TearScience Secures $70 Million For One-Of-A-Kind Eye Device

MEDTECH FINANCING

TearScience Inc. is ready to go into full-scale commercialization for a new device treatment for the most prevalent form of dry eye. In late February, the young company secured up to $70 million from **HealthCare Royalty Partners** to help make that happen.

TearScience was founded around a new mechanism discovered to be at the root of evaporative dry eye. While it was previously thought that dry eye resulted from insufficient tear production, company co-founder Donald R. Korb, OD, an optometrist from Boston, discovered that many dry eye patients suffer from inadequate lipid secretion due to blocked meibomian glands in the eyelid. Without this buffer of oil, tears evaporate rapidly, resulting in soreness, redness, foreign body sensation, inflammation, and all the other uncomfortable symptoms of dry eye syndrome. Of the 23 million people in the US with dry eye syndrome, recent research indicates that 86% is evaporative dry eye due to meibomian gland dysfunction.

TearScience, which was founded in 2005 by Korb and CEO Tim Willis, a medical device entrepreneur, has developed an entirely new way to diagnose and treat evaporative dry eye. The company offers a diagnostic device called *LipiView*, which measures the thickness of the tear film lipid layer to determine if the patient's dry eye is caused by meibomian gland dysfunction. If that's the case, the company's *LipiFlow* can deliver pulsed heat and pressure to liquefy the lipids and unblock meibomian glands. "It's a complete solution for dry eye," says Nicole Wicker, CFO. With no predicate device (apart from warm compresses) on which to base its clinical studies, TearScience was the first ophthalmic company to enter the de novo 510(k) process, and it was granted its clearance in February 2012.

At the end of 2012, the company's first year of commercialization, TearScience had sold its systems to more than 100 eye care practitioners, most of them ophthalmologists. The company spent last year building out its infrastructure, increasing from 28 to more than 100 employees. "We have no plans to hire many more people in 2013; we plan to put the money into sales, marketing, practice training and making sure that the ophthalmologists and other eye care practitioners who buy our system are successful," says Wicker.

TearScience has not sought insurance reimbursement for its treatment, which physicians are pricing at $1,600 to $2,000 for two eyes, with patients bearing the cost. This might have been an insurmountable barrier in the past, but in this changing health care environment people with high health plan deductibles and health savings accounts are prepared to foot more of their health care bill than ever before. Wicker says the company is convinced that there is a large, underserved patient population willing to pay for an effective treatment, and also points out that surveys indicate that patients with moderate to severe dry eye are already spending more than $2,000 each year for prescription and non-prescription eyedrops, punctal plugs, hot compresses, goggles, ointments and other palliative remedies that are inconvenient.

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Clinicians are on board with the self-pay model, which is similar to Lasik surgery and premium cataract offerings. They've seen other technologies in ophthalmology, intraocular lenses, for example, drop to a third of their price because of reimbursement pressures. Patients are willing to pay out-of-pocket for LASIK and cosmetic products such as *Botox* (onabotulinumtoxinA) and *Latisse* (bimatoprost). In addition to the extreme discomfort dry eye causes, says Wicker, "For many people, it is also a cosmetic issue. Women can't wear makeup and their eyes are red and inflamed. Many people can't wear contact lenses because of dry eye."

Alan Carlson, MD, chief of corneal and refractive surgery at the Duke Eye Center of Duke University's School of Medicine and a consultant to TearScience, says that dealing with this large patient population used to be frustrating. "I didn't have a lot to offer, and we are seeing more and more of this problem, not simply because people are living longer, but because of lifestyles. We are looking at computers more, driving more, checking smartphones, watching TV, and sleeping less. We are living longer, but we are blinking millions of times less." Blinking is part of the mechanism that fosters the stability of tear film, Carlson points out. "LipiFlow allows glands to function more normally and returns patients to a more normal state of lipid production and tear stability."

Once a skeptic, Carlson says now he's one of the biggest proponents of the new treatment, having done nearly 600 procedures in the last 16 months. Patients are willing to pay, he says. "A week ago I had a patient who was becoming contact lens intolerant. At first he said, 'Why don't I wait until the insurance covers it?' But when I explained what was involved, and that he could get his eyes taken care of there and then, he decided to do it. That's the way most people are."

Carlson describes the procedure. "An activator placed up against the eye tightly controls the heat to the meibomian glands at 108.5 degrees Fahrenheit, without increasing the temperature on the cornea beyond safe levels encountered in a low grade fever. The entire process lasts 12 minutes. The lids are heated to a degree that is not uncomfortable, and then they are massaged. Some patients have described it as a 'spa treatment' for the eye." The diagnostic helps with treatment planning, Carlson says, with monitoring response to the treatment, and in following

patients to make sure they get retreated in the future before the condition returns and becomes painful. It's expected that in many cases, meibomian gland dysfunction will recur. But Carlson says, "I have been treating patients for 16 months and I have only retreated a handful of patients. Most patients are still enjoying the benefits of the treatment at one year."

Carlson is a refractive surgeon with a business built around procedures, but TearScience believes LipiFlow is suitable for large, general ophthalmology practices as well. The device will turn an unprofitable and unsatisfied patient population into satisfied customers, the company believes. "Now you have a treatment that works and is a practice builder," says **Greg Brown, MD, founding managing director of HealthCare Royalty Partners**.

With its recurring revenues – the LipiFlow single-use activator and a per-use fee on the diagnostic – TearScience's business model suits the focus of Healthcare Royalty Partners, which until recently has mainly invested its royalty fund in pharmaceutical companies. (*See "Cowen Doubles Down On Royalties"* — START-UP, *January 2012*.) The recent $70 million financing for TearScience was in the form of structured debt, says Brown, who explains that the company took down some capital at closing and has the ability to draw down up to the full $70 million over the next three years.

HealthCare Royalty Partners shares in the risk and the rewards of TearScience's commercialization efforts; it gets a percentage of the company's revenues, which, again, consist of diagnostic and therapeutic capital equipment, and the single-procedure activators. Brown says his firm looked carefully at TearScience's pricing model before going into the deal. "We think the pricing is such that when patients compare this procedure with what they are currently paying out-of-pocket for compresses, and prescription and non-prescription eyedrops, it compares favorably, and quality of life improves." So far the company has been able to hit its sales projections. Brown says HealthCare Royalty's profitability models don't depend on every patient getting repeat procedures every year. "When we build our models, we are always conservative. The company doesn't need to have a high percentage of annual retreatments for it to do very well and for us to do well."

Prior to the recent funding round, the company had raised $2 million in its Series A round; then it did a Series B of about $15 million, a Series C of $44.5 million, and two rounds of venture debt totaling $21 million. There was a point in the company's history when fundraising was tough, according to Wicker. "It took us 10 months to raise the Series C, which closed in May 2010. It was the bottom of the financial crisis, we had a brand new kind of product and no FDA clearance, and we weren't reimbursed by insurance at a time when everyone thought we had to be." In the past year, however, numerous VCs who had turned Wicker down for the Series C approached her for an opportunity to invest. "When I did the analysis, the royalty fund was the best option to avoid dilution for our current investors," she says, which include Essex Woodlands Health Ventures, Investor Growth Capital, General Catalyst, De Novo Ventures, Spray Ventures, and Quaker BioVentures. [A#2013900052]

– Mary Stuart