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## Exact Sciences battens down the hatches, seeks M&A rescue

By LYNN YOFFEE

*Medical Device Daily Staff Writer*

An FDA warning letter, a notice of potential delisting of its shares from Nasdaq and a serious shortage of cash in a down market are enough to send any med-tech company into emergency mode.

Executives at troubled **Exact Sciences** (Marlborough, Massachusetts) have taken major steps to preserve existing cash while pursuing a strategic alternative for the business – specifically, a merger or acquisition.

Exact has been working to bring its promising non-invasive DNA-based colon cancer test technology to market but has encountered numerous hurdles. As a result, president/CEO Jeffrey Luber in a conference call Friday said he has dismissed most of the R&D staff (eight employees), suspended the clinical validation study of its Version 2 technology of a colon cancer diagnostic known as PreGen

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## Web-survey predicts pregnancy chances via *in vitro* fertilization

By OMAR FORD

*Medical Device Daily Staff Writer*

After numerous attempts at trying to conceive, a patient may elect to try *in vitro* fertilization (IVF). But questions remain if this is the best route to take for a particular individual.

It's an all too common scenario that some are faced with according to Christopher Jones, MD, CEO of **FORMYODDS.COM** (Chicago).

But thanks in part to an algorithm-based method the company has devised, women undergoing IVF can complete an online survey that will determine if they will in fact become pregnant from the procedure.

The results are touted to have an accuracy of 80%.

"It presents them with a method for determining if they're taking home a baby at the end of the day," Jones told *Medical Device Daily*. "FORMYODDS.COM is such a

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### *International report*

## Japan gives OK for Medtronic's Reveal DX cardiac monitor

A *Medical Device Daily Staff Report*

**Medtronic** (Minneapolis) reported that it has received Japanese regulatory approval for the Reveal DX Insertable Cardiac Monitor (ICM). The device has been designated by the Japanese government as a high-priority medical device, and the company says it is the first insertable cardiac monitor to be introduced in Japan.

The Reveal DX ICM provides insight into syncope, unexplained fainting episodes. Syncope is difficult to diagnose as episodes are often too infrequent and unpredictable for detection with conventional monitoring techniques such as ECG Holter monitors or external loop recorders. These tests are limited to 24 hours and one month, respectively; combined with the constraints placed on the patient's daily life and the limited likelihood of an event occurring during the monitoring period, the testing may fail to determine the cause of the episodes, according to Medtronic.

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## EyeGate in Phase II study of ocular drug delivery device

By AMANDA PEDERSEN

*Medical Device Daily Staff Writer*

Even the best eye medicine won't work very well if it doesn't reach the part of the eye that is causing the disease. That understanding is at the core of **EyeGate Pharma's** (Waltham, Massachusetts) approach to ocular drug delivery, the company says.

EyeGate, a private specialty pharmaceutical company using iontophoresis technology to deliver therapeutics into the front and back of the eye to treat serious ocular diseases, said it has begun enrolling patients in a U.S. Phase II proof-of-concept study of its EyeGate II ocular drug delivery system.

The prospective, multi-center, randomized, double-masked study represents the first U.S. study under an open IND to employ iontophoresis technology to deliver an active compound into the eye.

Iontophoresis is an active method of drug delivery in which an electrical field created by a low-level of electrical

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## EyeGate

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current is used to ionize a drug and to modify the permeability of the cells so that the drug can be delivered through different tissues to targeted areas, EyeGate said. The company believes it is the only one to have successfully used iontophoresis to safely and effectively deliver medication to both the anterior and posterior segments of the human eye.

Although there are several competitors in the ophthalmology space, Stephen From, president/CEO of EyeGate, told *Medical Device Daily* that there are no similar devices on the market that are using iontophoresis to deliver drugs into the eye. He said other delivery options include: eye injections, which is associated with pain and severe complications; implants, which also is linked with pain and severe complications and has no ability to modulate dosage; and eye drops, which are associated with toxicity and significant side effects and have less than optimal efficiency due to limited penetration.

**Virginia Eye Consultants** (Norfolk, Virginia), a private, university affiliated medical and surgical ophthalmology practice, enrolled the first patient.

"Enrolling the first patient in this important clinical trial is a key step toward finding a predictably effective treatment for acute anterior uveitis," said John Sheppard, MD, the clinical investigator at Virginia Eye Consultants. "Uveitis is an inflammatory condition of the internal structures of the eye that can lead to cataract, glaucoma, scarring, pain, photophobia, and even permanent loss of vision when undiagnosed or poorly treated. This condition occurs more frequently than most patients or doctors realize, often requires a long time for full recovery and may flare repeatedly, if inadequately treated."

The company says EyeGate II consists of two parts: a reusable battery powered generator and a disposable applicator, which contains the drug. EyeGate's iontophoresis technology is coulomb-controlled, the company said, which means that it regulates each unit of drug used for treatment.

Sheppard said he believes the EyeGate II will lead to better predictability of clinical response to drug treatment due to reliable delivery of consistently therapeutic concentrations directly to the interior of the inflamed eye.

The study is delivering the company's lead clinical compound, EGP-437, in up to 40 patients with non-infectious acute anterior segment uveitis. It is designed to assess the safety, tolerability and efficacy of four transscleral iontophoretic doses of EGP-437, a formulation of a well studied corticosteroid, delivered by the EyeGate II.

"Anterior uveitis is a serious disorder of the eye with inflammation of the uvea, particularly in the iris and/or the ciliary body," said C. Stephen Foster, MD, principal investigator, founder and director of the Massachusetts Eye Research and Surgery Institution (MERSI), and a clinical pro-

fessor of ophthalmology at **Harvard Medical School** (Cambridge, Massachusetts). "Uveitis is a leading cause of blindness and is estimated to occur in 102 of every 100,000 adults in the U.S. per year."

Foster, who is also the founder and president of the **Ocular Immunology and Uveitis Foundation** (Cambridge, Massachusetts), added that patients with severe anterior uveitis are typically treated aggressively with a potent topical steroid agent during the initial stage of inflammation. It is imperative to intervene early and aggressively, which usually means topical instillation hourly around the clock, sometimes along with periocular and / or oral corticosteroids, Foster said.

"The need for an alternative, patient-friendly, effective ophthalmic delivery method, such as the EyeGate II, is clear. I look forward to reporting the results of this important study in peer reviewed literature," Foster said.

From said that ophthalmic drug development has not kept pace with the advances seen in other medical specialties, partly because of the limits and invasive nature of current drug delivery modalities.

"The EyeGate II delivery system represents a fundamental advance in non-invasive ocular drug delivery, and EyeGate Pharma is accelerating the commercialization of this novel technology as a potential alternative to current ocular delivery methods, From said.

The study builds on a series of clinical studies, including a pilot and a Phase I study, EyeGate said. The pilot study was designed to assess the safety, tolerability and efficacy of EyeGate's first generation iontophoretic drug delivery device. In that trial, 89 patients with severe ocular inflammation participated, which involved a total of 216 iontophoretic applications of a corticosteroid in a number of inflammatory ocular indications. According to the company, the pilot study demonstrated "exceptional safety and patient tolerance with significant decreases in inflammatory markers and concurrent increases in visual acuity." The pilot study was "instrumental in establishing EyeGate's clinical development roadmap," the company added. The ongoing voluntary Phase I safety and tolerability study in healthy volunteers is designed to establish the maximum tolerated current that can be employed with the EyeGate II delivery system, the company noted. This Phase I study is expected to yield results later this year, EyeGate said.

The company said it has concentrated its efforts on optimizing the EyeGate II system to deliver a wide range of therapeutics while developing a highly specialized laboratory dedicated to formulating drugs for iontophoretic delivery. While times will vary by medication, the company said the actual delivery time may be just three to five minutes for most drugs.

EyeGate was founded in 1998 with technology licensed from Bascom Palmer Eye Institute at the **University of Miami**. ■