UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) February 27, 2019

EYENOVIA, INC.

(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-38365		**47-1178401**
(Commission File Number)		**(IRS Employer Identification No.)**

295 Madison Avenue, Suite 2400, New York, NY 10017
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code 917-289-1117

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 7.01. Regulation FD Disclosure.

On February 27, 2019, Eyenovia, Inc. (the "Company") presented a corporate update to analysts and investors. A copy of the corporate update is attached hereto as Exhibit 99.1 and is incorporated herein in by reference.

The information contained in, or incorporated into, Item 7.01, including the corporate update attached as Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Eyenovia, Inc. corporate update dated February 27, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EYENOVIA, INC.

Date: February 27, 2019

By: /s/ John Gandolfo
Name: John Gandolfo
Title: Chief Financial Officer

Exhibit 99.1


Making it Possible
Analyst & Investor Lunch
February 27, 2019
eyenovia

Agenda

1. Brief overview of Eyenovia
2. Recent updates and accomplishments
3. Micro**Stat** MIST-1 and MIST-2 results
4. Discussion on in-office efficiency with Micro**Stat** with Robert Stapper, Director of Research at Keystone Research
5. Manufacturing strategy
6. Commercial strategy
7. Future opportunities
8. Summary
9. Q&A

Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this presentation are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in documents which we file with the SEC.

In addition, such statements could be affected by risks and uncertainties related to, among other things: risks involved in clinical trials, including, but not limited to, the initiation, timing, progress and results of such trials; the timing and our ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates and to raise money, including in light of U.S. government shut-downs; our ability to develop and implement commercialization, marketing and manufacturing capabilities and strategies; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; intellectual property risks; the impact of government laws and regulations; and our competitive position.

Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, we do not undertake any obligation to update any forward-looking statements.

Eyenovia: Building the Smart Eye Care Company of the Future

- Specialty ophthalmic bio-pharma with a smart, microdose therapeutic technology platform called Optejet™
- Unique patented piezo-print technology designed to enable new indications in high-value disease targets
- Breakthrough treatments for back-of-the-eye and front-of-the-eye indications

ORIGINAL PLAN

* US market only
1 Glaucoma estimate is first-line treatments only
2 Updated estimate for in office and cataract surgery uses
3 OTC eye care market

eyenovia

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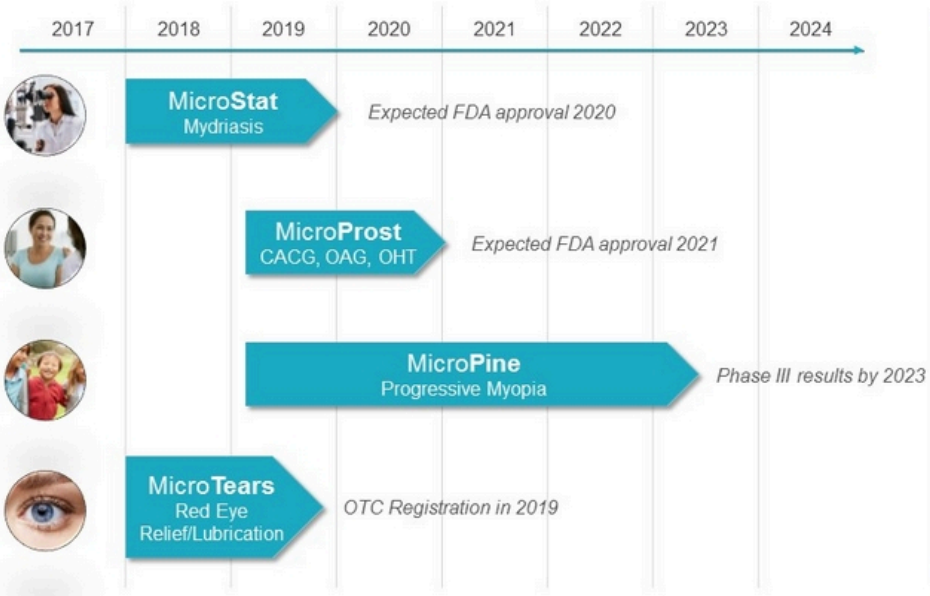
UPDATED PLAN

* US market only
[1] Glaucoma estimate is first-line treatments only
[2] Updated estimate for in office and cataract surgery uses
[3] OTC eye care market

Eyenovia: Strategy Aligned with Near, Mid and Long Term Opportunities



Recent Updates

MicroStat: Successful **Phase III** MIST-1 and MIST-2 registration studies; Preparing to initiate registration and stability manufacturing lot.

MicroProst: Targeting the larger, first-line market with a new program design.

MicroPine: Received FDA acceptance of IND application to initiate **Phase III** registration CHAPERONE study.

MicroTears: Conducted extensive market research with consumers and optometrists. Initiated formulation of ocular decongestant and anti-pruritic.

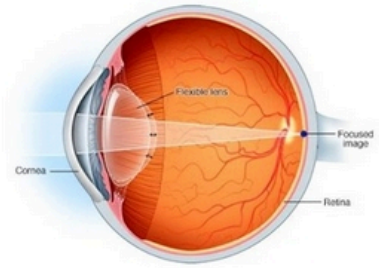
Sources: Analyst reports; Eyenovia corporate presentation

MicroStat for Pharmacologic Mydriasis

Estimated 80+ million mydriatic exams performed annually

Estimated 4 million pharmacologic mydriasis applications annually for cataract surgery

- Indispensable part of:
  - Comprehensive Eye Exam
  - Diabetic Retinal Exam
  - Macular Degeneration Retinal Exam
  - Retinopathy of Prematurity Screening
- Current eyedropper paradigm use two medications, which can overdose the eye (100µL vs 7 µL)[1]
  - Phenylephrine 2.5% (1-2 drops) and Tropicamide 1% (1-2 drops)
- Can be inefficient, and result in patient discomfort…and increased systemic/ocular exposure



[1] Bhurayanontachai, P., Saengkaew, S., & Apiromruck, P. (2016). Efficacy of an eye drop mixture for pupillary dilatation: A randomized comparative study. Journal of optometry, 10(2), 111-116.

Why should we be concerned about overdosing with eye drops?

- Many ophthalmic drugs are compounds that were designed for cardiovascular or other systemic effect (beta blockers, phenylephrine and others)
- When these drugs are overdosed to eye, they can seep into systemic circulation through periocular absorption and via nasolacrimal duct (bypassing liver metabolism, similar to IV delivery)
- The result can be changes in blood pressure, heart rate and lung function

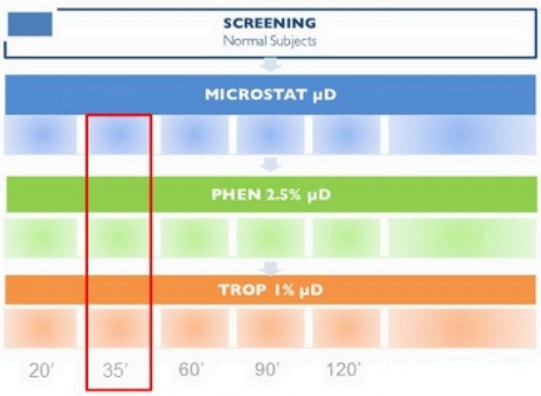
"Mean blood pressure increased significantly in infants given standard dilating drops.."[1]

[1] Acta Ophthalmol Scand. 1997

MicroStat: Two Phase III Registration Studies

- Double-masked, active-controlled, cross-over design
- Primary EP: Mean change in pupil diameter at 35 minutes vs baseline
- Powered at 90% for each study, assuming 54 evaluable subjects
- **MIST-1** (N=64 randomized):µD phenylephrine-tropicamide vs µD tropicamide vs µD phenylephrine
- **MIST-2** (N=70 randomized):µD phenylephrine-tropicamide VS µD placebo

MIST-1 Study Design



MIST-2 Study Design

MIST-1 Results: Primary Endpoint Analysis

1. Met primary efficacy endpoint of pupil dilation change from baseline at 35 minutes
2. Statistically larger 35 minute dilation for Micro**Stat** vs components
3. Additional outcomes:
   - 94% of eyes achieved 6 mm or greater pupil dilation at 35 minutes compared with 78% and 1.6% for the tropicamide-only and phenylephrine-only groups, respectively.
   - 57% of Micro**Stat**-treated eyes achieved 6 mm dilation or greater at 20 minutes versus 38% of the tropicamide-treated eyes and none in the phenylephrine-treated eyes
4. Treatment-emergent adverse events were mild and transient. There were no non-ocular adverse events.

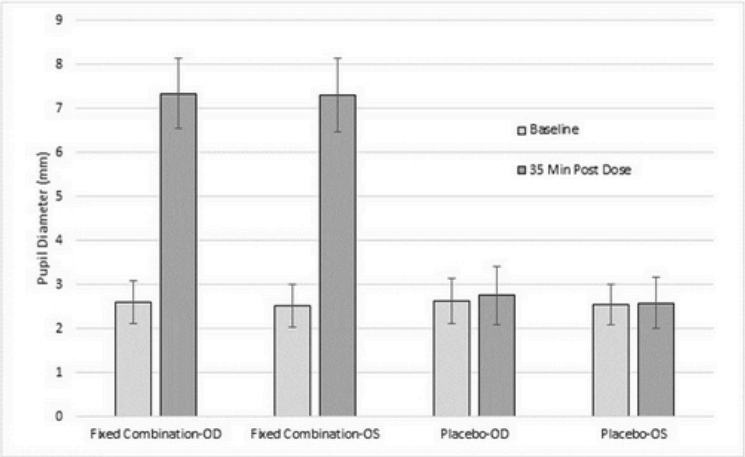
MIST-2 Results: Primary Endpoint Analysis

1. Met primary efficacy endpoint of pupil dilation change from baseline at 35 minutes
2. Micro**Stat** was clinically and statistically superior to placebo in terms of mydriatic effect
3. Additional outcomes:
   - 93% of eyes achieved 6 mm or greater pupil dilation
   - 68% of eyes achieved 7 mm or more pupil dilation at 35 minutes post-administration

MIST-2 Study Design

MIST-2 Results: MicroStat achieved significant dilation at 35 minutes

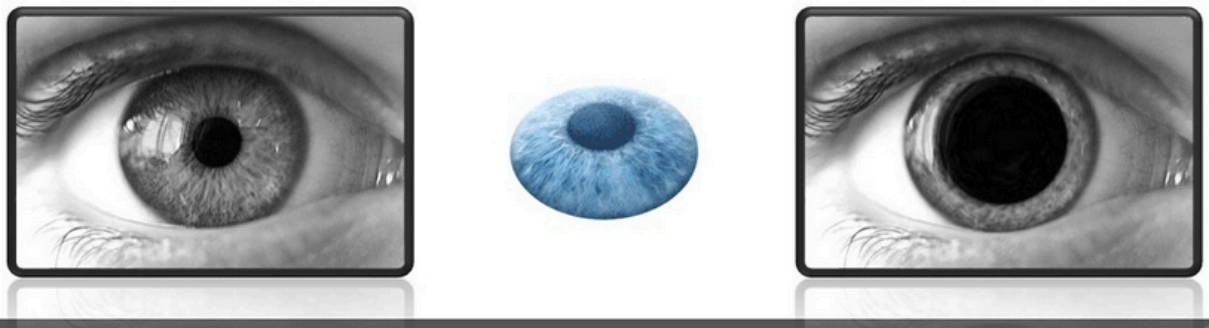
Pupil Diameter by Treatment at Baseline and 35 Minutes
(PP Population)



MicroStat: Key take-aways

Phase III results

1. Significant, prompt mydriasis achieved with microdose fixed-combination Phen-Trop
2. MicroStat achieved superior efficacy over single-agent components
3. Mydriasis >6 mm achieved in >93% of patients
   - Clinically meaningful for both office retinal exam and surgical dilation



MicroStat: Key take-aways

Additional context from our Phase II trial

- Phenylephrine is a cardioactive drug and micro-dosing reduced systemic exposure

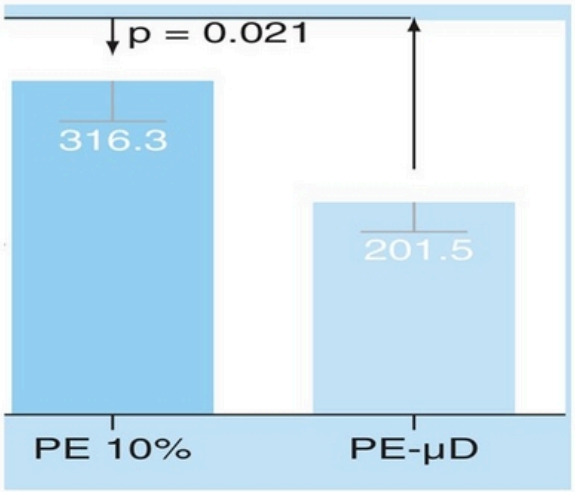
Therapeutic Delivery

High-precision piezo-ejection ocular microdosing: Phase II study on local and systemic effects of topical phenylephrine

Tsontcho Ianchulev[*,1], Robert Weinreb[2], James C Tsai[3], Shan Lin[3] & Louis R Pasquale[4,5]
[1]New York Eye & Ear Infirmary of Mount Sinai, New York, NY, USA
[2]Hamilton Glaucoma Center & Shiley Eye Institute, UCSD, San Diego, CA, USA
[3]UCSF Medical Center, San Francisco, CA, USA
[4]Glaucoma Service, Massachusetts Eye & Ear, Boston, MA, USA
[5]Channing Division of Network Medicine, Brigham & Women's Hospital, Boston, MA, USA
* Author for correspondence: Tel.: +617 216 4369; ianchul@yahoo.com

Aim: Conventional eyedropper-delivered volumes (25–50 µl) exceed the eye's usual tear-film volume (7 µl) and precorneal reservoir capacity, risking overflow and ocular/systemic complications. Piezoelectric high-precision microdosing may circumvent these limitations. **Results & methodology:** In this masked, nonrandomized, cross-over study, subjects (n = 12) underwent pupil dilation with topical phenylephrine (PE) administered by 32-µl eyedropper (2.5% or 10% formulation) and 8-µl electronic microdosing (10% formulation). Microdosing with PE-10% achieved comparable peak dilation as 10% eyedropper-delivery and superior dilation to 2.5% eyedropper-delivery ($p = 0.009$) at 75 min. Microdosing significantly reduced 20-min plasma PE levels versus PE10% eyedropper; neither treatment altered heart rate/blood pressure. Eye irritation occurred significantly less frequently with microdosing than PE10% eyedrops. **Conclusion:** Piezo-ejection PE microdosing achieves comparable biological effect as eyedropper dosing; reduced systemic absorption may decrease risk of systemic side effects.

First draft submitted: 15 September 2017; Accepted for publication: 16 October 2017; Published online: 27 October 2017



Robert Stapper, Director of Research at Keystone Research

- Discussion on how Micro**Stat** can improve in office efficiency and economics and the ease of use of Optejet, patient satisfaction and what it means for in office usage

Optejet: Eyenovia's Unique Technology

Microdosing
The micro-droplet achieves precise volumetric control to deliver 6-8 µL, which is physiological capacity of tear film

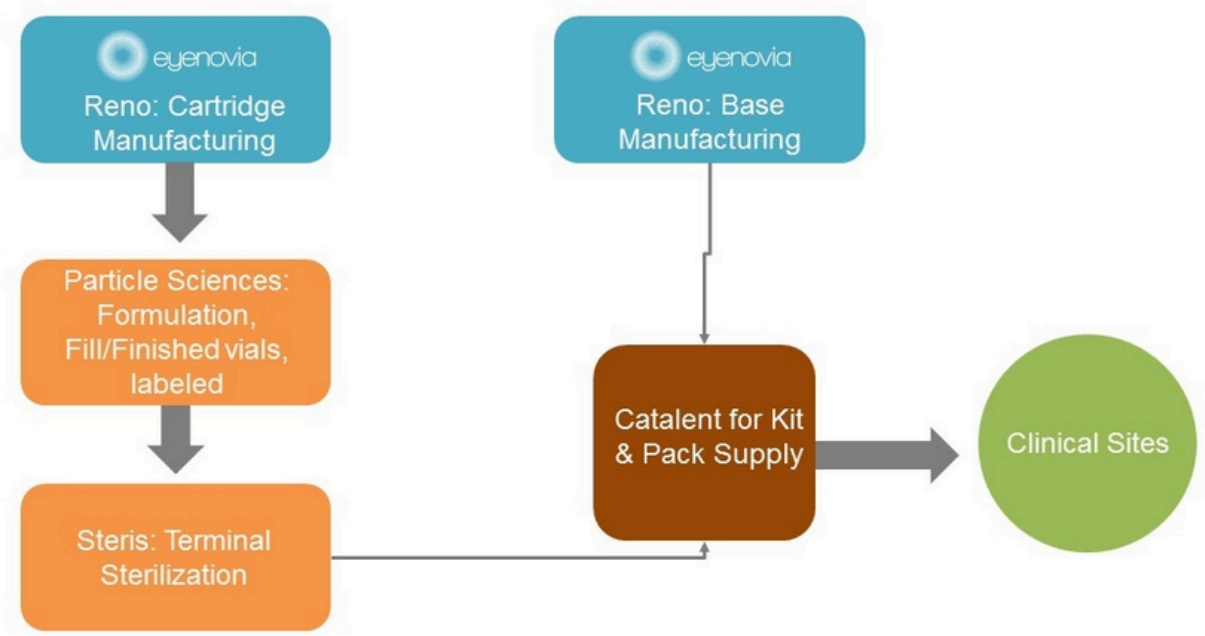
Precise, targeted topical delivery
Targeted delivery to the ocular surface and cornea, avoiding the conjunctival cul-de-sac

Beat-the-blink speed of delivery
Delivery of drug to ocular surface in less than 80 milliseconds beating the eye's blink reflex of 100 milliseconds

Smart electronics
Mobile e-health technology integration designed to support improved compliance, monitoring and disease management

Intellectual property
8 issued/7 pending patents U.S. & 27 issued/54 pending patents WW with runway to 2031

Manufacturing overview



Eyenovia is unlocking value in an estimated multi-billion dollar eye care market

Optejet microdosing value proposition is the foundation for our strategy

Optejet Platform

Technology Capabilities	Patient Benefits
Microdosing of less than 9µL	Retains **efficacy** but potentially **minimizes local and systemic side effects**, thus increasing **tolerability**
Precise targeted topical delivery to the ocular surface and cornea	**Ease of use – 88% success vs. 50% for traditional eye droppers - and gentle delivery** provide a better patient and physician **user experience and potential outcome**
Beat-the-blink speed of delivery at 80 milliseconds	Faster than the eye's blink reflex of 100 milliseconds which **optimizes drug delivery** and **reduces irritation**
Smart electronics and mobile connectivity	Assists in **adherence/compliance** and facilitates **patient-to-physician discussion**

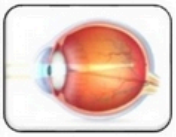
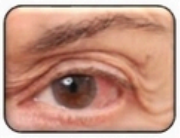
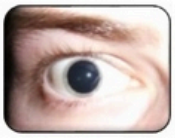
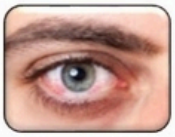
Alignment of unmet need and our value proposition

Eyenovia Vision

Eyenovia is making new approaches in topical ophthalmic drug therapy possible through the Optejet platform

- **Microdosing**
- **Precise, targeted topical delivery**
- **Beat-the-blink speed of delivery**
- **Smart electronics**

Indications / Applications

Progressive Myopia	Glaucoma CACG, OAG, OHT	Mydriasis	Red/Itchy Eyes
			
			
MicroPine	MicroProst	MicroStat	MicroTears

Eyenovia Programs

Development Pipeline

* US market only
[1] Glaucoma estimate is first-line treatments only
[2] Updated estimate for in office and cataract surgery uses
[3] OTC eye care market

Micro**Prost:** Updated Strategy

- Expanded Micro**Prost** Phase III program to include chronic angle closure glaucoma (CACG), open angle glaucoma (OAG) and ocular hypertension (OHT) patients
- Potential total addressable population of approximately 4 million patients in the U.S.
- Optimized trial design to consist of a single Phase III trial
- Patients who are currently prescribed or are candidates for prostaglandin therapy may have the option for next-generation, smart, microdose delivery

MicroTears: Update

- **Formulation**
  - Updated formulation for ocular decongestant and anti-pruritic
  - Will address both lubrication and eye redness relief in order to expand use for more cosmetic applications
  - Designed to address unmet medical and consumer needs:
    - lower medication rebound effect[1]
    - lower preservative exposure
    - easier and more pleasant to use
- **Commercial model similar to MicroStat with direct sales to optometrists using specialty pharmacy network (SPN)**

[1] Abelson MB, Butrus SI, Weston JH, Rosner B. Tolerance and absence of rebound vasodilation following topical ocular decongestant usage. Ophthalmology. 1984;91:1364–1367.

Two recently completed market research projects

- 17 consumers in two, 2-hour long focus groups in Long Beach, CA
  - One group of OTC eye drop users, mix of ages (21-65 years old, some over 65 years old), mix of male/female, must be people who use artificial tears, eye whiteners, etc. at least once daily
  - One group must include prescription eye drop users (e.g. glaucoma or Restatis or Xiidra), mix of ages (again including >65 years old), mix of male/female
- 50 optometrists in an internet-based study
  - Prescreened for importance of retail to their overall practice

Consumers reported many advantages of Optejet

Some of Optejet's key attributes include:

- **Accurate doses** - "it's literally one drop"
- **Less waste**
- **Less messy**
- **Connects with phone** - "it's great to know how much is left"
- **Less time consuming than drops** - "it goes right in"
- **High tech (particularly younger participants)** - "I thought it was super fun, super cool…I think it's very appealing"
- **Accessibility** - easier for patients with arthritis, older patients, large hands, etc.
- **Better with makeup** - "I would definitely try this…I'm intrigued, because it didn't run all over my face"

Optometrists were presented with the Micro**Tears** profile

Caveat that the dispenser would be smaller than what was seen here.

Tested Product Profile

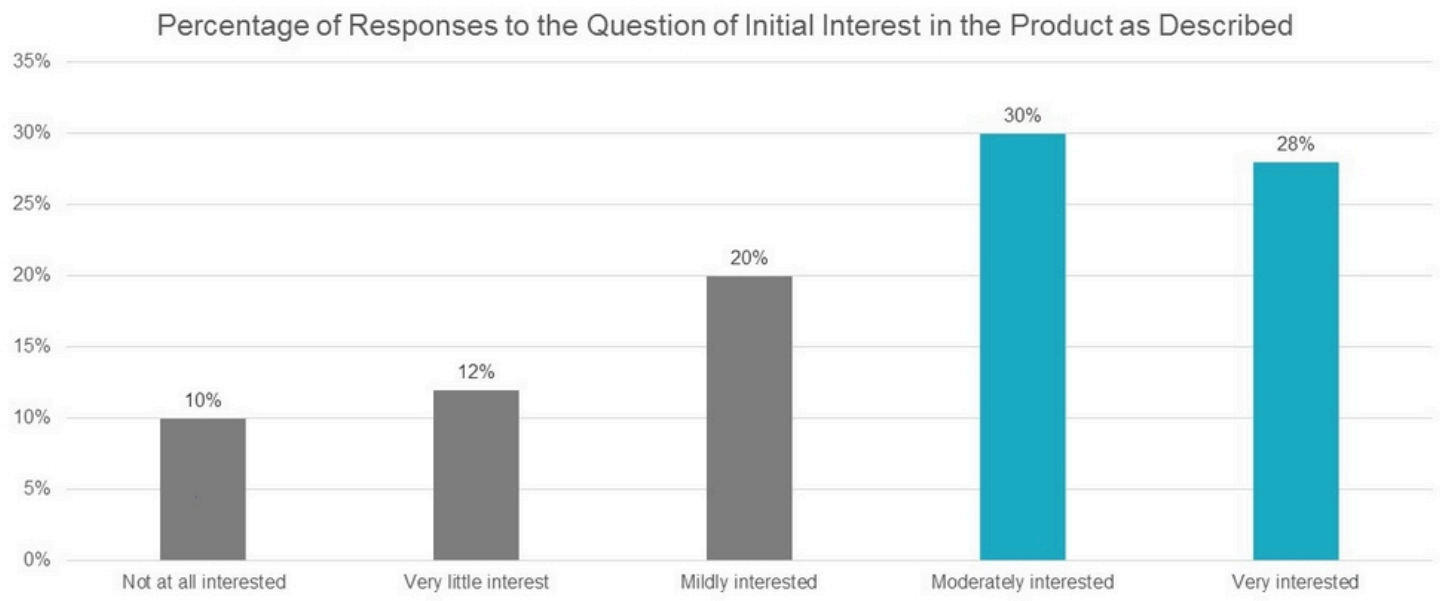
A NASDAQ listed publicly traded ophthalmic pharmaceutical company has an FDA-approved over-the-counter medication for the treatment of ocular redness and itch. The medication is delivered in a patented microdosing dispenser (the Optejet), delivering ¼ of the volume of a typical eye drop through a horizontally-applied (e.g., no need to tilt the head) "inkjet" technology that avoids spillage out of the eye (see image below).

In usability tests with patients, the Optejet dispenser has been found easier to use than eye dropper bottles, providing a neater, more comfortable experience for patients and avoiding nuisances such as messing make-up and the ability to instill the medication without needing to look into a mirror.

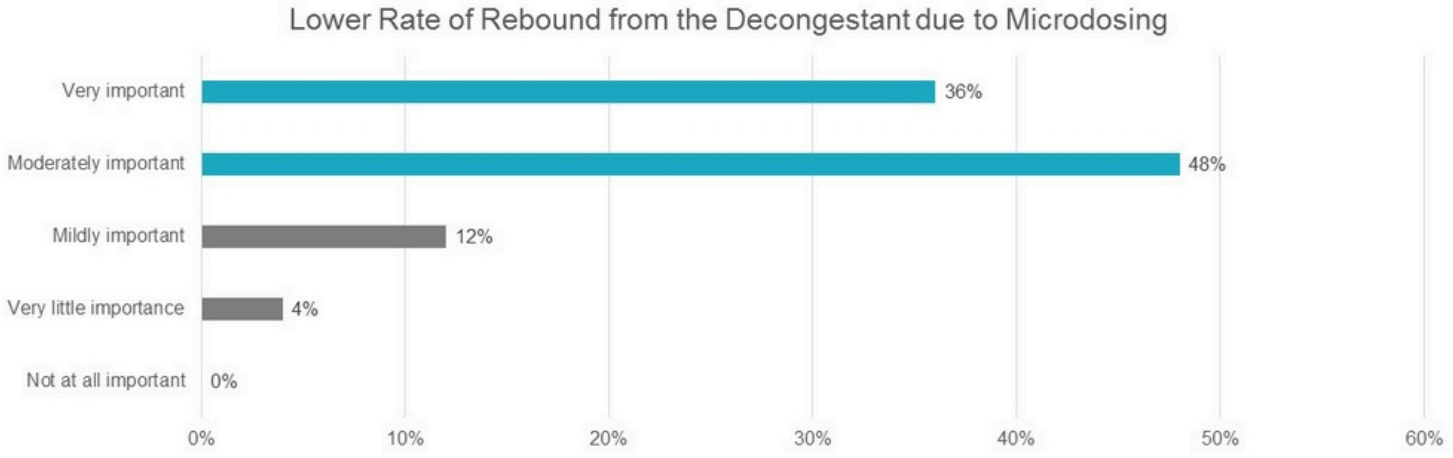
The contents of the Optejet include an ocular decongestant and an anti-itch medication. Both are available without prescription.

The product is only sold through eye care professional offices.

Majority of optometrists were moderately to very interested in selling Optejet



Medical differentiation was important

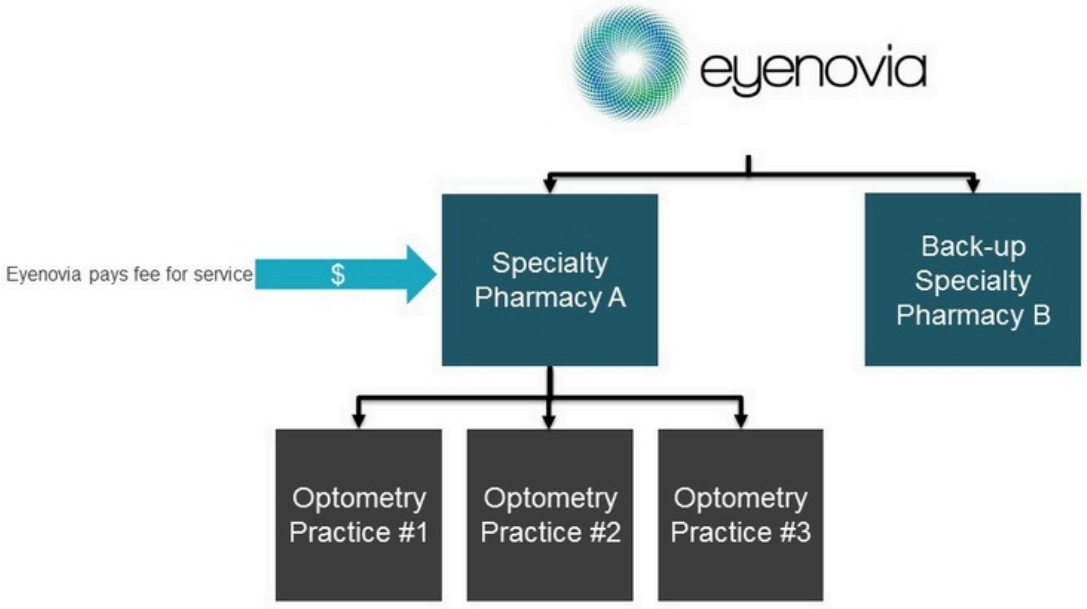


The added features of lower incidence of rebound from the decongestant and lower exposure to preservatives, both due to microdosing, were seen as desirable by these optometrists.

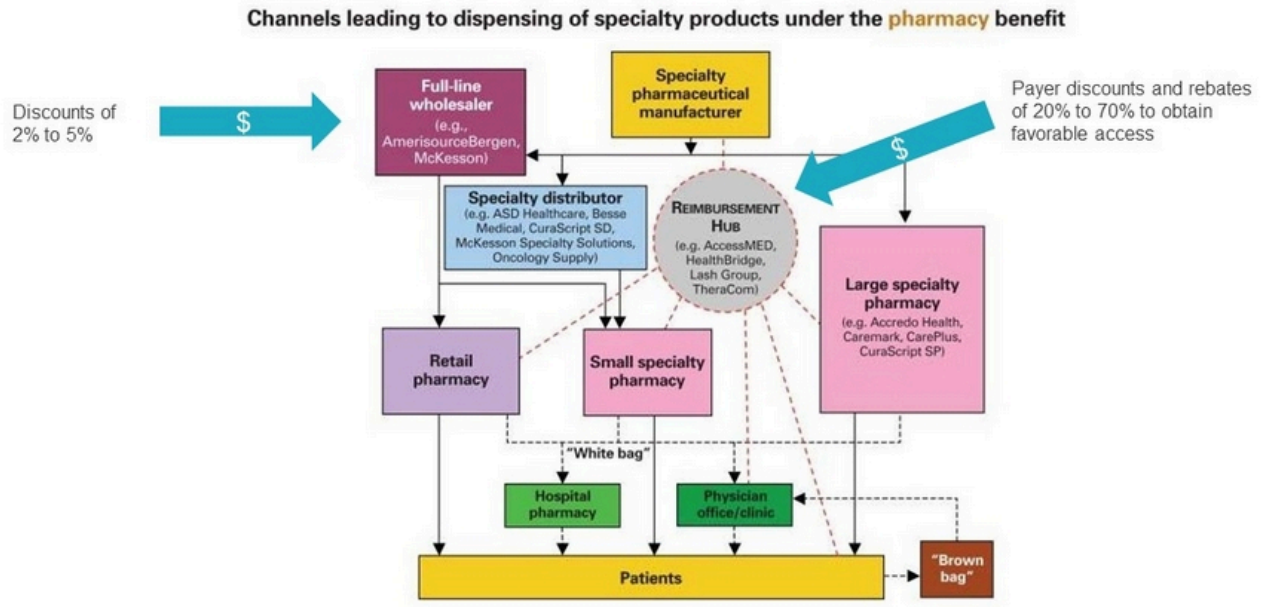
Optometrist Research: Conclusion

- **The retail portion of the business is very important to optometrists**
  - Currently less than 30% sell eye drops due to lack of differentiated products
  - Majority would be interested in selling Micro**Tears**
- **High interest in the MicroTears product profile with a focus on:**
  - Promoting benefits of microdosed drug and preservatives
    - Lower incidence of rebound from decongestant (naphazoline)
    - Better for the ocular surface
    - Cleaner, easier delivery (horizontal without waste overflowing the eye)

Go-to-market model: What is a specialty pharmacy network (SPN)?



Traditional Prescribing Process



Source: Pembroke Consulting, 2012

Traditional distribution can add costs to company and prescribers

- Sales representatives competing for time with the doctors and space in the sample closet
- Payments to distributers
- Rebates to managed care organizations contracting to cover the product
  - Branded copays can average $40-$50
- Prescribers often employ staff at their own expense to manage “call backs” – calls from pharmacies and patients when patients cannot obtain product at a reasonable cost

Closed distribution model (SPN) potentially provides major benefits and cost savings

Benefits of closed distribution model (SPN)

Reduced costs – no wholesaler discounts; no need for large staff at EYEN to manage distribution

Customer data sharing – EYEN strives to know who orders and when in order to link directly to sales force

Consistent customer experience

Similar programs already exist in eye care

Akorn (Cosopt and Zioptin)

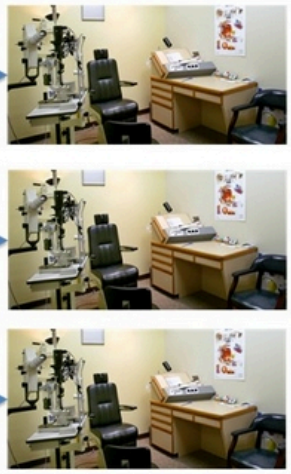
Sun Pharma (Xelpros)

MicroStat will use the same SPN as MicroTears

No branded options
No sales support
Current price: $125 for 15ml*

Office technician orders either directly on-line or through wholesaler **for entire practice**

Replacement stock kept on site



Product remains in each exam lane until it needs to be replaced

*Suppleyes.net price as of 15 Feb 2019

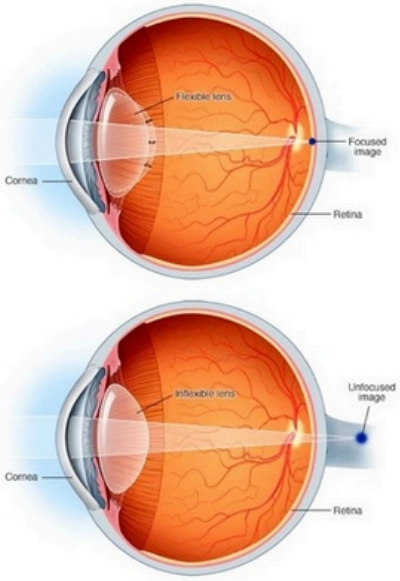
Key Account Directors

MicroProst will explore SPN and reimbursement model

- May be available to patients immediately
- No discounts to distribution partners
  - Fee for service to SPN
- Cost to patients may be similar to branded copays; less for patients using high-deductible plans
- Requires smaller in-house staff to manage
- ECPs report a strong preference for consistency in the patient experience when the Rx is filled

Future Opportunities: Presbyopia

Etiology	• Non-preventable, age-related hardening of the lens
Symptoms	• Tendency to hold reading material farther away to make the letters clearer • Blurred vision at normal reading distance • Eyestrain, headaches after reading or doing close-up work
Risk Factors	• Age • Medical conditions and co-morbidities such as CV conditions, MS, T2D can increase risk of premature presbyopia • Drugs associated with premature symptoms include antidepressants, anti-histamines, diuretics
Diagnosis	• Basic eye exam, with refraction assessment



Sources: Mayo Clinic Presbyopia Overview. Wolffsohn et al. Prog Retin Eye Res. Fernandez et al. J Ophthalm. Accessed December 2018

Presbyopia: Prevalent Vision Correction Issue

113 Million Americans with Presbyopia

20 Million Americans (age 45-55) with Presbyopia

- Prevalence expected to increase and reach ~123 million by 2020, representing over 1/3 of US population; driven by aging population
- Nearly everyone experiences some degree of presbyopia after age 40
- Up to 1/3 of presbyopia sufferers are un-managed
- Presbyopia is a significant and emotional event in an adult's life – and often seen as the first sign of aging they cannot hide
- **Psychosocial impact is most important between onset (~40yo) and age 50-55; this subset is also most likely to respond to Rx treatment, and willing to pay for it**

Sources: T, Fricke and N, Tahhan, Global Prevalence of Presbyopia and Vision Impairment from Uncorrected Presbyopia. 2018 Global Presbyopia Market Scope Research Report. Cataract & Refractive Surgery Today Europe. Accessed December 2018.

Current Treatment Options are Exclusively Device-based Modalities

High unmet need for consumers with presbyopia unwilling to use glasses or ineligible / unwilling to go undergo invasive treatments

Treatment Options	Reading Glasses (Non-Prescription, Prescription)	Contact Lenses (Bifocal, Mono, Modified Mono, Monovision)	Refractive Surgery (Keratoplasty, LASIK, LASEK, PRK)	Corneal Inlays	Refractive Lens Exchange (Multifocal, Accommodative)
					
Cons & Potential Issues	Visible treatment option	May not eliminate need for glasses fully, not indicated if other ocular surface conditions	Dry eye, under/over correction, astigmatism, flap problems	Corneal haze, glare, drop in best-corrected visual acuity	Risk of retinal detachments, increased IOP, ptosis, glare, halos

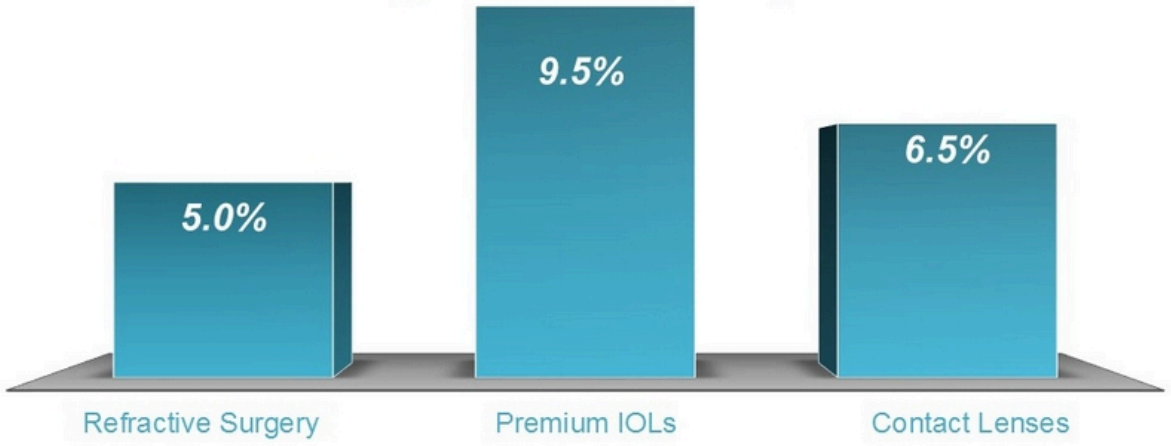
Increasing Invasiveness

Optejet: Highly Differentiated Value Proposition in Presbyopia

- **Short-term improvement in vision in patients with presbyopia (3–4 hours, for patients who require ≤2.0 diopters correction)**
- **Microdosing should address issues of brow ache associated with pilocarpine**
- **Optejet allows for fast & precise instillation (e.g. cosmetically acceptable and easy to use for episodic use)**
- **Same SPN distribution system and cash-pay model as MicroTears, MicroStat and MicroProst**

Ophthalmology Consumer Market Continues to Grow in the US

Ophthalmology Consumer Market 2017-2023 Projected CAGR
(Unit or Procedure Volume)



Willingness to pay cash for refractive outcomes creates large opportunity for presbyopia

Sources: Ophthalmic Single Use Surgical Product Market Report. 2015. MarketScope. Accessed December 2018.

Eyenovia Aims to Successfully Launch Four Products in Ophthalmology by 2023

	MicroPine	MicroProst	MicroStat	MicroTears
				
FDA Registration	2023	2021	2020	2019
Population Size	Moderate	Moderate	High	High
Competitive Position	High	Medium	Medium	Low-Medium
Value Proposition	Designed to maximize treatment success for slowing Pediatric Progressive Myopia	Addresses issues of self-instillation, tolerability and compliance within the broadest patient population	Fast and effective mydriatic that may improve patient satisfaction and practice flow	MicroTears is a safe, easy-to-use product to relieve ocular itch and redness
Go-to-Market strategy	Available through the retail channel and expected to be covered by insurance	Available through closed SPN and expected to be a cash-pay product at launch	Sold directly to ECP offices	MicroTears will be sold as a premium cash-pay product in ECP offices