

The MedTech STRATEGIST

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IP STRATEGIES

Occlutech's David-and-Goliath IP Battle

David Cassak, 6

DEALS AROUND THE INDUSTRY

Strategic Deals Thrive as Medtech Consolidates

Mary Thompson, 18

■ Historical Perspective: How Volcano Started Philips on the Path toward Spectranetics, David Cassak, 25

MID-YEAR M&A/FINANCING REPORT

First Half IPO Window Remains Shut, Despite Strong M&A and Valuations

Stephen Levin, 28

DIABETES DEVICES

Bigfoot and Abbott: A Match Made in Heaven?

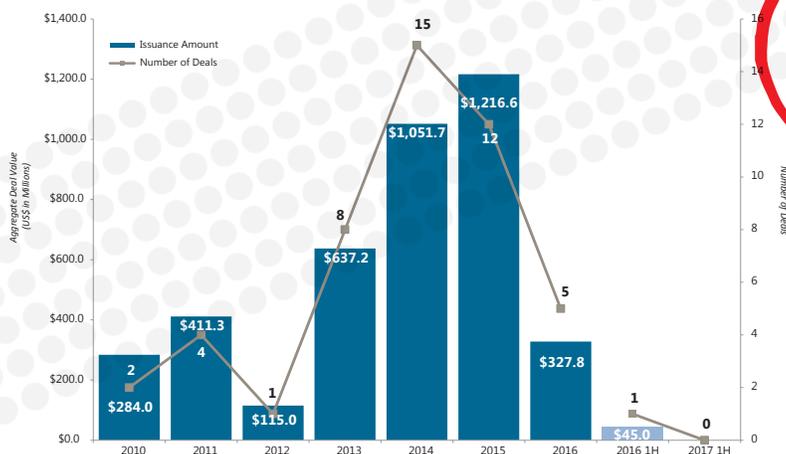
An Interview with Bigfoot Biomedical CEO Jeffrey Brewer

Mary Thompson, 34

MARKET TRACK

See page 28

US Medical Device Financings
Device & Diagnostic IPOs, 2010-1H 2017



START-UPS TO WATCH

TEARCLEAR:

A Novel Means of Making Ophthalmic Solutions Preservative Free

Mary Thompson, 44

EXIMIS SURGICAL:

Filling a Gap in Laparoscopic Tissue Removal

Mary Stuart, 48

TearClearORANGE COUNTY
CALIFORNIA**CONTACT**Kevin Hershfield,
CEOkhershfield@
tearclear.com**YEAR FOUNDED**

2015

WHO'S BEHIND ITRick Heinick, co-founder
and Board Chairman;
Anuj Chauhan, PhD,
inventor and co-founder**UNMET CLINICAL NEED**Preservatives in
ophthalmic (eye drop)
medications can cause
a number of serious
adverse events,
particularly in patients
exposed through chronic
use, such as people with
glaucoma**SOLUTION**The TearClear technology
is a chemical filter
mechanism designed to
remove the preservative
from standard eye
drop bottles before
the medication is
administered into the eye**FUNDING**A \$4.5 million
Series A round was
completed in May, led
by Visionary Ventures
and Bluestem Capital**BOARD OF DIRECTORS**Includes Rick Heinick,
Chairman; William
Link, PhD, previously
Managing Director
at Versant Ventures;
Jeffrey Weinhuff,
Managing Partner
at Visionary Venture
Fund; Tyler Stowater,
Partner at Bluestem
Capital; Kevin
Hershfield, CEO

TEARCLEAR: A NOVEL MEANS OF MAKING OPHTHALMIC SOLUTIONS PRESERVATIVE FREE

Preservatives in multi-dose eye-drop prescriptions used to treat glaucoma and other eye disorders put patients at risk of a range of serious adverse reactions. Early-stage start-up TearClear believes it has come up with a safe and economically feasible way to solve this problem and bring preservative-free eye drops to a wider patient population.

by
MARY THOMPSON

Preservatives are a common ingredient in multi-dose eye-drop prescriptions used to treat glaucoma and other eye disorders. Although they are important to maintaining solution sterility, chronic exposure to preservatives puts patients at risk of a range of serious adverse reactions, ranging from tear film instability and ocular discomfort to inflammation, conjunctival fibrosis, and eye surgery failure.

TearClear is developing a chemical filter technology that it believes is capable of removing the vast majority of BAK in an ophthalmic solution at the point of care.

Since glaucoma requires life-long treatment with medications designed to lower intraocular pressure, adverse reactions to eye drop preservatives are particularly common in this patient population, although they occur in other groups as well, such as people with chronic dry eye. Such reactions are not only inflammatory in nature, but according to a 2013 review article on the subject (Stalmans, et al, Preservative-free treatment in glaucoma: who, when, and why? *Eur J Ophthalmol* 2013;23(4):518-525), preservatives also can have toxic effects on the surface of the eye. Those toxic effects are exacerbated in glaucoma patients, who tend to have a higher prevalence of ocular surface disorders (OSD), such as dry-eye syndrome, to begin with. (And OSD, which can

have such uncomfortable symptoms as itching, burning, pain, and foreign body sensation, contributes to poor adherence to glaucoma medications, putting patients at risk of progressive blindness.) Moreover, many glaucoma patients require multiple prescriptions, which increases their total preservative dose—and the negative impact is dose-dependent. One recent study cited by the authors above documented the presence of severe dry eye, which greatly impacts quality of life, in 9% of glaucoma patients using two eye drop prescriptions and 15% of patients using three.

Benzalkonium chloride (BAK), which is a detergent, is the most common preservative used in ophthalmic solutions, and its toxic effects on the eye are well known. Studies have linked prolonged BAK exposure to a variety of problems, including nonallergic blepharitis, Meibomian gland dysfunction, chronic conjunctival inflammation, tear film instability, and keratitis (see Baudouin, et al. Preservatives in eyedrops: The good, the bad and the ugly. *Progress in Retinal and Eye Research* 29(2010): 312-334).

Although some glaucoma drugs are now available in sterile, preservative-free single-dose vials, due to higher manufacturing costs, single-dose vials are too expensive for routine use. Thus, Stalmans et al recommend that preservative-free options be reserved for the 20% of glaucoma patients who are at highest risk of adverse reactions. However, they concede that if cost were not an issue, preservative-free solutions would be preferred for all patients.

Early-stage start-up **TearClear Corp.**, based in Orange County, CA, believes it has come up with a safe and economically feasible way to solve this problem and bring preservative-free eye drops to a wider patient population—by integrating a unique filter mechanism into the tip of a standard multi-dose eye drop bottle. Founded in December 2015, TearClear is developing a chemical filter technology that it believes is capable of removing the vast majority of BAK in an ophthalmic solution at the point of care—that is to say, as the eye drop is being dispensed into the eye. As the drug passes through the bottle tip, the integrated filter captures the BAK, binding it via a chemical reaction. Thus, the patient receives a dose largely free of preservative, yet perceives no difference in how the drop is delivered, and the solution in the bottle remains safe and preserved.

TearClear's technology is still in the early development stages, but company co-founder and Board Chairman, Rick Heinick—a former EVP at Bausch & Lomb and prior CEO of several early-stage ophthalmic businesses—says the firm has patents pending in seven countries on this “very novel and groundbreaking” technology. The company's initial focus is on BAK-preserved solutions, since BAK is the most commonly used ophthalmic preservative, and there is a “critical medical need” to reduce patient exposure to this chemical. However, Heinick says the technology could eventually be tailored to other preservatives as well.

TearClear's filter technology was originally invented by co-founder and Chief Technology Officer Anuj Chauhan, PhD, professor and associate

chair of chemical engineering at the University of Florida. When Heinick was introduced to Chauhan's work, he believed the technology was “poten-

TearClear's initial focus is on BAK-preserved solutions, since BAK is the most commonly used ophthalmic preservative; however, company officials believe the technology could eventually be tailored to other preservatives as well.

tially transformative,” and he immediately set about to build a “world class team” to support the company, bringing in CEO Kevin Hershfield, who has expertise in chemical manufacturing start-ups, and assembling an impressive group of investors and advisory board members.

In fact, TearClear enjoys the backing of a number of highly regarded ophthalmologists and ophthalmic industry investors, including Bill Link, PhD, formerly Managing Director at Versant Ventures, who sits on the company's Board of Directors. Link, who has one of the most successful company track-records in the ophthalmic

device industry, was founder, chairman, and CEO of Chiron Vision, which was sold to Bausch & Lomb in 1997. He also founded and served as president of American Medical Optics (AMO), which was sold to Allergan in 1986, and later served on the Board of AMO's successor company, Advanced Medical Optics (AMO), which was acquired by Abbott in 2009. Over the past several years, he has been involved with a number of successful ophthalmic start-ups, including Eyeonics (acquired by B&L in 2008), Glaukos (now public), IntraLase (acquired by AMO in 2007), LenSx (acquired by Alcon in 2010), and Oculieve (acquired by Allergan in 2015).

The TearClear team also includes Richard Lindstrom, MD, and John Berdhal, MD, two well-known ophthalmic surgeons who are on the company's medical advisory board, as well as Richard D'Souza, PhD, chief science and technology officer and formerly head of R&D at Bausch & Lomb; and Howard Golub, MD, PhD, head of clinical development.

TearClear completed a \$4.5 million Series A financing round in May co-led by Visionary Ventures (a fund focused exclusively on innovation in the ophthalmic field) and Bluestem Capital. According to Hershfield, TearClear's technology offers advantages in terms of cost, ease of use, patient comfort, and outcomes. And that, notes Heinick, means the technology will be of “significant value” and interest to pharmaceutical companies operating in the ophthalmic space. “When a group of highly regarded ophthalmologists invests and believes in the technology,” he adds, “you know you're doing something right.” 🟡