



Aesthetic Medicine Company, Lithera is developing a New and Novel Way to Treat a Condition that nearly everyone wrestles with - Excess Localized Fat Deposits on their Abdomens

**Healthcare
Lifestyle**

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**George W. Mahaffey
CEO**

BIO:

Mr. Mahaffey has 26 years of pharmaceutical and biotechnology industry experience. Since 2011, Mr. Mahaffey has been President and CEO of Lithera, Inc., a privately held biopharmaceutical company developing drugs for aesthetic and medical indications. Before Lithera he served as CEO of Peplin, Inc. after the dermatology company's acquisition by LEO Pharma A/S in 2009; he was instrumental in this \$287.5M transaction. Prior to the acquisition he served as Peplin's Chief Commercial Officer and VP, Sales and Marketing. Mr. Mahaffey also served as Sr. VP, Sales and Marketing for Cotherix, Inc. where he led the corporate commercialization and successful launch of Ventavis® (iloprost), an orphan drug to treat Pulmonary Arterial Hyperten-

sion. He was heavily involved in the acquisition of CoTherix by Actelion Ltd. for \$420M in 2007. Prior to CoTherix Mr. Mahaffey worked at Scios, Inc. (acquired by Johnson & Johnson for \$2.4B in 2003) where he directed the launch of Natrecor® (nesiritide) to treat acutely decompensated congestive heart failure that proved to be one of the most successful launches of any acute care cardiovascular product. Mr. Mahaffey also led the marketing function at Neurex, Inc. (acquired by Elan Corp. for \$700M in 1998). He began his pharmaceutical career at DuPont Pharmaceuticals where he held several sales and marketing positions. Mr. Mahaffey earned a Bachelor of Science degree in Chemical Engineering from the University of Delaware and an MBA from the University of South Florida.

About Lithera:

Lithera is developing products for aesthetic medicine to address both medical and lifestyle indications. Our lead product is a novel injectable treatment to achieve local, selective fat tissue reduction (pharmaceutical lipoplasty). Using FDA registered drugs proven safe and effective in other indications, our product targets and stimulates natural fat metabolism and achieves non-ablative, non-surgical fat tissue reduction in specific locations.

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

CEOCFO: Mr. Mahaffey, would you tell us about Lithera?

Mr. Mahaffey: We are a small biotechnology company developing products for aesthetic and medical conditions. Our lead program focuses on development of an injectable drug for body contouring, or local fat reduction targeted toward the abdomen.

CEOCFO: What are some of the options to address the problem today, and what does Lithera have that is different, better, cheaper, easier, etc...?

Mr. Mahaffey: Again, our product is in development, so it is not approved yet. But what we are developing is an alternative to either invasive surgery which is liposuction, or for other devices that are used on the patients' abdomen to improve their body shape, or body contour. Our drug will be an injectable drug that will help patients improve their body contour of their abdomen.

CEOCFO: How does it work?

Mr. Mahaffey: It actually mimics the body's own metabolic process. That means that where the drug has been injected it actually shrinks the size of fat cells. Then because that happens in a large group of fat cells throughout the abdomen, the patient sees a change in the abdominal shape. Another way to think about it is "spot dieting" where the loss of volume is targeted where the drug has been injected, rather than a diet in general; meaning that you lose volume throughout your whole body.

CEOCFO: Many people would be quite skeptical. Can you explain the science: what is it you are injecting,

and what is the interaction that is allowing the positive results?

Mr. Mahaffey: The drug that we are injecting is a long-acting selective beta 2 agonist. That is important because beta agonists and beta receptors have long been known to have a role in lipolysis, or fat metabolism. Our drug binds to the beta 2 receptor on the surface of the fat cell, basically triggering the normal metabolic process where the fat cells cleave triglycerides, which make up the volume of the cell. Those triglycerides are released into the body just like normal, like what happens with all of us on a continuing basis, and the result is that the cells at the end of the treatment, or the end of the metabolic process is smaller in size. It shrinks the fat cells.

CEOCFO: How are you able to find such a combination that would work?

Mr. Mahaffey: We are developing only a single agent which is Salmeterol. We began developing a combination drug, but we have recently learned in our clinical work that the beta agonist is the drug that we will take forward on its own. It will be a single agent. The concept of this was first discovered or developed in the mid 1970s, where a doctor used the beta agonists available at the time and injected them into lipomas; the little small areas of fat we typically get as we get older. He observed that the lipomas shrank in size and while an interesting observation, it was commercially not feasible because the drugs that he had to chose from at the time required several treatments per day for very prolonged periods to see this observed effect. That science sat dormant for decades, until the idea that now there are long-acting and selective beta agonists, maybe we should go back and revisit this. Thus the birth of Lithera in 2007-2008, and we began a development program at that time, focusing on the aesthetic indication of abdominal contour improvement. We also have a medical indication for the fat behind the eyes—it is for Graves disease; it is called Exophthalmos.

CEOCFO: Can you tell me about the recent Notice of Allowance for you patent?

Mr. Mahaffey: When we developed our patent strategy, the initial patent that was first issued in the U.S. and throughout the world protected the combination product containing the beta agonist Salmeterol, and a steroid Fluticasone. The initial patents covered the combination product of the beta agonist and the steroid. Now, as we learn that the beta agonist is the drug that we will move forward we will no longer have the steroid as part of the drug. The recent Notice of Allowance is very important because it protects the single agent Salmeterol, and all long-acting beta-2 agonists for injectable local fat reduction. This Notice of Allowance we recently received targets exactly the product that we will be continuing through our clinical development program.

CEOCFO: What are the next steps?

Mr. Mahaffey: The next steps are to use the proceeds from the most recent financing in December 2012. We are going to be back into the clinic to do our last Phase 2 study; a large multi-center dose ranging study with endpoints that we believe are quite close, if not identical to what will eventually be our Phase 3 endpoints. This will be a large study for us that we will plan to do complete this year. We expect to get data from that study sometime during the third quarter of this year, and then we will be back meeting with FDA to determine our Phase 3 program.

CEOCFO: You have a long history in the development healthcare drug business. What have you learned that is most applicable to Lithera and most helpful for you as you move forward?

Mr. Mahaffey: First, when it comes to development programs, a company must follow FDA guidance to the letter, and to not try to interpret what they are telling you or what they are writing to you. The company must take what they are telling you to do and do it exactly as they are prescribing. The second point from a corporate perspective is to build the company for the long haul and to make the required spends that one must do to set the company up for long-term success. The reason this is important is as, you consider other alternatives,

whether it may be a sale of the company, or whether it is an IPO, or if it is a continued private financing, the company is in a strong enough position to be able to execute whatever strategy is the best at that time.

CEOCFO: How far will your current funding take you?

Mr. Mahaffey: Well into toward the end of this year and we are not giving any guidance really beyond that.

CEOCFO: Has the medical community been paying attention?

Mr. Mahaffey: Yes and no. We are a small company. We consciously wanted to make sure that we generated the right data before we tried to elevate our profile. But now that we have good solid data and we have funding that will allow us to create what we consider to be very important large scale data, we will become more active in making them aware. I

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would say the awareness is relatively low at this point, but that is something now we are progressing is time to work on.

CEOCFO: Is the area that you are looking at in favor with the investment people these days? Are you in a favored cycle?

Mr. Mahaffey: We are in a favored cycle for several reasons. One is because it is aesthetic medicine insurance is irrelevant, because this is a cash pay business. Patients pay for aesthetic drugs out of their own pocket to the doctors. During the economic downturn several years ago the area of aesthetic medicine is relatively recession proof. Patients will forgo other purchases, but will maintain their spending in aesthetic areas of medicine to improve their looks, or how they feel about their looks. Lastly, one looks at the aesthetic companies and the recent IPO from Kythera, which

was arguably the best IPO that has gone out in biotechnology and pharmaceuticals in the last eight years. After going public earlier this year they have had wonderful after market support, and I think this strong support shows the appetite from the public investors for products such as what Lithera is developing. Then lastly, there have been an awful lot of mergers and acquisitions in the aesthetic space over the last several years as well, including the purchase of Medicis by Valeant several months ago for well over \$2 billion dollars. It is a very active space from investments. It is a very active space from mergers and acquisitions.

CEO CFO: Why should investors and people in the business community pay attention to Lithera? Why does Lithera stand out?

Mr. Mahaffey: Lithera is developing a new and novel way to treat a condition that nearly everyone wrestles with; excess localized fat deposits on their abdomens. Again, our drug is only for normal, healthy, thin people who despite good habits with exercise and diet cannot get rid of that small area of fat, often called the love handle or the pooch. Because that is an area that most people throughout the world are very interested in improving, their abdominal profile, we believe that we will be developing a product that will be the first product to give doctors an option to treat these

patients without invasive surgery or without using devices. Because our product will offer rapid onset of effects with virtually no recovery period, we are clearly differentiated from any other options that they have to choose from at this point.

CEO CFO: Final thoughts?

Mr. Mahaffey: The aesthetic medicine area is a very exciting area. Not only because it is not tied to governmental or insurance changes that are clearly coming over the next few years, but it has also been shown to be relatively recession proof and very active when it comes to financing, corporate consolidation and mergers. It appears to be a very interesting area of medicine.



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