non-restorative sleep was identified by other scientists and has been the subject of two or three papers by Professors Terzano and Parrino and their colleagues in Parma, Italy and connected to fibromyalgia by Professors Sergi and Rizzi in Milan. The signature of disordered sleep is called the Cyclic Alternating Pattern or CAP. We are building on their groundbreaking work. We believe our contributions are important because our lead product can decrease the pathological CAP signals, improve the quality of sleep, and improve the symptoms of fibromyalgia.

CEO CFO: What is the market potential in treating fibromyalgia?

Dr. Lederman: The market in the US for prescription drugs for fibromyalgia is over \$1 billion and growing at about 20% a year. There are three distinct segments in the market that are represented by different classes of medications. The first product that was FDA approved was Lyrica. Lyrica represents the first class of drugs that target the pain in fibromyalgia. Lyrica is a very important medication in the history of fibromyalgia, because it led

to a recognition by the FDA that fibromyalgia was a syndrome that could be effectively treated. The second class of medications is represented by Cymbalta, which was previously approved as an antidepressant. The sponsor of that product Eli Lilly has shown that there is a connection between depressed mood and pain. Our product will be the first member of a new class of medications that improve the quality of sleep. So we believe that after pain drugs and depression drugs, sleep quality drugs will be the third class of medications approved for fibromyalgia. It is hard to develop a model of to estimate that market. We retained a consulting firm and they concluded that about 150 million tablets of off-label drugs are used for fibromyalgia that could be replaced by sleep quality drugs. These 150 million tablets are approved as muscle relaxants and they do not have FDA approval for fibromyalgia. If our product wins FDA approval and is able to replace 100% of these tablets, it would result in sales of about \$900 million annually. However, we believe an effective medicine in the sleep quality category for fibromyalgia would expand the market and not just replace off-label muscle relaxants.

CEO CFO: It is my impression, just anecdotally, that nothing is really very effective yet for fibromyalgia; is that still the general feeling?

Dr. Lederman: We hope that the situation is changing. Certainly, a number of fibromyalgia patients respond to Lyrica; a number of fibromyalgia patients respond to Cymbalta; and a number of fibromyalgia patients respond to certain off-label medications. Certainly, the FDA approved medications have been shown to make a difference enough to satisfy the rigorous criteria of the FDA at least in a group of patients. However, as doctors and drug-developers we think we can do a lot better. The existing medications obviously have not solved the problem, and most patients remain unsatisfied. A large number of patients move from one medication to another. Patients sometimes get a benefit from one medication for a while, but then feel that the beneficial effect has been lost. That is when

they want to try something else. Overall, now that some medications are FDA-approved, I am optimistic that more science will be applied to the area and better therapies will be developed. We believe we are part of that evolution, if not the leader.

CEO CFO: Tonix does have a significant pipeline; would you tell us about some of the other products?

Dr. Lederman: Our second most advanced product in development is a treatment for post-traumatic stress disorder, or PTSD. PTSD is classified an anxiety disorder and is not a pain syndrome like fibromyalgia. We believe that the same treatment paradigm of improving the sleep quality might be important for treating PTSD patients. Doctors and PTSD patients have known for a long time that PTSD patients have poor sleep quality. For example, PTSD patients suffer from nightmares, which is a symptom of poor and non-restorative sleep. We think that improving sleep quality of PTSD patients might also result in some benefit for them in other symptoms. Although fibromyalgia is a pain disorder and PTSD is an anxiety disorder, some thought leaders believe that there may be an overlap between the two conditions. For example, many chronic PTSD patients become addicted to prescription pain-killers called opiates, which indicates these patients are experiencing a form of pain. In addition, a number of patients suffer from both fibromyalgia and PTSD. So it may be that our treatment paradigm will target that group of PTSD patients who have concomitant fibromyalgia. Or it may turn out that our technology would have benefit for a broader group of PTSD patients.

We also have a program in treating migraine, which is another pain syndrome that originates as a CNS disorder. Our migraine program is modernizing a drug that has been widely used by migraine sufferers in the US for more than 50 years, but needs modern manufacturing and clinical studies to bring it up to contemporary FDA standards.

Finally, we have a program to treat alcoholism and alcohol dependence.

Although alcoholism is not classified as a pain disorder or a sleep disorder, most alcoholics themselves believe they suffer from both a form of pain disorder and a sleep disorder. Although alcoholism is complex. Most physicians focus on the addictive element, get frustrated by the lack of any effective therapy, or get angry at the way alcoholics destroy relationships, families and businesses. However, our program focuses on the idea that alcoholics often use alcohol to try to manage some kind of pain and to help themselves sleep. Although alcoholics are delusional, and they may complain about poor sleep and chronic pain to justify their drinking, we believe trying to help them fits with our mission of unraveling connections between chronic pain and sleep disorders. Our program targets the phase of alcoholism, called "early recovery." That is the period after an alcohol dependent person has undergone successful detox, but is at high risk of going back to drinking again, which is called recidivism. We are working to develop drugs that will decrease recidivism during early recovery. A common excuse that alcoholics blame for falling off the wagon is their belief that drinking will help them sleep.

CEOCFO: Would you tell us about your entrepreneurial background, and how does it help you know where to focus with so much potential at Tonix?

Dr. Lederman: Vela Pharmaceuticals was the first of three successive companies that I've founded which have been based on "repurposing". Repurposing is a way of making new drugs that are reformulations of older drugs. At Vela we tried repurposing to develop novel treatments for depression, social anxiety, anorexia nervosa and other important CNS disorders. One of the repurposing projects at Vela was low-dose cyclobenzaprine at bedtime for fibromyalgia, which has now become Tonix's lead program. Vela was also very important in my development as an entrepreneur, because it introduced me to a network of clinical development experts and

regulatory experts who have followed me to several subsequent start-up companies. Whatever successes I have had in specialty pharmaceuticals has come from working together with remarkable teams of professionals. It has been even more exhilarating to work on several different projects with some of the same people. More than anything else, drug development and entrepreneurship is a social enterprise and you depend on the energy, passion, expertise and cooperative efforts of smart and gifted people.

My second notable repurposing company was Targent Pharmaceuticals which developed drugs for cancer. One of Targent's drugs was pure isomer levofolinic acid which involved some repurposing. We sold Targent to Spectrum Pharmaceuticals which now sells levo-folinic acid under the trade name Fusilev®. Fusilev was FDA approved last year for the treatment of colorectal cancer, which is obviously an important problem in the US. Treating colorectal cancer is a new purpose, since Fusilev was already approved for use in treating a rare form of blood cancer that mostly affects children.

My third notable repurposing company was Validus that markets a product called Equetro®, which is the only FDA approved carbamazepine for bipolar disorder. Carbamazepine was initially developed for treating epilepsy and was marketed as Tegretol®. The Equetro brand of carbamazepine is a very important medication for bipolar disorder, but unfortunately the vast majority of patients feel compelled by the economics of their health insurance plans to take generic carbamazepine products. These generics are copies of Tegretol, which was never FDA approved for bipolar disorder. Therefore, one of the important goals of Validus was to improve the care of bipolar patients by getting them access to FDA-approved Equetro. That goal translates into the challenge of getting Equetro reimbursed by insurance plans. Hopefully the incentives in the healthcare reimbursement system will

evolve so that bipolar patients get access to Equetro, because no generic can give bipolar patients the assurance that they would get the benefit of taking an FDA approved product. We believe that Tonix's cyclobenzaprine product for fibromyalgia will have much less substitution by generic cyclobenzaprine because of the distinctive advantages of Tonix's formulation.

CEOCFO: What is the financial picture for Tonix Pharmaceuticals Holding today?

Dr. Lederman: We have decided to become a public company in order to increase the possible ways to finance our drug development activities. Developing prescription drugs is capital intensive and involves a significant amount of risk. Being public, we make it possible for a number of different types of investors to participate in funding our programs. The financing environment is improving in the US for public companies like ours. We think that the top quality companies will continue to be attractive to investors, particularly those who take pride in participating as investors in the development of new medications.

CEOCFO: Final thoughts, why does Tonix stand out as a potential investment?

Dr. Lederman: We think it is unique for a company of our size and market cap to have a lead product in clinical development that addresses a potential market of 5 million patients in the US. We believe that our product for fibromyalgia will be covered by strong patents for a period of time that will reward the risk our investors have taken. Most importantly, we think that we are going to make a big impact in the care of fibromyalgia patients. Other companies of our size typically focus on orphan diseases or smaller indications, so we think it is distinctive that we have such big ambitions, but also we have the team and the technology that make our goals realistic and attainable.