

Eye Drops for Dry Eye based on a Nanosized Naturally Occurring Castor Oil Lipid Particle



Michael Sawaya
General Counsel
Altaire Pharmaceuticals, Inc.

CEOCFO: Mr. Sawaya, what is the focus for Altaire Pharmaceuticals today?

Mr. Sawaya: The biggest thing we have on the horizon now is our NanoTears® Eye drops. This is a dry eye preparation that is based on a patented technology invented by our president Al Sawaya. What we have done is taken the naturally occurring castor oil lipid; that is the lipid that is naturally occurs in the tear film, and through this patented process, gotten it down to a polarized, nanosized lipid particle. As a result we deliver the lipid in a clear, colloidal solution rather than an emulsion such as you might find with a mineral oil based drop, so that when the drop is applied to the eye blurring does not occur. That is a significant advantage, because a dry patient is going to use a drop many, many times in the course of a day. By contrast these mineral oil emulsion drops that are sort of a milky, opaque type of drop; you put them on and you have a lot of blurriness in the eye.

CEOCFO: What has been the challenge in creating the clear method?

Mr. Sawaya: In terms of the technology to make it work, I cannot reveal much as that is a proprietary process. However, the big challenge was getting a lipid into a polarized, nanosized particle. That is not an easy process to do! However, when you get it into that state you are able to create, again, a clear solution verses an emulsion.

CEOCFO: Where are you in the process of development and commercialization for NanoTears?

Mr. Sawaya: I am glad you asked that, because that also leads back into your last question about the biggest challenges! What we are very good at is technology - developing products, engineering and reverse engineering products. The marketing is something new for us. The biggest challenge for us has been getting NanoTears in front of the doctors so that they can make an evaluation of it and see if it is something they want to recommend to their patients; and getting it in front of consumers. I am happy to tell you that as of fall, 2015, the NanoTears products are available in select CVS locations. We are in about fifteen hundred of their stores across the country. We are now also available in Kinney Drugs, which is a regional chain that primarily focuses on NY State and there are some New England stores as well. We are taking advantage of the digital age that we are in and so are also marketing this product on Amazon.com and our own website, www.nanotearseyedrops.com

CEOCFO: What about organizations? Is there a dry eye association that you are able to engage in the process?

Mr. Sawaya: That is a very interesting question, too! We have been reaching out to them. There are some very good organizations out there and we are trying to develop relationships with them. Some of them, we have had the opportunity to attend some of their events and give samples to their members. We are very interested in talking to different grass roots or patient groups. Its often difficult for dry eye patients to get relief. That is because there are many different reasons why dry eye occurs and of course everyone is different. What works for one person might not necessarily work for another person. The groups that are out there have been very good at giving patients information and exposing them to different available products. So these organizations represent a great opportunity to get NanoTears in front of Dry Eye patients.

NanoTears®

CEOCFO: Is dry eye becoming more common and are people seeking solutions more than they might have five or ten years ago?

Mr. Sawaya: Absolutely. When we look at the demographics, dry eye has traditionally skewed older, for people over fifty and skewed female. However, as

people spend more time in front of computers and smart phones and iPads and so forth, all that does seem to have an impact on people's eyes. Therefore, we are seeing increased incidents of dry eye. I think that people are more aware of it and become more aware that there are treatment options available.

CEOCFO: *You have several versions - mild and of moderate, intensive and in severe. What are the differences? Would you comment on the preservative free version as well?*

Mr. Sawaya: We have created levels of concentration of the castor oil lipid along with the active ingredients which are the replacement tears. Therefore, a mild will have less lipids than the moderate, which will have less lipids than the severe. The idea is that it gives the doctor or the patient the option that if they try one level and they are not getting quite the relief they had hoped for, there is another level to move up to and then another level from there. We think that it is important to give doctors treatment options. The preservative free is an interesting thing, because the preserved versions of the products are using a very gently preservative that does its job in the bottle, but disappears upon administration to the eye. That is why we call it Vanish. However, there are patients that are sensitive to any preservative. Then there are other patients who do not want to use any products with a preservative. In either case they have a legitimate need for a preservative free product. Therefore, what we have taken the mild and the severe formulas and made them available in a preservative free formula. Up to this point they have been in packed in sterile, single dose vials. The idea is that you open the vial, you administer the drops into your eye and then you discard anything that is left. That is because one you open a preservative free vial, you potentially expose whatever product that's left in the vials to airborne contamination. That is why our labeling on these products says, "Use it and then discard it." However, at the American Academy of Ophthalmology 2015 Annual meeting we are introducing a preservative free NanoTears formulation in a multi-dose container. It is a container that is designed so that when you dispense the drop there is no ingress back into the bottle. That is why drops are preserved, because with traditional multidose containers after you administer a drop air or residual product can get inside the container. However, with this container no ingress is possible. Therefore, you can take a preservative free drop and put it in a multidose container. Now, instead of having to carry around with you a dozen of these little vials, you can just carry the one little vial, which we think is very convenient. It also addresses the fact that no one likes to feel like they are throwing something away that they have paid for. When we fill the single dose vials we put more in there than you are going to need for that application, because patients perceive the single dose fill as a vial that was not filled with enough product. The multidose preservative free actually gives consumers a better value, because the amount of product in the multidose container is greater than the amount that you get in the vials, all totaled.

CEOCFO: *Would you give us just a little background on Altaire Pharmaceuticals?*

Mr. Sawaya: Altaire is a privately held company. All of our products are made in the United States. It has been around since 1991. The two principals of Altaire; one of them has more than fifty years experience in this business and the other one has around thirty five years of experience in this business. Therefore, although we are a small company there is a lot of knowledge and experience behind it and because it is privately held we take a lot of pride in what we do. We feel that our personal reputations and so forth are tied up in what we do. Therefore, it is very important to us that what we do be right and be good and that people get a good product and a good value from us. It is not a situation like these huge, multinational corporations that make their products somewhere overseas, and then sell them here, but they are not employing Americans. Not that these corporations are bad. They have a business model and it is a valid business model. However, I think that small businesses are really the backbone of our economy and particularly when we are doing our work and creating manufacturing jobs here in America and I would hope that that is something Americans want to support.

CEOCFO: *What has been the reaction from ophthalmologists when you have been able to reach them?*

Mr. Sawaya: It has been universally positive. Everyone that has worked with the drop has had good things to say. We are finding that patients are experiencing relief. We are finding that the experience with the drops is positive. However, it is still new and we are still getting it into people's hands. We are still trying to develop awareness of the product with the doctors and the dry eye patients.

CEOCFO: *Do many people purchase drops for dry eye outside of talking to the ophthalmologist?*

Mr. Sawaya: I would expect that it would be a little overwhelming for any consumer that walks into a pharmacy and sees all of the different drops that are out there. We think that it is a good idea for dry eye patients to talk to their doctors about what might be good for them. That is why we are very interested in providing samples to the ophthalmologists, so that they can become familiar with the product, decide whether they think it is right for their patients or not and that is really a doctor's judgment. The doctor is the best person to make that sort of judgment for their patient, but they need to have the samples of the product to give them to their patients to try. To go into a store or online and spend the fifteen dollars for a drop and then have it not work for you could be very frustrating. Therefore, what we are doing is giving doctors sample sizes of the different formulations and if they like and they think it is appropriate for a patient we encourage them to give

the patient the sample size. If they patient likes it, when they are done with the sample hopefully they will go out and buy it.

CEOCFO: *What is the strategy for the next year? You mentioned conferences and presentations, but will you be having a sales staff? Might you be working with third parties to get through to the ophthalmologists?*

Mr. Sawaya: There is a strategy. We are going to be moving forward, hopefully before the end of this quarter, with more digital based advertising. That is because dry eye patients do tend to research. They are faced with many choices, so they do tend to research. Therefore, we want to make information available to them on the net so that they can consider the NanoTears products when they are reviewing what their options are. Therefore, there is certainly going to be an increased digital presence in that regard. We are looking to increase our sales staff and a launch a detailing group that can spend more time with the doctors, one on one, teaching them about the product and letting them understand what the benefits are, so that then the doctors can make an informed judgment for their patients. Obviously, we are also going to be reaching out to the grass roots groups, going to the professional meetings and we are also looking to bring doctors in and help us develop a medical advisory board. We want to get feedback from the professional community; not just about the NanoTears drops, but about other things they would like to see companies develop. We are unique in that we can develop niche products that the huge companies might not even be interested in. It does not make sense for them. However, for us it does. That is something that we hope is going to continue to develop further.

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CEOCFO: *Why paying attention to Altaire and NanoTears?*

Mr. Sawaya: We would hope that we are able to help patients with dry eyes with NanoTears. You were asking why consumers might want to trust us. For many, many years now we have done a lot of contract manufacturing in the OTC eye care category for several retail chains. I will not say specifically who, because we feel like it is not our place to fly our flag in this regard. However, there are several retail chains that have had OTC private label eye care products manufactured by Altaire for several years. There are also some branded products that we do that sort of work for. There are even some prescription products that we do that sort of work for. Obviously, we are an FDA compliant facility. The FDA inspects us every year. We welcome them and we do whatever we need to do if the FDA feels that they want to us to improve in an area. FDA compliance is very, very important and that dovetails with the other direction that we are moving in. We are developing our own portfolio of ANDA products; Abbreviated New Drug Applications, in the eye care area. Our hope is that as we get approvals for these generic versions of the branded prescription products, we will positively impact the pricing that consumers will pay. In other words; more competition and more sources for these products will ultimately result in better pricing for the consumer.

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



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<http://store.nanotearseyedrops.com/index.aspx>**