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Morrisville's TearScience aims to clear up dry eye  
Triangle Business Journal - by Frank Vinluan

MORRISVILLE – For years, patients who suffer from evaporative dry eye have been instructed on a simple course of treatment: warm compresses to the eye several times a day.

Medication and eye drops also can address dry eye symptoms, but Morrisville startup TearScience says it can get to the underlying cause with its technology.

TearScience has received clearance from the U.S. Food and Drug Administration to begin producing and selling an imaging device designed to allow doctors to diagnose dry eye. The firm is awaiting clearance on a second device designed to treat it.

In preparation for production, sales and marketing efforts, TearScience earlier this month hired industry veteran Mike Judy from Bausch & Lomb to be the company's vice president of sales. "It's a valuable product that addresses an untreated marketplace out there," Judy says.

He says the two devices would be sold together at a cost of around \$80,000.

Dry eye is a common condition that is seen in older patients but can also affect younger patients, says Dr. Eric Oberdorf, a north Raleigh optometrist. Many patients self-treat with over-the-counter products such as artificial tears. Oberdorf says that by the time he sees patients, symptoms of dryness and scratchiness have worsened considerably.

Dry eye can result from the failure of the eye to produce enough tears. But it also can be caused by a malfunction of the meibomian glands in the eyelids that produce an oily film that prevents tears from evaporating, says Dr. Barry Schechter of the Florida Eye Microsurgical Institute in Boynton Beach, Fla. When the glands function properly, the oils sit on top of the tear film like olive oil on water, Schechter says. But when there is a problem, the oil becomes viscous and clogs the glands. Warm compresses are a suggested treatment because the heat "melts" the oil so it secretes properly.

Judy says TearScience's patented device will allow doctors to provide heat and therapy to the glands. The company was founded as Kolis Scientific in 2006. TearScience has raised more than \$15 million in two rounds of venture financing from De Novo Ventures, Spray Venture Partners and Quaker BioVentures.

Judy says TearScience will need another round as the company ramps up commercialization efforts and adds a sales force. He declined to say how much TearScience would seek in its next round, but he says the company will turn to current backers and also seek new investors.

Patients who suffer from dry eye can take medication for the condition. Schechter says that although the condition is not bacterial, antibiotics reduce inflammation of the glands, which helps. Doctors also

prescribe Restasis. The prescription eye drops, which are Irvine, Calif.-based Allergan's biggest selling product, brought in \$444 million in revenue in 2008. But Judy says Restasis does not treat the underlying cause of dry eye – the failure of the meibomian glands to secrete oils properly. That, he says, will be TearScience's advantage.

Oberdorf says if TearScience's device treats the underlying condition, it would be a welcome tool for doctors. Current treatments address symptoms but don't cure the problem, he says.

When TearScience does enter the market, its treatment will not be reimbursed by insurance at first. Judy says insurance companies need information and education about the technology before they will agree to pay for it.

Insurance companies aren't the only ones that have to be convinced. Schechter says TearScience's technology should work. But in this tough economy, he says, getting doctors to invest \$80,000 for the devices could be an even harder sell.

TearScience is not the first Triangle company to tackle dry eye. Durham-based Inspire Pharmaceuticals co-promotes Restasis under an agreement with Allergan. Inspire also is working on its own dry eye product, Prolacria, which is in phase III clinical trials. Prolacria is designed to stimulate release of components of natural tears.

But Inspire has had problems developing the drug. In 2002, when the product was called INS365, test results showed the drug worked no better than saline, results that caused Inspire's stock price to plummet. Inspire revisited the research on the drug and filed a New Drug Application with the FDA in 2003.

According to regulatory filings, amending the NDA for Prolacria and resubmitting the application for approval in the United States cost Inspire \$10 million to \$15 million.

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