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): **January 20, 2021**

OCULAR THERAPEUTIX, INC.
(Exact Name of Company as Specified in Charter)

Delaware	**001-36554**	**20-5560161**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

24 Crosby Drive
Bedford, MA 01730
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: **(781) 357-4000**

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**OCUL**	**The Nasdaq Global Market**

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 ☐

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 January 20, 2021, Ocular Therapeutix, Inc. (the "Company") announced its intent to present interim data at the Glaucoma 360 Conference from the Company's ongoing multi-center, open-label, dose-escalation, proof-of-concept Phase 1 clinical trial of product candidate OTX-TIC compared to topical travoprost eye drops in patients with primary open-angle glaucoma or ocular hypertension. OTX-TIC is a bioresorbable hydrogel implant incorporating travoprost that is designed to be administered by a physician as an intracameral injection with an initial target duration of drug release of four to six months. Information to be provided during such presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be deemed to be "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 such section, nor will such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

99.1	Ocular Therapeutix, Inc. slide presentation, dated January 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

OCULAR THERAPEUTIX, INC.

Date: January 20, 2021

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer

(NASDAQ: OCUL)

OTX-TIC, AN INTRACAMERAL HYDROGEL-BASED TRAVOPROST IMPLANT TO TREAT PATIENTS WITH GLAUCOMA & OCULAR HYPERTENSION

PHASE 1 TRIAL UPDATE

MICHAEL GOLDSTEIN, MD, MBA
PRESIDENT, OPHTHALMOLOGY & CHIEF MEDICAL OFFICER

GLAUCOMA 360 | VIRTUAL | JANUARY, 2021

Ocular Therapeutix™

FINANCIAL DISCLOSURE

Sponsorship for the clinical trial: Ocular Therapeutix, Inc.

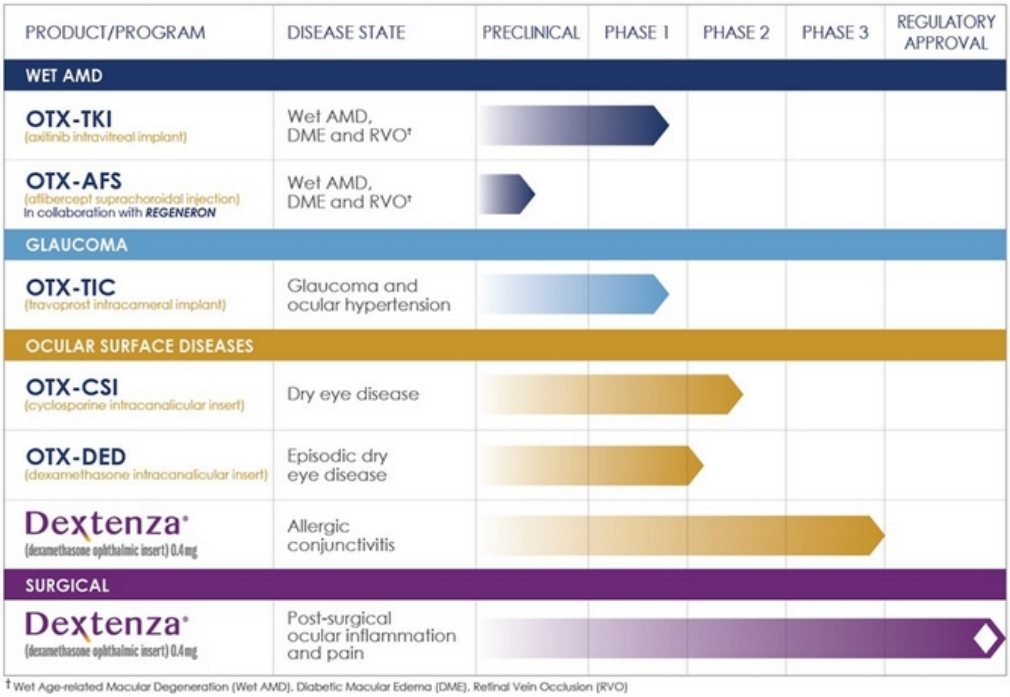
The author(s) do have financial interest in this presentation:
Dr. Goldstein is an employee of Ocular Therapeutix

Ocular Therapeutix™

FORWARD LOOKING STATEMENTS

Any statements in this presentation about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA®, ReSure® Sealant, or any of the Company's product candidates; the commercial launch of, and effectiveness of reimbursement codes for DEXTENZA, the conduct of post-approval studies of DEXTENZA, the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of DEXTENZA for additional indications including allergic conjunctivitis, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-CSI for the chronic treatment of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-AFS as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the size of potential markets for our product candidates; the potential utility of any of the Company's product candidates; the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, including any potential future payments thereunder; projected net product revenue, unit sales and other financial and operational metrics of DEXTENZA; the expected impact of the COVID-19 pandemic on the Company and its operations; the sufficiency of the Company's cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain reimbursement codes for DEXTENZA, the initiation, timing and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the Company's ability to generate its projected net product revenue and unit sales on the timeline expected, if at all, the sufficiency of cash resources, the Company's existing indebtedness, the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default, the outcome of the Company's ongoing legal proceedings, the severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, any additional financing needs or other actions and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this presentation represent the Company's views as of the date of this presentation. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this presentation.

PIPELINE AT A GLANCE



† Wet Age-related Macular Degeneration (Wet AMD), Diabetic Macular Edema (DME), Retinal Vein Occlusion (RVO)

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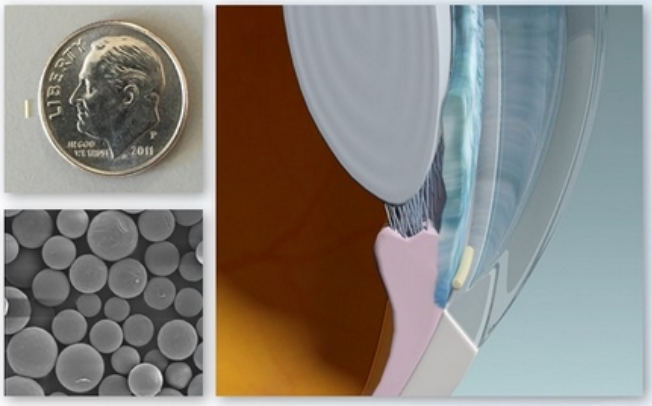
DRUG DELIVERY TO THE INTRACAMERAL SPACE

Factors for Consideration in Designing a Long Duration Intracameral Implant:

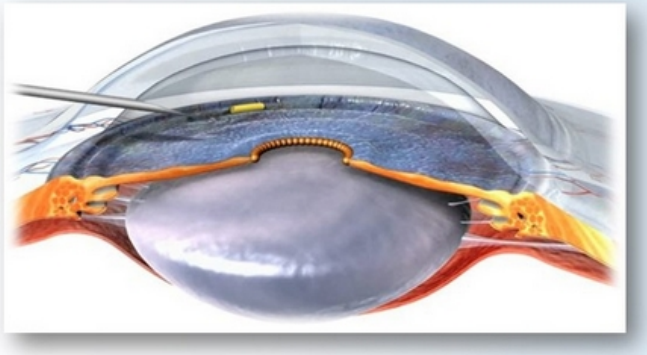
- Clinically-meaningful decrease in IOP
  Well-tolerated with clinically-meaningful efficacy
- Duration of therapy
  4 months or more
- Bioresorbable
  Duration of drug and duration of carrier vehicle
- Implant location and movement
  Limited movement and cosmetically invisible, but able to be monitored
- Corneal health
  Gentle to the endothelium



OTX-TIC (TRAVOPROST IMPLANT) FOR INTRACAMERAL INJECTION

Product Attributes

- Travoprost loaded microparticles in hydrogel
- Preservative-free
- Hands-free alternative to traditional eye drops
- Administered via a single injection with proprietary injector (26G-27G)
- Implant resides in the iridocorneal angle, hydrates in less than 2 minutes
- Fully biodegradable



In preclinical models (beagle dogs):

- Steady state *in vitro* and *in vivo* release through 4 months, which correlates to a duration of 4-6 months in humans
- Demonstrated IOP lowering effect of approximately 25-30% through 4 months

OTX-TIC PHASE 1 STUDY

OBJECTIVE: To evaluate the safety, tolerability and efficacy of a single OTX-TIC implant, in subjects with primary open-angle glaucoma or ocular hypertension in a Phase 1 study

DESIGN

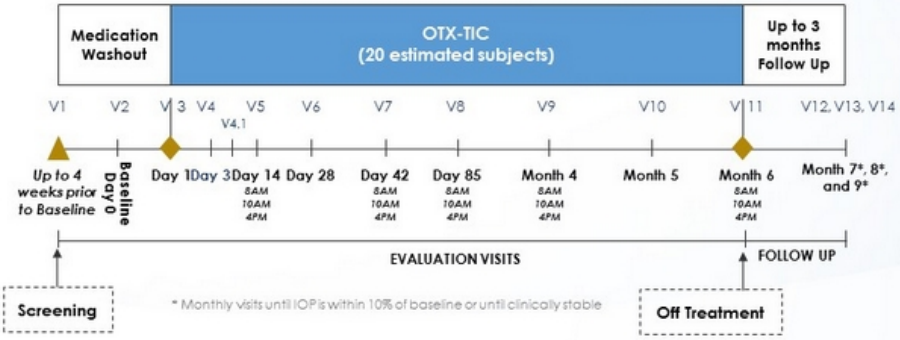
- Open-label, proof-of-concept study
- US study, approximately 20 subjects at 5 sites
- One eye per patient will be treated
- Key Inclusion criteria:
  - Controlled ocular HTN or POAG
  - Open, normal anterior chamber angles on gonioscopy

EVALUATIONS

- Safety, tolerability, and biological activity
- Diurnal IOP at Baseline, 2 weeks, 6 weeks, 12 weeks, Month 4, and Month 6 (8 AM, 10 AM, 4 PM)

ACTIVE COMPARATOR

- Non-study eye receives **topical travoprost** daily



Cohort 1: 15µg
(n=5; 22-month follow-up)

Cohort 2: 26µg
(n=4; 9-month follow-up)

Cohort 3: 15µg
[Fast Degrading Hydrogel]
(n=5; 6-month follow-up)

Cohort 4: 5µg
(n=5; 6-month follow-up)‡

NB: Interim look as of 01/12/2021; Unmonitored data.
‡Ongoing follow-up

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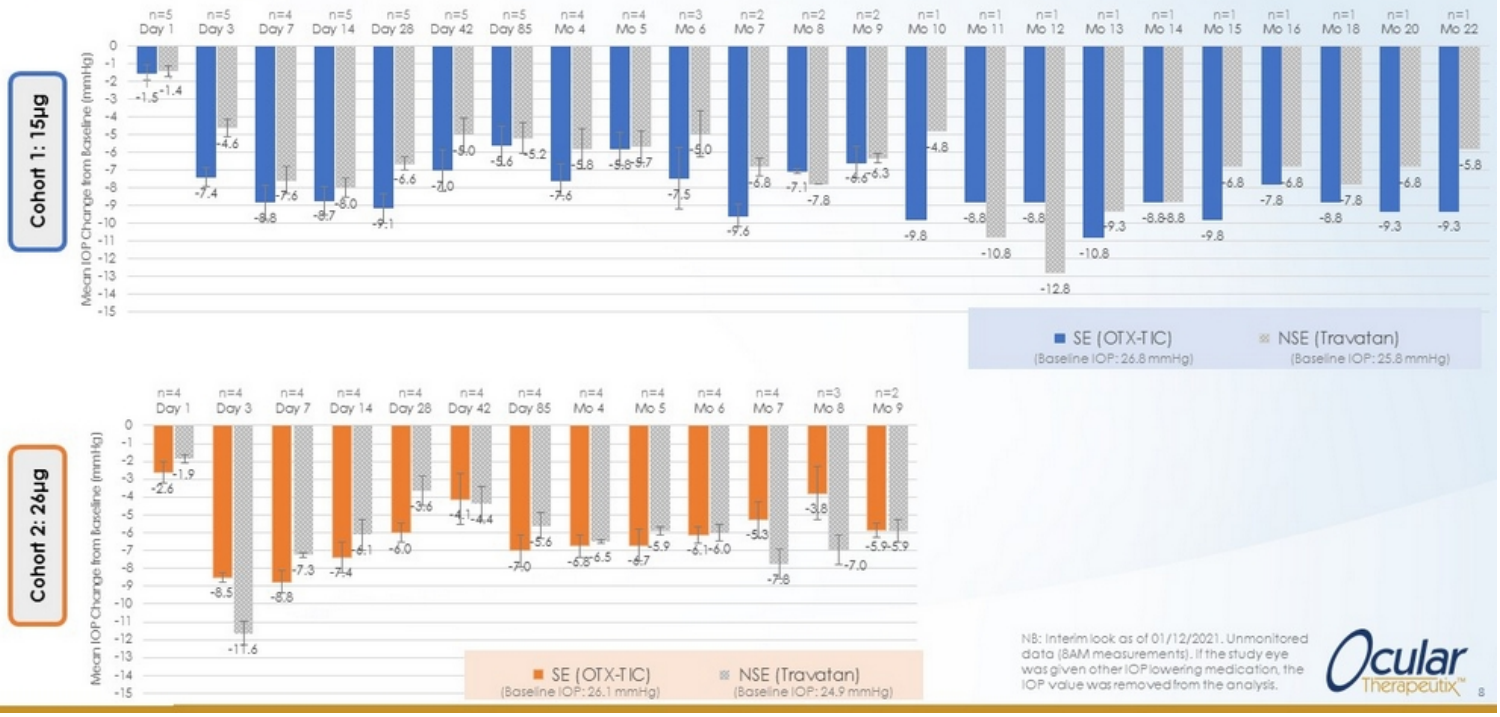
COHORTS 1 & 2: MEAN IOP CHANGE FROM BASELINE



NB: Interim look as of 01/12/2021. Unmonitored data (8AM measurements). If the study eye was given other IOP lowering medication, the IOP value was removed from the analysis.

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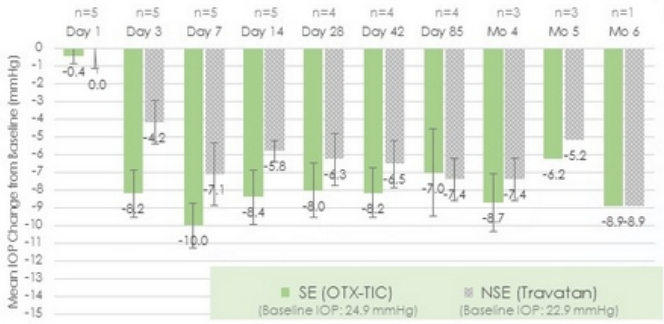
COHORTS 3 & 4: MEAN IOP CHANGE FROM BASELINE

Cohort 3: 15µg (Fast-degrading)

*Visits missed by 2 subjects due to COVID-19
** Visits missed by 1 subject due to COVID-19

Cohort 4: 5µg (Fast-degrading)



On-going follow-up: 1 subject at Day 14 FU, 2 subjects at 5 month

NB: Interim look as of 01/12/2021. Unmonitored data (8AM measurements). If the study eye was given other IOP lowering medication, the IOP value was removed from the analysis.

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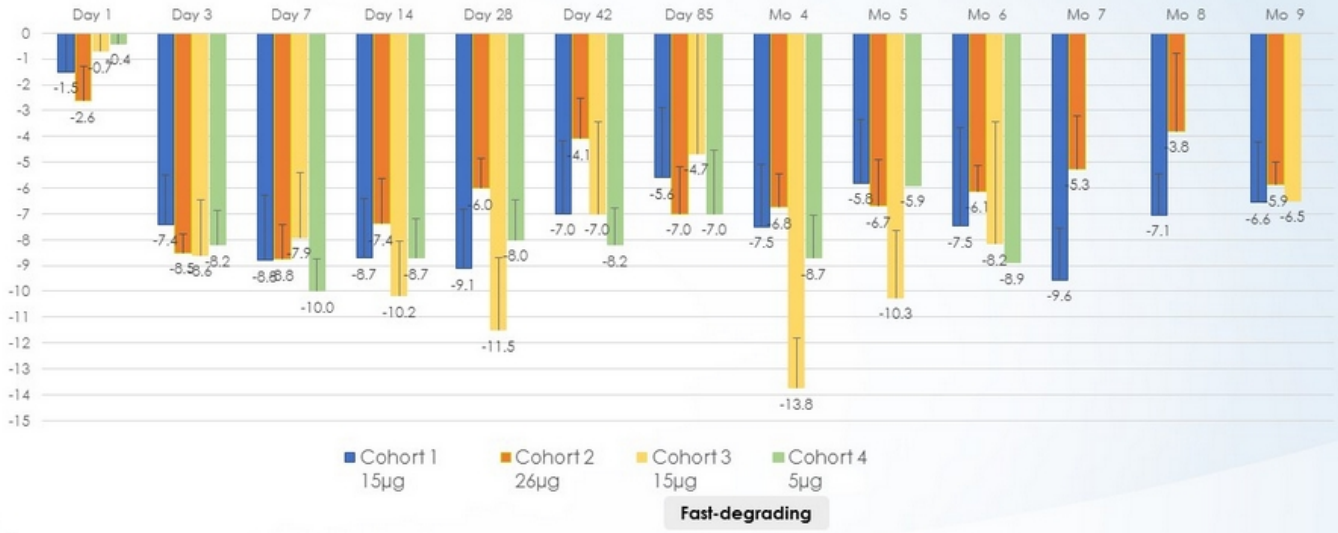
ALL COHORTS: MEAN IOP CHANGE FROM BASELINE

IOP Decreased after 2 days following OTX-TIC implantation & Lowering up to 7-11 mmHg Recorded



NB: Interim look as of 01/12/2021. Unmonitored data (8AM measurements). If the study eye was given other IOP lowering medication, the IOP value was removed from the analysis.

ALL COHORTS: DURATION OF EFFECT WITH ONE IMPLANT

Cohort 2 Showed the Most Consistent Durable Response in all Subjects up to Month 6 & 50% of Subjects up to Month 9

	Day 42 % (n/N)	Day 85 % (n/N)	Month 4 % (n/N)	Month 5 % (n/N)	Month 6 % (n/N)	Month 7 % (n/N)	Month 8 % (n/N)	Month 9 % (n/N)	Month 10-22 % (n/N)
Cohort 1 (15 µg) N=5	**100**(5/5)	**100**(5/5)	**80**(4/5)	**80**(4/5)	**60**(3/5)	40 (2/5)	40 (2/5)	40 (2/4)	20 (1/5)
Cohort 2 (26 µg) N=4	**100**(4/4)	**100**(4/4)	**100**(4/4)	**100**(4/4)	**100**(4/4)	**100**(4/4)	**75**(3/4)	**50**(2/4)	NA
Cohort 3 (15 µg) (Fast-degrading) N=5	**100**(5/5)	**60**(3/5)	40 (2/5)	40 (2/5)	40 (2/5)	20 (1/5)	20 (1/5)	20 (1/5)	NA
Cohort 4 (5 µg) (Fast-degrading) N=5‡	**100**(4/4)	**100**(4/4)	**75**(3/4)	**75**(3/4)	**50**(1/2)	NA	NA	NA	NA
Total‡	100 (18/18)	89 (16/18)	72 (13/18)	72 (13/18)	63 (10/16)	50 (7/14)	43 (6/14)	39 (5/13)	20 (1/5)

NB: Interim look as of 01/12/2021. Unmonitored data (8AM measurements)
‡Ongoing follow-up

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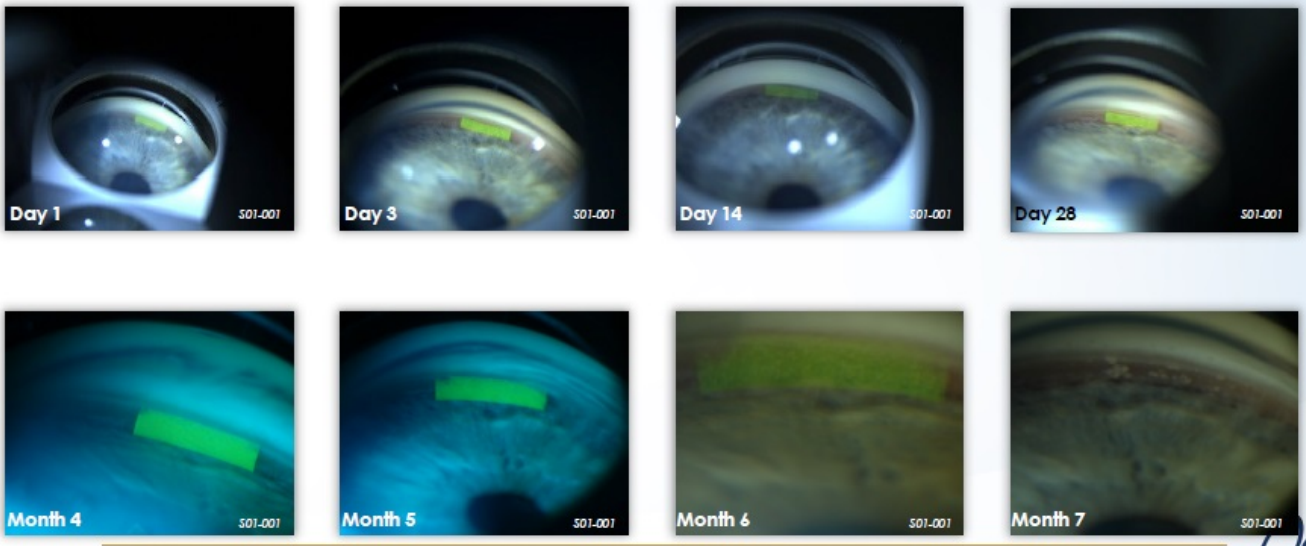
IMPLANT VISUALIZATION: NO NOTICEABLE MOVEMENT OBSERVED

- **Cohorts 1 & 2:** Implant biodegraded by 5-7 Months
- **Cohorts 3 & 4:** Fast-degrading implants biodegraded by 3-5 months in majority of patients in Cohort 3 (except 1 subject) and appears to have a similar timeline in Cohort 4 (follow-up on-going)



NB: Interim look as of 01/12/2021; Unmonitored data.

ALL COHORTS: SAFETY OVERVIEW

Ocular Adverse Events in the Study Eye

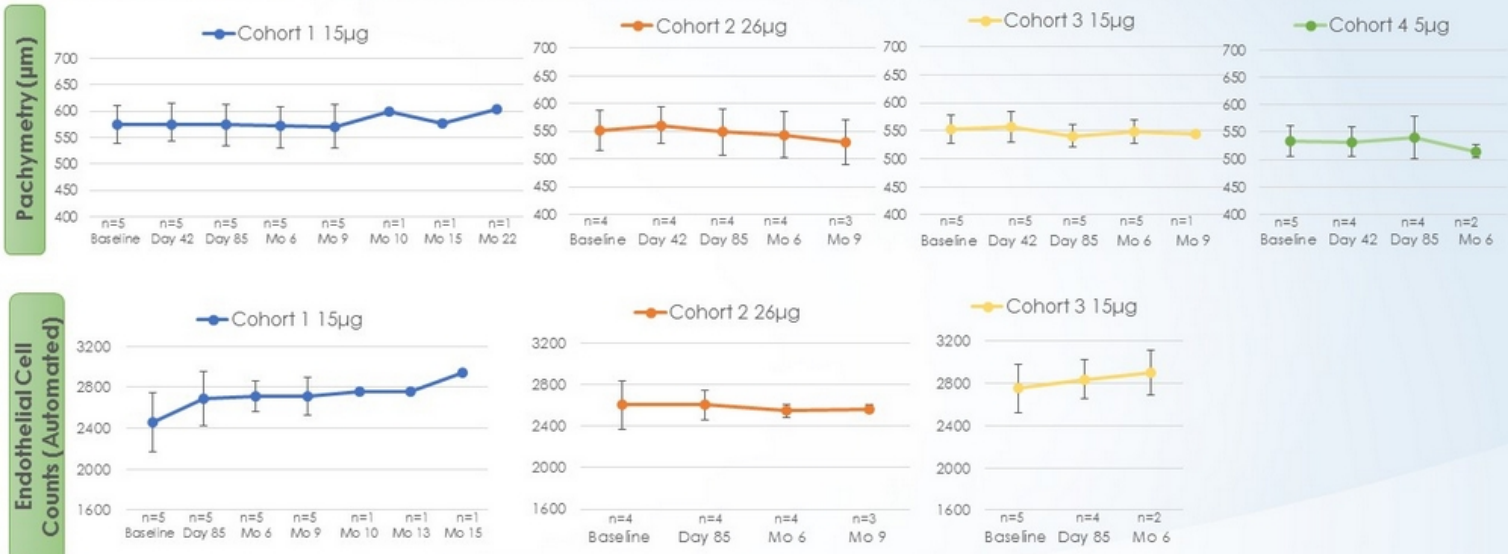
			Fast-degrading		
Number of subjects with ocular AEs:	Cohort 1 (15µg) N=5	Cohort 2 (26µg) N=4	Cohort 3 (15µg) N=5	Cohort 4 (5µg) N=5	OTX-TIC N=19
Iritis	2	2	1	1	6
Peripheral anterior synechiae	3	0	0	0	3
Corneal Edema	0	1	0	0	1
Subconjunctival Hemorrhage	0	0	1	0	1
Elevated IOP	0	0	2	0	2
Total AEs per cohort	**5**	**5**	**4**	**1**	**13**

NB: In Cohort 1, two same subjects had iritis and peripheral anterior synechiae.

NB: Interim look as of 01/12/2021; Unmonitored data.

ALL COHORTS: NO EFFECT OBSERVED ON CORNEAL HEALTH

Pachymetry & Endothelial Cell Counts Indicate No Clinically-Meaningful Change from Baseline



NB: Interim look as of 01/12/2021; Unmonitored data.

CONCLUSIONS

OTX-TIC shows Promise as a Sustained-Release Therapy with a Long Duration of Action

- **Clinically-meaningful decrease in IOP**
  Mean IOP values were decreased in patients receiving both OTX-TIC as early as two days following administration, and mean IOP decrease was comparable to topical travoprost therapy
- **Duration of therapy**
  Many subjects exhibited duration of IOP-lowering effect of 6+ months in Cohorts 1 and 2, and between 3-6 months in Cohorts 3 and 4 (fast degrading implant) with a single implant: Longest and most consistent IOP lowering in Cohort 2
- **Bioresorbable**
  Implant biodegraded in 5- 7 months (Cohorts 1 & 2); Fast degrading implants biodegraded in 3-5 months (Cohorts 3 & 4)
- **Implant location and movement**
  Implant was not observed to move at slit lamp and was visible at all exams in all patients using gonioscopy
- **Corneal health**
  Endothelial cell counts, pachymetry assessments, and slit lamp examinations indicate no changes from baseline

NB: Interim look as of 01/12/2021; Unmonitored data.

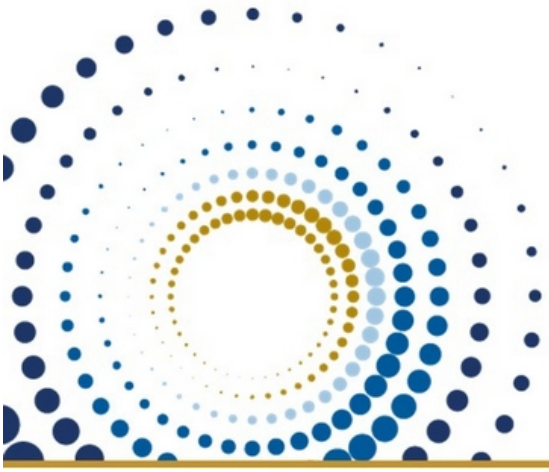
NEXT STEPS:
- **Ongoing Study; Continued long-term evaluation in 3 subjects in Cohort 4**
- **Phase II Trial Planning Initiated; Planned start-up mid-year 2021**

(NASDAQ: OCUL)

TRANSFORMING DRUG DELIVERY

LEVERAGING A NOVEL TECHNOLOGY PLATFORM

THANK YOU



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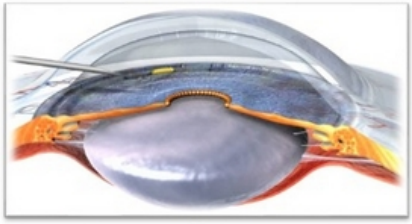
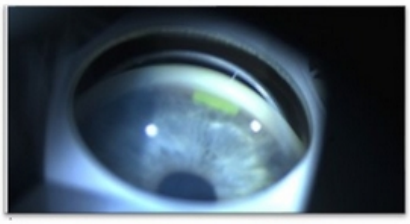
OTX-TIC (TRAVOPROST IMPLANT) FOR INTRACAMERAL INJECTION

- Open-label, proof-of-concept study in subjects with Primary POAG or OHT in a **Phase 1 trial**
- Non-study eye receives **topical travoprost** daily
- **Four cohorts** being evaluated (15µg, 26µg, 15µg fast-degrading and 5µg fast-degrading)





- CLINICALLY-MEANINGFUL DECREASE IN IOP: As early as two days following implantation and lowering up to 7-11 mmHg recorded; Comparable to topical travoprost therapy
- DURATION OF THERAPY: Many subjects showed durability of 6 months or longer with a single implant; Longest and most consistent IOP lowering with 26 µg dose up to 6+ months
- BIORESORBABLE: Complete implant resorption in 5-7 months (Cohort 1 and 2) and ~3-5 months (Cohort 3 and 4)
- IMPLANT LOCATION AND MOVEMENT: Visible with no movement observed using gonioscopy and slit lamp exam
- CORNEAL HEALTH: Endothelial cell counts, pachymetry & slit lamp examinations indicate no changes from baseline

NEXT STEPS: Ongoing Study; Continued long-term evaluation in 3 subjects in Cohort 4 and Phase II Trial Planning Initiated; Planned start-up mid-year 2021

NB: Interim look as of 01/12/2021; Unmonitored data.

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