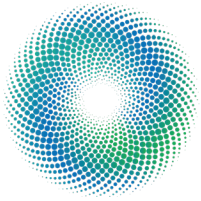
at a glance™



eyenovia

In a Blink: ***Eyenovia's (www.eyenoviabio.com) patented micro-dosing technology is on deck to replace century-old eye droppers for delivering topical eye care therapies. It dispenses a precise micro volume of drug to the surface of the eye, allowing the drug to coat the eye without the risk of adverse events. This brings with it a promise of more effective eye care through better compliance and fewer side effects. A Phase 3 trial in pupil dilation is expected to start 2H18, with results due 1H19. Next up: the start of two more Phase 3 trials (glaucoma and near sightedness), and a planned registration of an over-the-counter dry eye product in 1H19.***

Key Considerations

- **Eyenovia's patented micro-dosing technology delivers a precise volume of drug to the surface of the eye, a potential game-changing technology in a category dominated by century-old eye droppers which, despite their ubiquity, are medical devils in disguise.**
- **Seventy percent of eye drop users miss their eyes when medicating, wasting the medicine. Hello, wet cheeks and moist tissues to say the least.**
- **The 30 percent of users who have good aim encounter another problem - flooding the cornea with a lot more drug than the eye's tear film can hold. This frequently leads to treatment-limiting side effects due mainly to the heavy use of toxic preservatives required to keep dropper bottle drugs stable.**
- **Side effects can range from local stinging, redness, and foreign body sensation, to more serious systemic effects such as bradycardia and arrhythmia.**
- **Eyenovia's technology utilizes special drug formulations that contain up to 80 percent less preservatives.**
- **Eyenovia's precise micro-dosing technology delivers 6-8 microliters of medicine, the maximum capacity of the eye's tear film.**
- **A gentle squeeze of an eye dropper typically releases 30-50 microliters, or nearly 300 percent more than what the eye's tear film can hold.**
- **Phase 2 clinicals have validated patient preference and the feasibility of Eyenovia's smart, e-health compliant technology.**
- **The positive attributes of Eyenovia's technology were cited by the Academy of Ophthalmolgy in a press release issued at its 2017 Annual Meeting, a very rare honor reserved for only the most promising breakthrough innovations.**
- **Eyenovia's portfolio includes six issued and nine pending U.S. patents, and 25 issued/ allowed and 56 pending international patents.**
- **Although Eyenovia's innovation is a device for dispensing drugs, its business model is to sell the device complete with drug in a replaceable cartridge.**

Eyenovia Inc.

(Nasdaq: EYEN)

Recent Price:	**$8.02**
Approx. Shares O/S:	**9.9 Million**
Approx. Mkt Cap:	**$74.4 Million**
Fiscal Year Ends:	**Dec. 31**

Two Buy Ratings: $20 and $35 PTs

(Analyst reports on request)

Published: June 2018

- **Planning is well underway for three Phase 3 trials with approved drugs in three indications.**
- **A fourth product candidate will be registered under a FDA Monograph for OTC drugs, with commercial launch planned for 1H20.**
- **By 2020 Eyenovia expects to have two marketed products and one other either in review or approved by the FDA under the accelerated 505(b)(2) pathway.**
- **Eyenovia's platform technology could potentially be utilized for more than 80 currently marketed products in the $13.5 billion topical eye care market, a significant opportunity to differentiate and re-brand many high-volume drugs.**
- **The company's four current programs address markets totaling more than $9 billion in annual sales.**
- **Cash at March 31, 2018 totaled approximately $27.6 million.**

Overview

A medical adaptation of ink-jet printer technology may revolutionize the way topical eye care drugs are delivered – rendering an overdue death knell to the ubiquitous but problematic eye dropper.

Sound too good to be true?

Utilizing piezoelectric-print technology, Eyenovia created a patented device that delivers a micronized droplet of drug to the surface of the eye in a precise amount, every time – with no under-dosing or overdosing.

The technology bears all the attributes of bringing a new era of performance, safety, and compliance to topical eye care while lessening the risks of over-medicating.

Better drug performance is made possible by precise dosing, which leads to more consistent pharmacological effects – an outcome nearly impossible to achieve with dropper administration.

Worried that a blink will block the medicine? Eyenovia engineered the unit to discharge a dose in 80 milliseconds, 20 percent faster than the average blink reflex.

The technology facilitates better safety by delivering just the right amount of drug needed for the desired therapeutic effect – and no more – and by utilizing special drug formulations that contain up to 80 percent less preservatives, the major causes of local and systemic side effects.

The unit is held horizontal to the eye, with no need to tilt your head back. Studies show this greatly enhances comfort, aim accuracy and compliance.

An optional pre-set alarm reminds users when to take their medication, and the actual dispensing will automatically create an e-health record which can be downloaded remotely or at the doctor's office.

Dosing histories can be important, especially with treatments for chronic eye diseases like glaucoma and myopia. Poor compliance may lead to new clinical

Planned Milestones

2H18 – Start of P3-dilation
1H19 – Top-line P3-dilation
1H19 – FDA registration-dry eye
1H19 – Start P3-glaucoma
1H19 – Start P3-myopia
2H19 – Submit NDA-dilation
1H20 – Launch dilation
1H20 – Launch dry eye
2020 – Top-line P3-glaucoma
2H21 – Launch glaucoma

symptoms and the prescribing of additional drugs.

Fifty percent of glaucoma patients are on multiple drugs, due mainly to poor compliance.

Robust Near & Mid-Term Pipeline

Eyenovia had its pick of some 80 generic eye care products whose delivery could be enhanced by the company's micro-dosing technology. It has chosen four to pursue initially, blending development costs and timetables with market opportunity and the potential for above-average shareholder returns.

The tradenames for Eyenovia's four current product candidates are: MicroTears (dry eye), MicroStat (dilation), MicroProst (glaucoma), and Micropine (nearsightedness).

Eyenovia Dry Eye -- Eyenovia's choice for a dry eye product doesn't need to undergo FDA clinical trials for marketing approval. The active ingredient, polyvinyl alcohol, is covered by the FDA's Monograph Registration process. The company plans to register the product with the FDA in 1H19. Manufacturing scale-up activities are scheduled to be completed 2H19 for an anticipated launch in 1H20.

Eyenovia's micro-dosing device has an exchangeable lower section prefilled with sterile drug. It snaps into the upper ejection system containing the piezo electronics and batteries. It's 4.93 inches high and weighs 3.4 ounces. The technology's electronically-regulated 'no waste' dosing means that 75-80 percent less drug is required for a 30-day prescription. What's more, the smaller volume of drug contains up to 80 percent less preservatives, owing to the sterility of the patented drug chamber.

More than 20 million people in the U.S. suffer from dry eye, a disease that can result in tear film instability, inflammation, discomfort, and ocular surface damage.

It's a $2 billion category, with more than 200 million units sold over-the-counter annually.

Instead of vying for shelf space at pharmacies, Eyenovia plans a more efficient and sophisticated sell-in.

It plans to distribute the product to ophthalmologists and optometrists as a differentiated dry eye agent, providing eye docs with an early introduction to Eyenovia's technology, and a new revenue opportunity which, at busy practices, could be meaningful. Some 25 percent of their patients experience dry eye. For Eyenovia, it could generate annual sales of $70-95 million, analysts say.

Eyenovia Pupil Dilation – Ever feel discomfort from drops landing in your eyes to dilate your pupils before an eye exam? If so, you're likely not alone. In this country alone, the drops are a required prep step for 80 million eye exams a year.

Two pharmacologic agents (tropicamide and phenylephrine) are sequentially delivered to the eye with a dropper.

Eyenovia's micro-dosing eliminates overdosing, delivering only the amount of solution the eye's tear film can hold. And it goes one better: it combines the two agents into a single solution, making the whole procedure simpler, faster and more convenient.

Eyenovia plans to initiate a Phase 3 clinical trial in pupil dilation in 2H18, with top-line data expected 1H19.

The U.S. market for dilating agents is roughly $150 million a year.

Of the two additional pipeline programs, one (glaucoma) is scheduled to enter Phase 3 clinical trials in 1Q19, the other (myopia) in 1H19.

Eyenovia Glaucoma – Glaucoma presents in two forms: Open Angle Glaucoma, and Chronic Angle Closure Glaucoma (CACG), the least prevalent form. There are nearly 600,000 CACG sufferers in the U.S. and with no FDA-approved drug available, it's viewed as a fertile opportunity for Eyenovia.

The disease is characterized by a build-up of fluid inside the eye, which increases interocular pressure (IOP), a condition that, if left unchecked, can lead to loss of vision and even blindness. Consequently, 90 percent of CACG patients need lifelong IOP-lowering therapy.

The most widely prescribed treatment is off-label latanoprost, which is approved for the prevalent form of glaucoma but not for CACG. It's a useful solution at present, but typical eye dropper overdosing causes significant treatment-limiting adverse events such as hyperemia and sore eyes in more than 40 percent of patients.

Eyenovia's micro-dosing provides a potentially ideal solution. Latanoprost's mechanism of action and its wide (and effective) off-label use in CACG bodes well for a potentially successful development program, with Eyenovia's micro-dosing technology addressing the critical issues of compliance and treatment-limiting side effects.

The FDA registration program is expected to commence 1H19 with two identical randomized, controlled trials of 200 patients each. The primary endpoint is the mean IOP difference from control at three months. Top-line data readout is expected in 2020, with a potential market launch in 2H21.

The addressable U.S. market for both forms of glaucoma is $2.5 billion. Analysts estimate that Eyenovia's entry could generate roughly $500 million yearly in U.S. sales.

Eyenovia Myopia – Caught early at a young age, modern drugs can slow the progression of myopia, or nearsightedness – the ability to see things at close range better than at a distance.

There are two forms of the disease, pathological degenerative myopia and what is called spontaneous onset, or school-age myopia. The latter is Eyenovia's focus.

The company is planning to initiate a Phase 3 study of the drug atropine in 1H19, with top-line data expected mid-2023. The study time is required because of the slow-moving nature of the disease and the need to detect separation between drug and placebo over a span of years.

Atropine's utility in slowing the progression of myopia was first reported in the late '70s. Numerous studies and publications later, it became the 'go-to' (although not FDA-approved) treatment for school-age myopia.

More is not always better. A five-year study of children with myopia found that atropine 0.01 percent was more effective in treating the condition than atropine 0.5 percent and atropine 0.1 percent. Low-dose atropine appears tailor-made for the inherent attributes of Eyenovia's micro-dosing technology – exact volumetric delivery and reduced side effects.

More than six million people suffer from progressive myopia in the U.S., putting the addressble market at $5 billion. Analysts say this could support a revenue opportunity to Eyenovia of well over $500 million annually.

Summary Points

◇ Transformative technology for topical eye care ◇ Eliminates serious eye dropper issues ◇ Advances eye care with e-health features ◇ Feasibility and patient preference validated ◇ Late-stage pipeline - the first Phase 3 reports 1H19 ◇ Robust U.S. and int'l patent portfolio ◇ Rich news flow throughout year and into 2019

◇ Current market cap allows for significant expansion ◇ Aerie Pharmaceuticals (AERI) with a recently approved glaucoma product and a market cap of roughly $2 billion, is cited as a relevant comp among ophthalmic companies

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