CEO CFO

Celsus Therapeutics

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Celcus Therapeutics is bringing a New Anti-Inflammatory Paradigm to the Market with their Lead Compound MRX-6 for Skin Inflammation, Eczema and Dermatitis in Phase II Clinical Trials and Therapies in Development for Conjunctivitis and Cystic Fibrosis

Healthcare
Drug Development

Gur Roshwalb
CEO

BIO:
Joined as CEO in March, 2013. From April 2008 to February 2013, Dr. Roshwalb was a Vice President at Venrock, where he was an investment professional on the healthcare team investing in both private and public companies. From May 2004 to March 2008, he was a vice president and equity analyst at Piper Jaffray, publishing research on specialty pharmaceutical companies. Prior to Piper, Dr. Roshwalb was in private practice in New York and Board Certified in Internal Medicine. He received his MD from Albert Einstein College of Medicine and his MBA from the NYU Stern School of Business. Dr. Roshwalb trained in internal medicine at the Mount Sinai medical center, where he also served as Chief Resident in 1997-1998.

About Celsus Therapeutics:
Celsus is developing therapies to address respiratory inflammatory diseases (Allergic Rhinitis and Asthma), inflammatory skin diseases (dermatitis), inflammatory bowel disease (IBD), ophthalmic inflammatory conditions (conjunctivitis and dry eye), and Cystic Fibrosis. More information on these conditions is provided below.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Roshwalb, would you give us some background on Celsus and why the change in name?
Dr. Roshwalb: Celsus Therapeutics was previously known as Morria Biopharmaceuticals. Our company started off in 2005 and has successfully raised about $13 million to date and taken the lead compounds in Phase II. For the last year and a half, the company has been unable to raise a significant amount of capital to continue driving programs forward. The board of directors felt at the end of the year that they needed to bring in new management. They hired a new chief medical officer, Alan Harris, who is now full time with the company. They hired me as the CEO to help them raise money and define the go-forward strategy for the company. We felt that while there was nothing wrong with the previous name, a rebranding to emphasize this was a new management with a new vision could drive the products forward. The name Celsus is based on the Roman physician, Aulus Cornelius Celsus, who first codified the description of inflammation, rubor, dolor, tumor and calor- redness, pain, swelling and heat. This is a company that is trying to bring in a new anti-inflammatory paradigm to the market.

CEOCFO: Would you tell us, in non-technical language, about Celsus Therapeutics' new anti-inflammatory?
Dr. Roshwalb: sPLA2 is an enzyme called serum phospholipase A2 (sPLA2). This is an enzyme that is ubiquitous in human tissues and cells such as white blood cells. When there is an inflammatory process causing tissue destruction or something else going on in the body, this enzyme comes pouring out of the cells. When this enzyme hits the cell that it is working on, it breaks down the fats on the cell's surface called lipids into a couple of different precursors. One of them is called lysophospholipid and the other is called arachidonic acid. The inside of the cell takes these precursors and turns them into inflammatory mediators. Arachidonic acid is probably the most famous one because that is what goes down the cyclo-oxygenase pathway and the leukotriene pathway. People are much more familiar with what is known as COX-1 and COX-2 inhibitors—Vioxx and Celebrex being COX-2 inhibitors and aspirin a COX-1 inhibitors, ibuprofen works on COX and leukotriene inhibitors like Zyflo and Singulair. The arachadonic acid is a precursor to make new inflammatory compounds downstream that drive the inflammatory process. There are drugs that stop midway, which steroids do a little bit differently. A person is given what is known as a glucocorticoid steroid—we are not talking about the steroids that athletes misuse, we are talking about a medical steroid—which is a very

important anti-inflammatory drug. They hit the glucocorticoid receptor, the GR receptor, on various different cells. It causes the increase in many different proteins, including the protein called lipocortin or annexin 1A. The protein lipocortin blocks phospholipase A2 upstream before it can make arachidonic acid and lysophospholipid. The problem with steroids is that along with the potent anti-inflammatory effects, they increase many other proteins and have many side-effects such as osteoporosis, high blood pressure, high blood sugar leading to diabetes, cataracts, glaucoma and sometimes psychiatric side-effects including depression, psychosis and anxiety. They are very potent anti-inflammatory drugs. If you look at the IMS data, in 2012 there were 207 million retail prescriptions for steroids in the United States—a lot of use but also many side-effects. We have a drug, a compound, which can block the phospholipase A2 enzyme at the cell level and all the approximately 13 different versions of it but does not do anything else. We hope to get the potency of the anti-inflammatory steroids without the side-effects of the steroids.

CEOCFO: Where is Celsus Therapeutics in the development process?

Dr. Roshwalb: Right now, our lead compound known as MRX-6 for skin inflammation, eczema or dermatitis is in Phase II. We had positive results from a similar study in Israel, which we published in 2007 and we are currently running a multi-centre, double blind, vehicle and active control sequential dose ranging trial in allergic contact dermatitis study. We will have results from the first cohort of the study in about 3 weeks and if those results are positive, we have shown in a few different studies that our MRX-6 cream has real benefits for patients with allergic contact dermatitis. We are going to take it forward from there.

CEOCFO: Do you see partnerships or joint ventures in the future?

Dr. Roshwalb: We are open to anything. Ideally, I would like to drive the program from where it is currently to Phase III, about a $6 million endeavor. We would like to take the program as far as we can to maximize the value for shareholders. This ideally means completing the current trial we are running through 2013, filing an IND in the United States and running a couple of Phase II trials in the United States in 2014 so that by the end of 2015 we would have a Phase III ready asset. Further along the path, we partner out or sell the asset because dermatology is a unique and special indication. For commercialization, you want a company that is familiar and has many dermatology assets. Ultimately, the goal for that particular product is probably out-licensing or resale.

CEOCFO: What made you decide to become CEO at Celsus Therapeutics?

Dr. Roshwalb: It was a meeting of various needs. I was very happy as an investor at Venrock, a venture capital firm based in Palo Alto, New York. Some of my background is that I was an internist from a private practice, then at the equity research side of Piper Jaffray covering biotech and specialty pharmaceuticals. As a senior I covered specialty pharmaceuticals and then moved to Venrock about 5 years ago investing in small capital healthcare companies. To be the best investor that I can be, I was interested in getting operational experience. Along with that, I saw Morria, now Celsus, about 2 years ago when they presented to Venrock and we liked the science but it was early and we had issues with the management at the time. Morria, a few years later, was looking for a new CEO and I was looking for management experience. I thought they had a phenomenal science and pipeline with an opportunity for shareholder returns. I said, "You know what, this is something I want to do."

"This is a company that is trying to bring in a new anti-inflammatory paradigm to the market."

- Gur Roshwalb

CEOCFO: What are one or two things you learned from previous endeavors that will hold you well at Celsus Therapeutics?

Dr. Roshwalb: The first thing is that you never want to take a shortcut as a biotech company. You have to ask the right questions and do the right study and not do the shortcuts because of monetary constraints or something else that drives them. The second thing is that I want to bring an investor viewpoint to what we are doing at Celsus Therapeutic. Oftentimes, companies will run these single arm, historical trials, which are nice for generating hypotheses but do not tell you much about the true value of what they are doing. My goal is to run the company for shareholders. The last thing is strategic vision. What I did get out of my many years on the sales side and buy side is a broad understanding of the healthcare landscape—what programs to drive forward and how to bring value to them. Hopefully I will be able to bring that to the company.

CEOCFO: Do you have confidence that Celsus Therapeutics will be able to get funding?

Dr. Roshwalb: Yes. Obviously, it depends on the results that we are going to get in May. I am a heavy believer in both the current drug MRX-6 and the pipeline in general.

CEOCFO: Would you tell us about the ophthalmology application?

Dr. Roshwalb: When you look at the pipeline as a whole, what we are trying to do is focus on the topical application of our technology. MRX-6 is for skin disease, MRX-4 is for allergic rhinitis, which is a nasal inhaled indication. OPX-1 is for ophthalmology and is an eyedrop. The enzyme that we spoke about, phospholipase A2, is actually found in human tears. It serves an important role in human tears by killing bacteria but it has also been implicated in ocular inflammation. It has a useful role but when it gets out of control, it causes inflammation in the eye. On the other hand steroids, which are very useful drugs with approximately 12 million retail prescriptions in the U.S. for ocular steroids in 2012, cause an increase in ocular pressure, at times leading to glaucoma, and cataracts. They are big drugs but they have issues. Because our compound sits on the cell's sur-

face and not out in the tears, we can inhibit sPLA2 activity at the cell surface with potent steroid anti-inflammatory effects without stopping the sPLA2 from being antibacterial. This is an ideal anti-inflammatory for the eye and also our drug has no mechanism of action to cause an increase in ocular pressure leading to glaucoma or cataracts—steroid-like efficacy without the side effects.

CEOCFO: Why should Celsus Therapeutics stand out to investors and people in the business community?

Dr. Roshwalb: As an investor, whenever a company told me about a pipeline I would say, "I do not want to hear about your pipeline, I want to hear about your lead asset because that is what investors value you for." That is true. One of the reasons Celsus stands out is because of the biology of the pipeline and the mechanism of action is the same throughout the pipeline. We can feel confident that if we sell efficacy in more particular sets of indications, this puts biologic mechanism to the rest. If it works in skin, we know we can get anti-inflammatory effects. We can do that work in the eye, work in the lungs for cystic fibrosis and work in the intestinal tract for Crohn's disease. At the end of the day, inflammation is a large product burden on the healthcare system. Anything that can safely help inflammation is going to bring great help to patients and the healthcare system as a whole. It is an opportunity to do what physicians always want to do, to help people, and another market opportunity.

CEOCFO: Final thoughts?

Dr. Roshwalb: The focus of the company is our lead asset in dermatitis, MRX-6. Our goal is to bring it to the maximum value so we can partner and sell that asset. As a single company we want to take ophthalmology and cystic fibrosis forward ourselves. Cystic fibrosis is a genetic disease and, unfortunately, common for an orphan disease. These patients have lung issues and inflammation of the lungs. It is not much to treat that inflammation. If you go to September of 2010, the FDA had a two day panel on how to design trials for antibiotic cystic fibrosis. In the transcript of the first morning, they addressed the problem of treating inflammation. We think that our drug is an ideal opportunity to stop inflammation in the lungs without causing other problems and bringing in a needed therapy. Our goal is to raise money throughout MRX-6 to maximum value to partner and sell it and then bring forward the ophthalmology and cystic fibrosis product on our own.

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