

**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 11, 2021**

OCULAR THERAPEUTIX, INC.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36554
(Commission
File Number)

20-5560161
(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 2.02 Results of Operations and Financial Condition.

Ocular Therapeutix, Inc. (the “Company”) intends to present a Company overview at a virtual conference on January 11, 2021. Information to be provided during such presentation is being filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The Company primarily derives its product revenues from the sale of DEXTENZA® in the United States to a network of specialty distributors, who then resell DEXTENZA to ambulatory surgical centers (“ASCs”) and hospital outpatient departments (“HOPDs”). The Company refers to these resales from the specialty distributors to the ASCs and HOPDs as in-market unit sales. Although the Company is currently in the process of finalizing its operational and financial results for the quarter ended December 31, 2020, the Company is reporting estimated in-market unit sales for DEXTENZA of 5,952 billable inserts in the month of December 2020. In-market unit sales were 4,198 billable inserts for October 2020 and 4,327 billable inserts for November 2020.

The estimated unit sales discussed above are based on preliminary information and management’s estimates as of the date of this Current Report on Form 8-K and are subject to completion of the Company’s customary closing procedures. The Company’s independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the estimated figures.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall be deemed to be “furnished” and not “filed” under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed to be incorporated by reference in applicable filings under the Securities Act of 1933, as amended, or the Exchange Act except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

The information set forth in or incorporated by reference into Item 2.02 of this Current Report on Form 8-K is incorporated by reference into this Item 7.01.

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 11, 2021

By: /s/ Donald Notman

Donald Notman

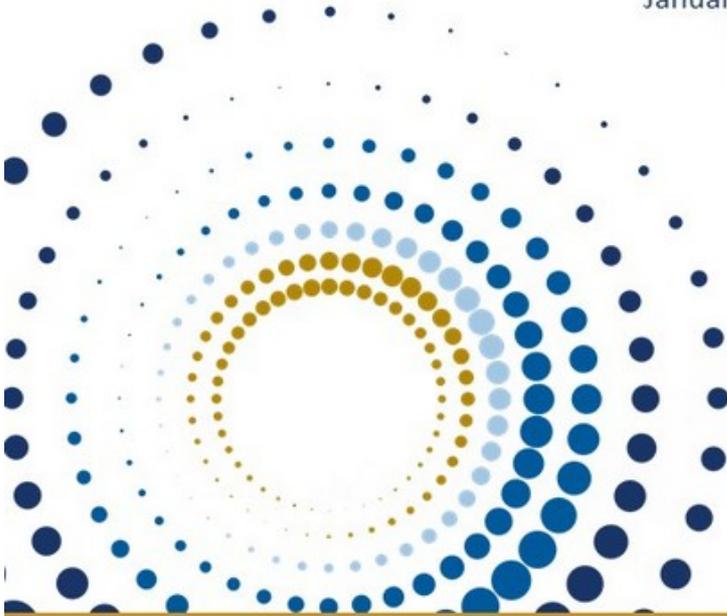
Chief Financial Officer

(NASDAQ: OCUL)

TRANSFORMING DRUG DELIVERY

LEVERAGING A NOVEL TECHNOLOGY PLATFORM

ANTONY MATTESSICH, CHIEF EXECUTIVE OFFICER
January 2021



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.



TRANSFORMING DRUG DELIVERY WITH A NOVEL TECHNOLOGY PLATFORM



PIPELINE AT A GLANCE

PRODUCT/PROGRAM	DISEASE STATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	REGULATORY APPROVAL
WET AMD						
OTX-TKI (axitinib intravitreal implant)	Wet AMD, DME and RVO†	▶				
OTX-AFS (aflibercept suprachoroidal injection) In collaboration with REGENERON	Wet AMD, DME and RVO†	▶				
GLAUCOMA						
OTX-TIC (travoprost intracameral implant)	Glaucoma and ocular hypertension	▶				
OCULAR SURFACE DISEASES						
OTX-CSI (cyclosporine intracanalicular insert)	Dry eye disease	▶				
OTX-DED (dexamethasone intracanalicular insert)	Episodic dry eye disease	▶				
Dextenza® (dexamethasone ophthalmic insert) 0.4 mg	Allergic conjunctivitis	▶				
SURGICAL						
Dextenza® (dexamethasone ophthalmic insert) 0.4 mg	Post-surgical ocular inflammation and pain	▶ ◆				

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



TOTAL GLOBAL MARKETS

DEVELOPING PRODUCTS WITH THE POTENTIAL TO BECOME A STANDARD OF CARE FOR SELECT INDICATIONS IN SEVERAL OF THE LARGEST SEGMENTS IN OPHTHALMOLOGY



KEY UNMET NEED

These data reflect the total global market for the respective indications. Our market opportunity for such indications reflects a portion of this market.

* in collaboration with REGENERON; †Data shown here is only representative of Dry Eye and not other Ocular Surface Diseases

1. 2019 Retina Pharma Market Scope Report 2. 2019 Glaucoma Pharma Market Scope Report 3. 2019 Dry Eye Market Scope Report 4. Estimated using historical costs of topical eye drops (not DEXTENZA) and the total addressable market based on the total US ocular surgical steroid market value 2019

OTX-TKI (AXITINIB INTRAVITREAL IMPLANT)

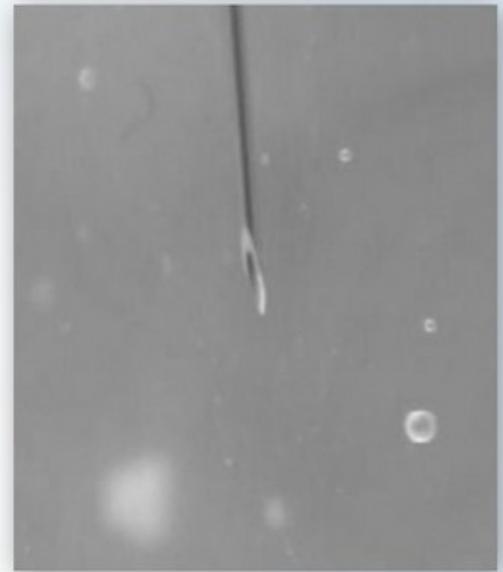
SUSTAINED RELEASE THERAPY FOR RETINAL DISEASES

ISSUES WITH EXISTING TREATMENTS

- Require injections every 4-8 weeks^{1,2}
- May cause endophthalmitis, hemorrhage, damage to the lens or retinal detachment due to repeated injections³
- Cause discomfort, eye pain, decreased vision, increased photosensitivity, and floaters³

KEY PRODUCT ATTRIBUTES

- Targeting sustained release for 6 months or longer
- Broader anti-angiogenic profile (small molecule) than anti-VEGF alone
- Small fiber (25-27G needle) with minimal/no visual impact
- Preservative-free



ONGOING PHASE 1 CLINICAL TRIAL

- First (200µg) and second (400µg) cohorts fully enrolled
- Currently dosing third cohort (two arms: 600ug vs 400ug + anti-VEGF induction injection)
- To date, observed to have a generally favorable safety profile

1. EYLEA Full Prescribing Information 2019 2. Lucentis Full Prescribing Information 2019 3. Bodhot A, Fattal E. Liposomes for intravitreal drug delivery: a state of the art. *J Control Release*. 2011;161(2):628-634.

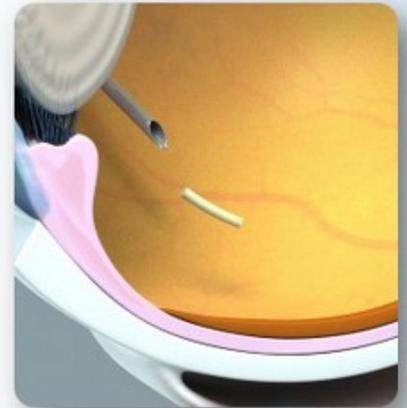
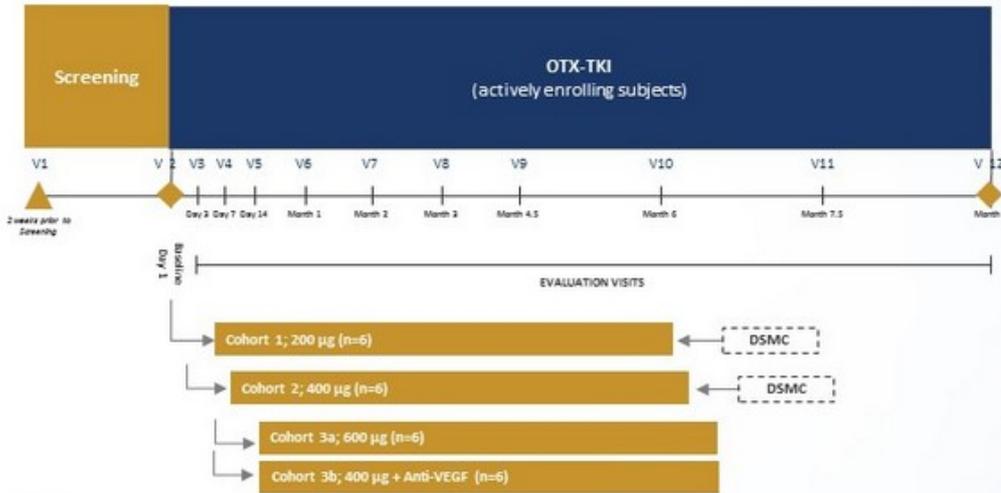
OTX-TKI PHASE 1 STUDY

DESIGN

- Open-label, dose-escalation, feasibility study
- 5 sites in Australia
- One eye treated per patient
- Key Inclusion criteria:
 - Active primary subfoveal neovascularization (SFNV) secondary to AMD – previously treated or naïve subjects but with retinal fluid present

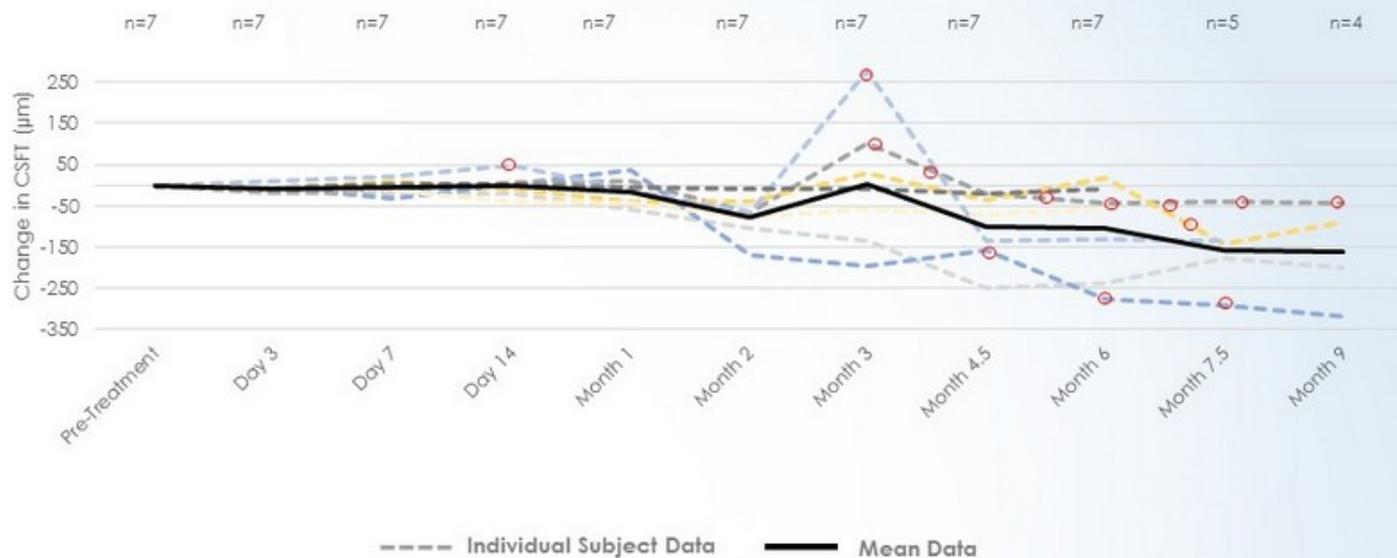
OBJECTIVES

- Safety, tolerability, and biological activity
- Safety evaluations at all visits; mean change in central subfield thickness (CSFT) measured by SD-OCT, BCVA, and clinically-significant leakage on FA and/or OCT-A at 6 months



INDIVIDUAL CHANGE IN CENTRAL SUBFIELD THICKNESS

OTX-TKI STUDY EYE – COHORT 2



*All CSFT values compared to Baseline visit

○ Denotes administration of rescue therapy

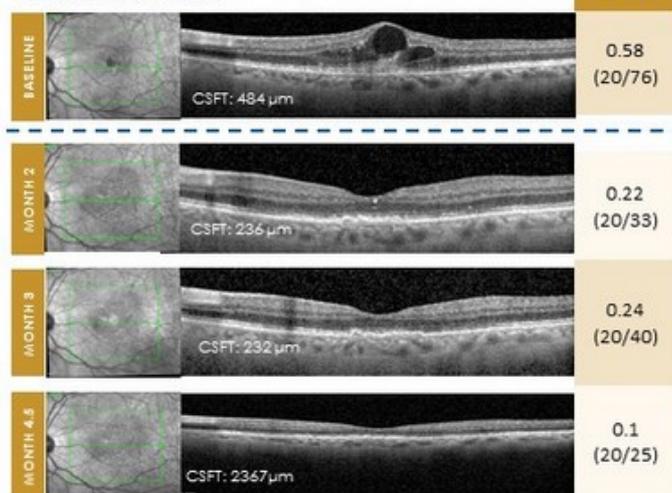


*All BCVA and CSFT values compared to Baseline visit

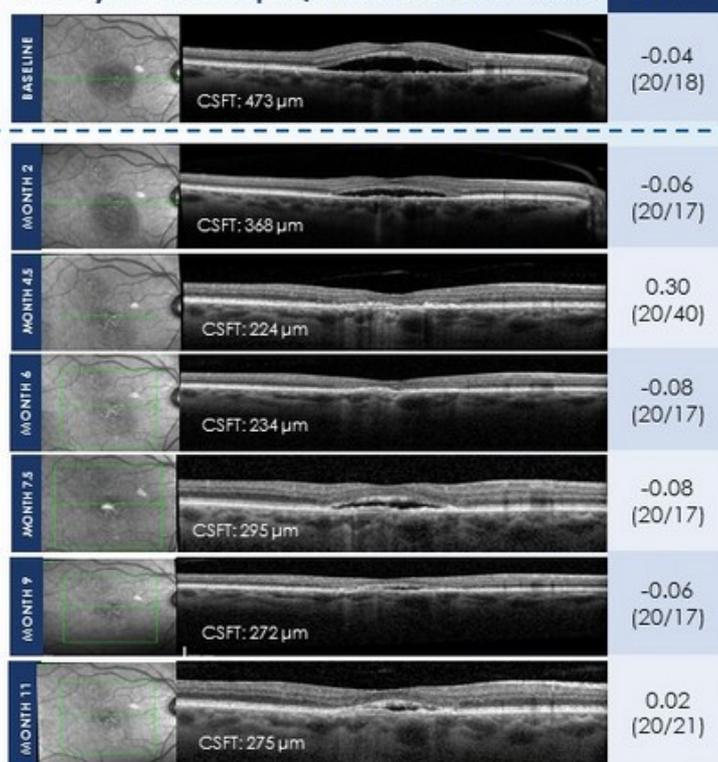
NOTE: Interim review, unmonitored data; Data cut on September 10th, 2020 (Cohorts 1 & 2 only)

OTX-TKI PHASE 1 SD-OCT EVALUATION

**COHORT 3A 600 µg - Subject 1 (OS):
Treatment Naïve**



**COHORT 2 400 µg - Subject 2 (OD):
History of Aflibercept Q4 Weeks for 16 months**



Preliminary biological signal of clinically-meaningful decrease in retinal fluid:
Some subjects showed a decrease in intraretinal and/or subretinal fluid by 2 months



*NOTE: Interim review, unmonitored data; Data cut on October 23rd, 2020

COHORTS 1-2: SAFETY OVERVIEW

Adverse Events

Number of subjects with:	Cohort 1 200 µg n=6	Cohort 2 400 µg n=7	Total n=13
Adverse Events (AEs)	14	17	31
Ocular AEs	12	12	24
Serious Ocular AEs	0	0	0
By severity			
Mild	12	14	26
Moderate	2	3	5
Severe	0	0	0
Treatment-related Ocular AEs	1	2	3

- No subjects had IOP elevation
- No subjects needed ocular steroids

Percentage of Subjects Without Needing Rescue Medications

Cohorts	At 3 months % (n/N)	At 6 months % (n/N)	At 7.5 months % (n/N)	At 9 months % (n/N)
Cohort 1 (200 µg)	66.7 (4/6)	50 (3/6)	50 (3/6)	50 (3/6)
Cohort 2 (400 µg)	71.4 (5/7)	57.1 (4/7)	42.9 (3/7)	20 (1/5)*

PHARMACOKINETICS

Plasma concentrations of axitinib were below the limit of quantification of assay (BLQ) <0.1 ng/ml at all sampled timepoints in all subjects in Cohorts 1 & 2

* Only 5 of 7 subjects reached 9 months in the study.
NOTE: Interim review, unmonitored data; Data cut on October 23rd, 2020. (Cohorts 1 & 2 only)

OTX-TKI CONCLUSIONS TO DATE

- ❑ **OTX-TKI was generally well tolerated**
To date, observed to have a generally favorable safety profile in both fully enrolled cohorts
- ❑ **Preliminary biological signal of clinically-meaningful decrease in retinal fluid**
Some cohort 2 subjects showed a decrease in intraretinal and/or subretinal fluid by 2 months
- ❑ **Therapy durability suggests extended duration of action**
In cohort 2 (400 ug), one subject has demonstrated durability of therapy for up to 11 months. Patients are still being followed in cohort 2.
- ❑ **Consistent bio-resorption observed**
Implant biodegraded in all subjects in cohort 1 by 9-10.5 months
- ❑ **Implant location observation suggests limited movement**
Implant has been able to be adequately monitored

Study is ongoing

Continued long-term evaluation of both cohorts

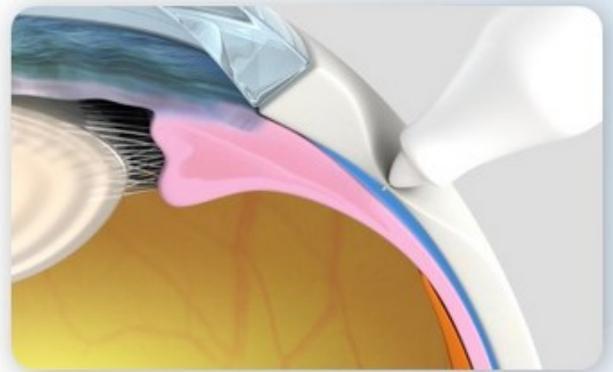
- Need to establish durability of treatment
- Identify Maximum Tolerated Dose (MTD)
- Understand utility of OTX-TKI with anti-VEGF injection

Plan to initiate US Phase 1 Trial mid-2021



AMENDED AGREEMENT TO DEVELOP A NOVEL, SUSTAINED-RELEASE FORMULATION OF EYLEA® (AFLIBERCEPT)

- **EYLEA is a vascular endothelial growth factor (VEGF) trap approved for the treatment of wet age-related macular degeneration (wet AMD) and other serious retinal diseases**
 - EYLEA is the global market leader with \$7.5 billion in revenue in 2019¹
- **Evaluating opportunity to incorporate aflibercept with our sustained release hydrogel for injection in the suprachoroidal space**
 - Goal is to overcome limitations of intravitreal injections and extend aflibercept's duration of activity, thereby decreasing dosing frequency
- **Deal parameters**
 - Regeneron subsidizes Ocular's formulation efforts
 - Regeneron to fund personnel and material costs associated with pre-clinical development
 - Regeneron to fund up to \$305 million in milestone payments with royalties in high single digits to low-to-mid-teens as a % of net sales
 - Includes only large molecule anti-VEGFs



1. 2019 Regeneron annual report
*Formerly known as OTX-IVT

TOTAL GLOBAL MARKETS

DEVELOPING PRODUCTS WITH THE POTENTIAL TO BECOME A STANDARD OF CARE FOR SELECT INDICATIONS IN SEVERAL OF THE LARGEST SEGMENTS IN OPHTHALMOLOGY



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OTX-TIC (TRAVOPROST INTRACAMERAL IMPLANT)

ADDRESSES THE ISSUE OF PATIENT NON-COMPLIANCE WITH EYE DROPS

ISSUES WITH EXISTING TREATMENTS

- High rates of non-adherence to glaucoma therapies
- Poor adherence has been shown to be associated with disease progression and blindness^{1,2}
- Ocular hyperemia
- Life-long daily burden of patient administration

KEY PRODUCT ATTRIBUTES

- Travoprost loaded microparticles embedded in hydrogel
- Administered with 27G or 26G needle
- Resides in the iridocorneal angle
- Fully biodegradable
- Preservative-free



1. Rossi GC, et al. Do adherence rates and glaucomatous visual field progression correlate? *Eur J Ophthalmol*. 2011; 21:410-4. 2. Sieth B, et al. The relationship between glaucoma medication adherence, eye drop technique, and visual field defect severity. *Ophthalmology*. 2011; 118:2398-402.

OTX-TIC FOR THE TREATMENT OF GLAUCOMA

Phase 1 Study Design

- Open-label, proof-of-concept study
- US study, 20 subjects at 5 sites
- 5 subjects per cohort, 4 cohorts
- One eye per patient will be treated
- Key Inclusion criteria:
 - Controlled ocular HTN or POAG
 - Open, normal anterior chamber angles on gonioscopy

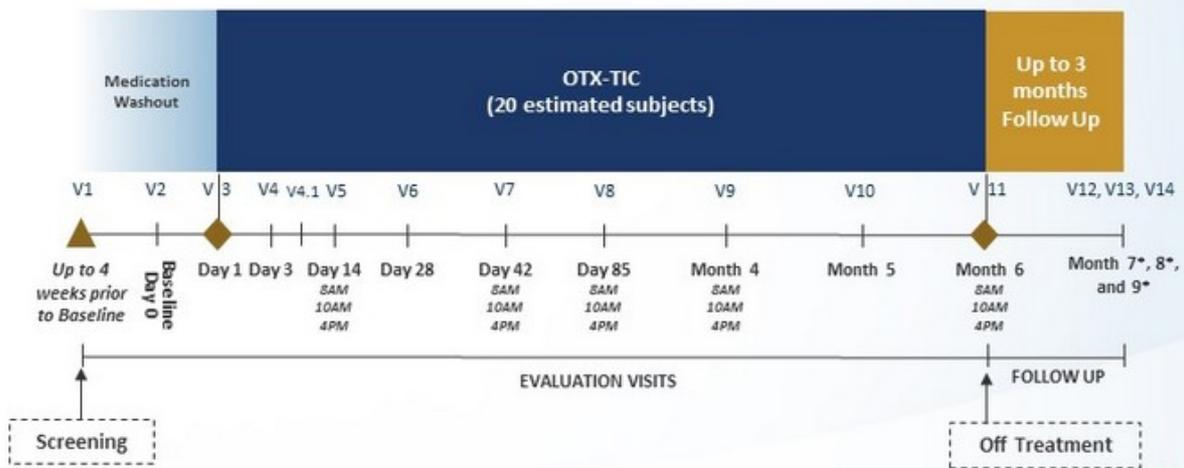
Objectives

- 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

PHASE 1 TRIAL NOW FULLY ENROLLED

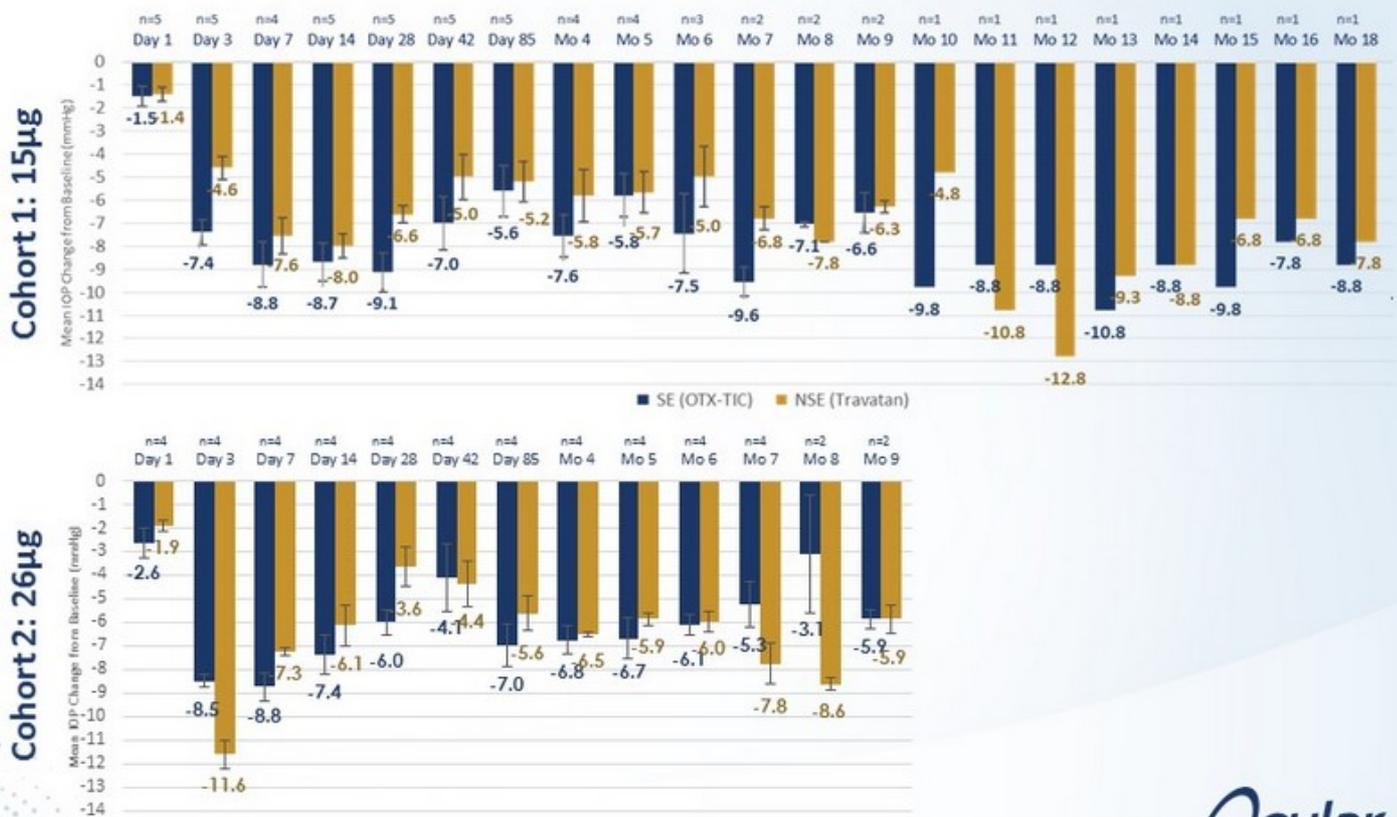


* Monthly visits until IOP is within 10% of baseline or until clinically stable



IOP DECREASE UP TO 7-10 MMHG RECORDED IN COHORTS 1 (UP TO 18 MONTHS) & 2 (UP TO 9 MONTHS)

DECREASED IOP AS EARLY AS TWO DAYS AFTER OTX-TIC IMPLANTATION

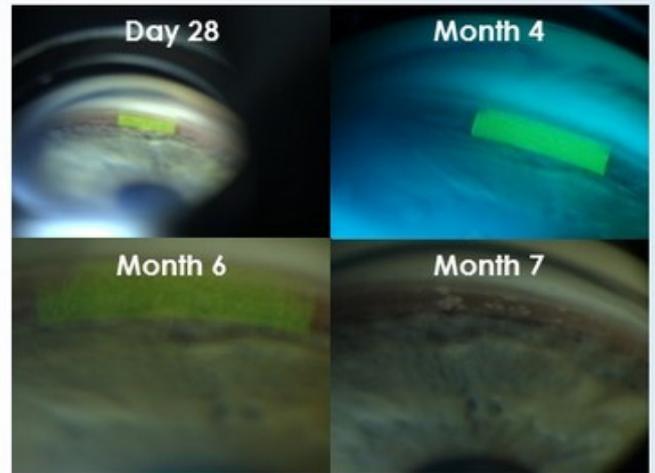


NB: Interim look; Unmonitored data *If the study eye was given other IOP lowering medication, the IOP value was removed from the analysis. Data as of April 2020.

OTX-TIC PHASE 1 INTERIM FINDINGS

- ✔ **Clinically-meaningful decrease in IOP**
Mean IOP values were decreased in patients receiving both OTX-TIC and topical travoprost as early as two days following administration, and mean IOP values remained decreased from baseline values
- ✔ **Extended duration of therapy**
Many subjects exhibited duration of IOP lowering effect of 6 months or longer
- ✔ **Consistently bioresorbable**
In most subjects by 5-7 months
- ✔ **Implant location and limited movement**
Implant was not observed to move at slit lamp and was visible at all exams in all patients; in one subject, there was slight rotation noted at the Day 14 visit as compared to the Day 7 visit
- ✔ **Corneal health**
Endothelial cell counts and pachymetry assessments indicate no clinically meaningful changes from baseline

VISUALIZATION OF IMPLANT



Plan to initiate Phase 2
clinical trial in mid-2021



TOTAL GLOBAL MARKETS

DEVELOPING PRODUCTS WITH THE POTENTIAL TO BECOME A STANDARD OF CARE FOR SELECT INDICATIONS IN SEVERAL OF THE LARGEST SEGMENTS IN OPHTHALMOLOGY



KEY UNMET NEED

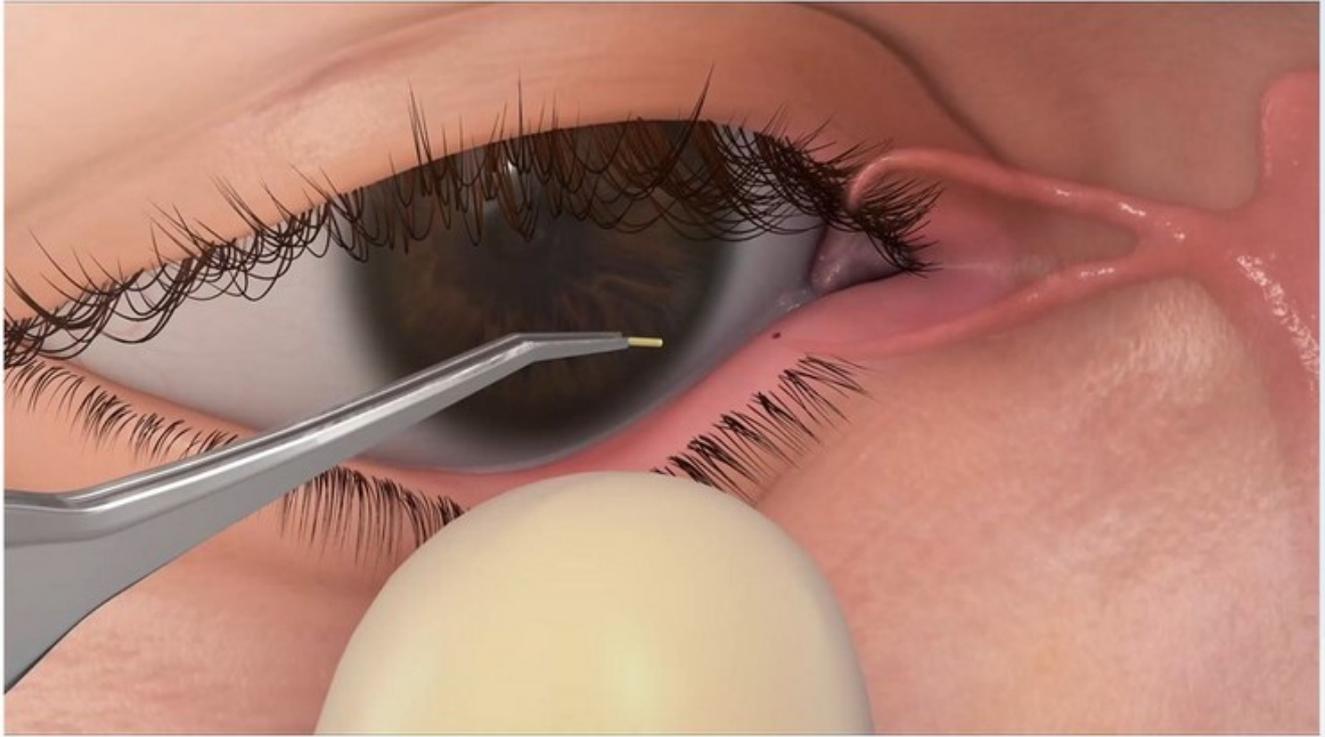
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INTRACANALICULAR INSERTS

AN INNOVATION IN DRUG DELIVERY TO THE OCULAR SURFACE



OTX-CSI (CYCLOSPORINE INTRACANALICULAR INSERT)

SUSTAINED RELEASE THERAPY FOR DRY EYE DISEASE

ISSUES WITH EXISTING TREATMENTS

- Slow onset of action for therapy
- High level of burning, stinging and irritation upon administration
- Burden of patient administration

KEY PRODUCT ATTRIBUTES

- Cyclosporine loaded in hydrogel
- Preservative-free
- Designed to deliver effective therapy up to 12 weeks with a single insert
- Occludes the punctum
- Fully biodegradable insert



OTX-CSI INITIATED PHASE 2
TRIAL IN Q3 2020



PHASE 1 STUDY OBJECTIVE AND DESIGN

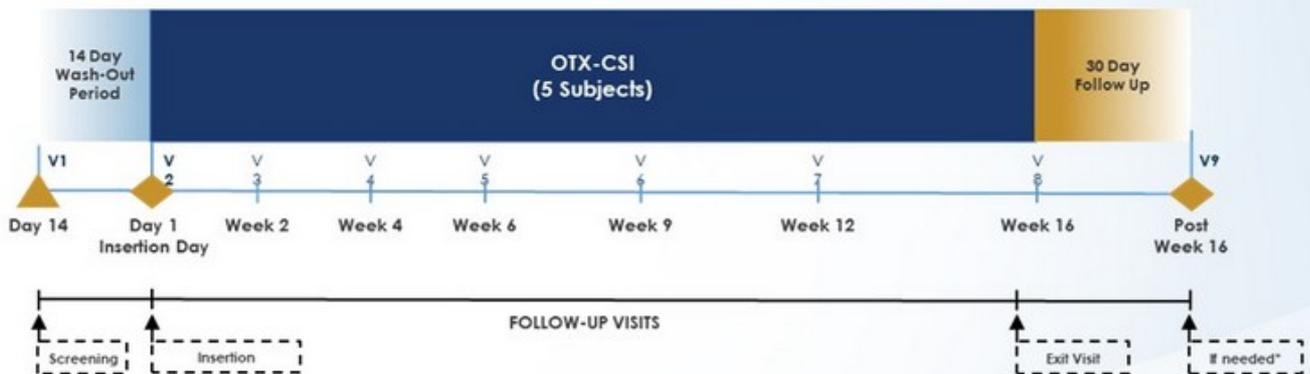
OBJECTIVE: EVALUATING THE SAFETY, TOLERABILITY, AND EFFICACY OF OTX-CSI FOR THE TREATMENT OF SUBJECTS WITH DRY EYE DISEASE

Design

- Phase 1, Prospective, Open-label study
- Key Inclusion criteria:
 - DED diagnosis in both eyes for ≥ 6 months
 - VAS eye dryness severity score ≥ 30

Endpoints

- Schirmer Test (without anesthesia) at Week 12
- Eye Dryness Score (visual analogue scale [VAS])
- Total Corneal Fluorescein Staining (tCFS) using NEI scale
- Presence of OTX-CSI or HV insert at all post-baseline visits
- Adverse Events (Ocular and Non-ocular)



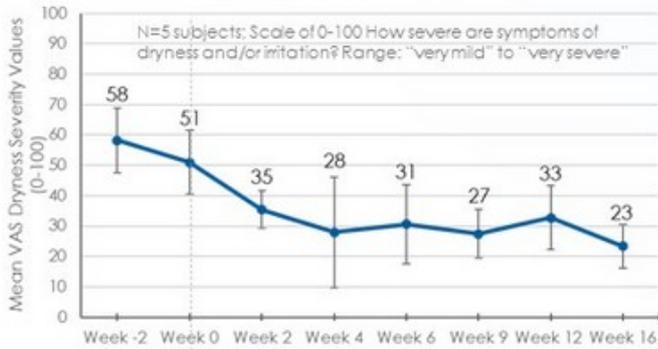
*Subject remains in study until insert is no longer visible and no evidence of biological activity

Study to Evaluate the Safety, Tolerability, and Efficacy of OTX-CSI in Subjects With Dry Eye Disease. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT04362670>. Accessed October 16, 2020.

OTX-CSI PHASE 1 TRIAL RESULTS

SUBJECTS REPORTED IMPROVEMENT IN DRYNESS SEVERITY ON A SCALE OF 0-100 (VERY MILD TO VERY SEVERE) OVER 16 WEEKS

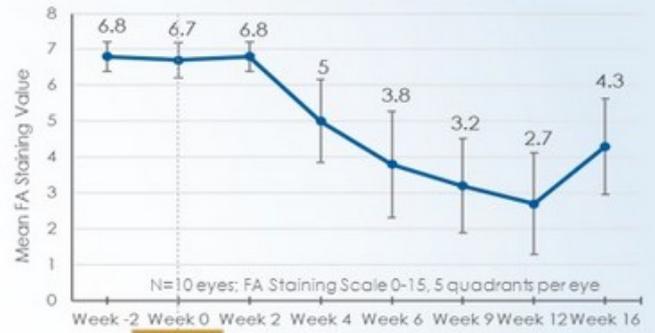
Mean Absolute Values



OTX-CSI Insertion

IMPROVED TOTAL CORNEAL FLUORESCIN STAINING VALUES WEEK 4 TO 16 COMPARED TO BASELINE

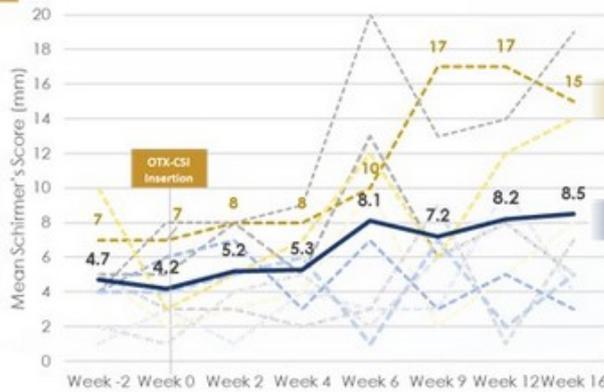
Mean Absolute Values



OTX-CSI Insertion

SUBJECTS SHOWED AN IMPROVEMENT IN MEAN SCHIRMER'S TEST SCORES FROM WEEK 0 TO WEEK 16

Schirmer's: ≥ 10 mm in 5 minutes



20% (1/5) of subjects showed ≥ 10 mm increase from baseline (7 mm at Week 0 to 17 mm at Week 12)

Mean Schirmer's Score improved from 4.2mm at Week 0 to 8.2mm at Week 12

--- Individual Eye Data (N=10 eyes)
 — Mean Data



OTX-CSI SHOWS PROMISE AS A POTENTIAL SUSTAINED RELEASE THERAPY FOR DRY EYE DISEASE

PHASE 1 TRIAL CONCLUSIONS:

- All subjects showed improvement as measured by Schirmer's test and decreased signs and symptoms of dry eye disease
 - ✓ 20% of subjects (1/5) showed ≥ 10 mm increase in Schirmer's score at Week 12 from baseline (Week 0)
 - ✓ Improvements in signs (corneal fluorescein staining) and symptoms (VAS dry eye severity and frequency) from baseline were observed
- OTX-CSI showed early onset of action and prolonged durability
 - ✓ Onset of action as early as 2 weeks for signs and symptoms of DED
 - ✓ Duration of activity continued until the 16-week, end-of-study visit for signs and symptoms of DED
- OTX-CSI was generally observed to have a favorable safety profile and be well tolerated in Cohort 1
 - ✓ No AEs of stinging, burning, irritation, tearing, or blurred vision were reported over the 16-week period



PHASE 2 STUDY OBJECTIVE AND DESIGN

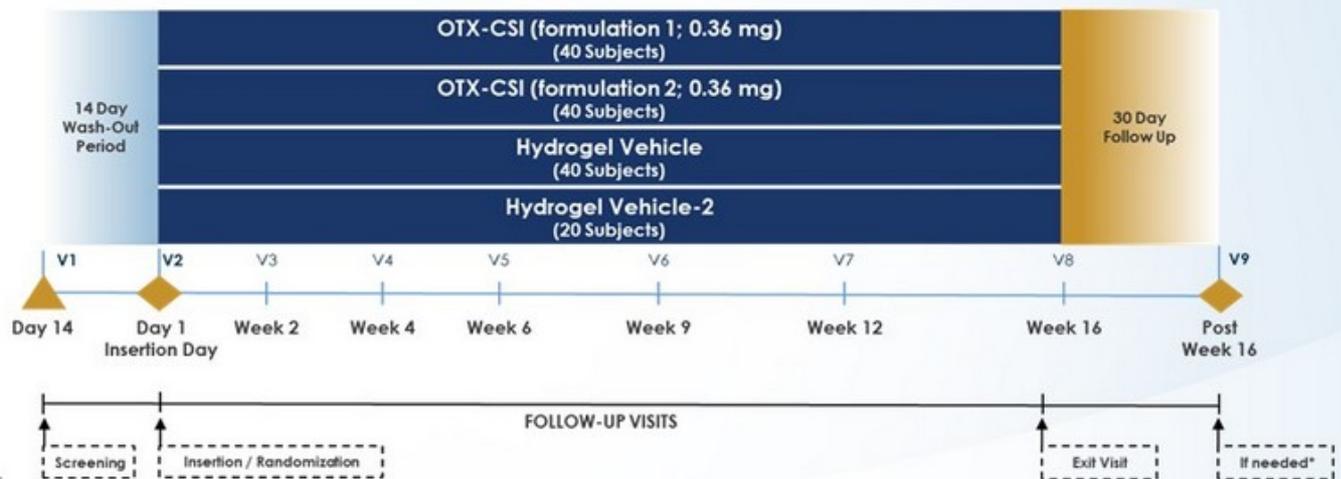
OBJECTIVE: EVALUATING THE SAFETY, TOLERABILITY, AND EFFICACY OF OTX-CSI FOR THE TREATMENT OF SUBJECTS WITH DRY EYE DISEASE

Design

- Prospective, Randomized, Double-Masked, Vehicle-controlled study
- Key Inclusion criteria:
 - DED diagnosis in both eyes for ≥ 6 months
 - VAS eye dryness severity score ≥ 30

Endpoints

- Schirmer Test (without anesthesia) at Week 12
- Eye Dryness Score (visual analogue scale [VAS])
- Total Corneal Fluorescein Staining (tCFS) using NEI scale
- Presence of OTX-CSI or HV insert at all post-baseline visits
- Adverse Events (Ocular and Non-ocular)



*Subject remains in study until insert is no longer visible and no evidence of biological activity

Study to Evaluate the Safety, Tolerability, and Efficacy of OTX-CSI in Subjects With Dry Eye Disease. [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/NCT04362670). Accessed October 16, 2020.

OTX-DED (DEXAMETHASONE INTRACANALICULAR INSERT)

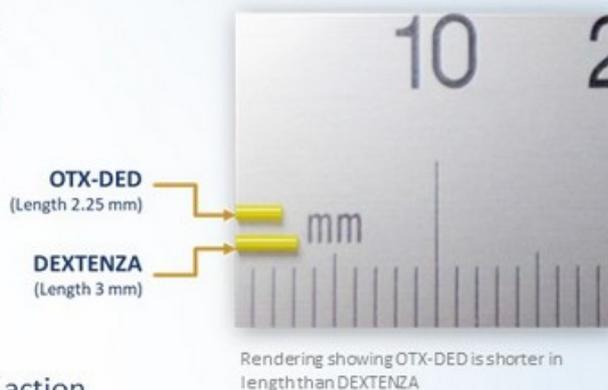
OFF-LABEL STEROIDS ARE CURRENTLY USED TO TREAT EPISODIC DRY EYE

ISSUES WITH EXISTING TREATMENTS

- Approved therapies for DED are known for slow onset of action and burning/stinging upon application
- Topical steroids (which are not FDA-approved for DED) can be abused and contain preservatives causing ocular toxicity

KEY PRODUCT ATTRIBUTES

- Dexamethasone loaded in hydrogel
- Preservative-free
- Occludes the canaliculus providing more rapid onset of action
- Fully biodegradable insert
- Leverages strong safety profile of DEXTENZA®



Plan to initiate Phase 2 clinical trial in Q1 2021



DEXTENZA FOR THE TREATMENT OF ALLERGIC CONJUNCTIVITIS

AN IN-OFFICE INDICATION FOR DEXTENZA

ISSUES WITH EXISTING TREATMENTS

- Corticosteroids are effective in treating both signs and symptoms of acute and chronic allergy
- Corticosteroids are not often prescribed due to the ability to abuse and/or overuse the treatment
- Treatment requires frequent administration of eyedrops, and hands touching the face several times per day

KEY PRODUCT ATTRIBUTES

- A non-abusable formulation
- Preservative-free
- Leverages strong safety profile for DEXTENZA in the treatment inflammation and pain following ophthalmic surgery

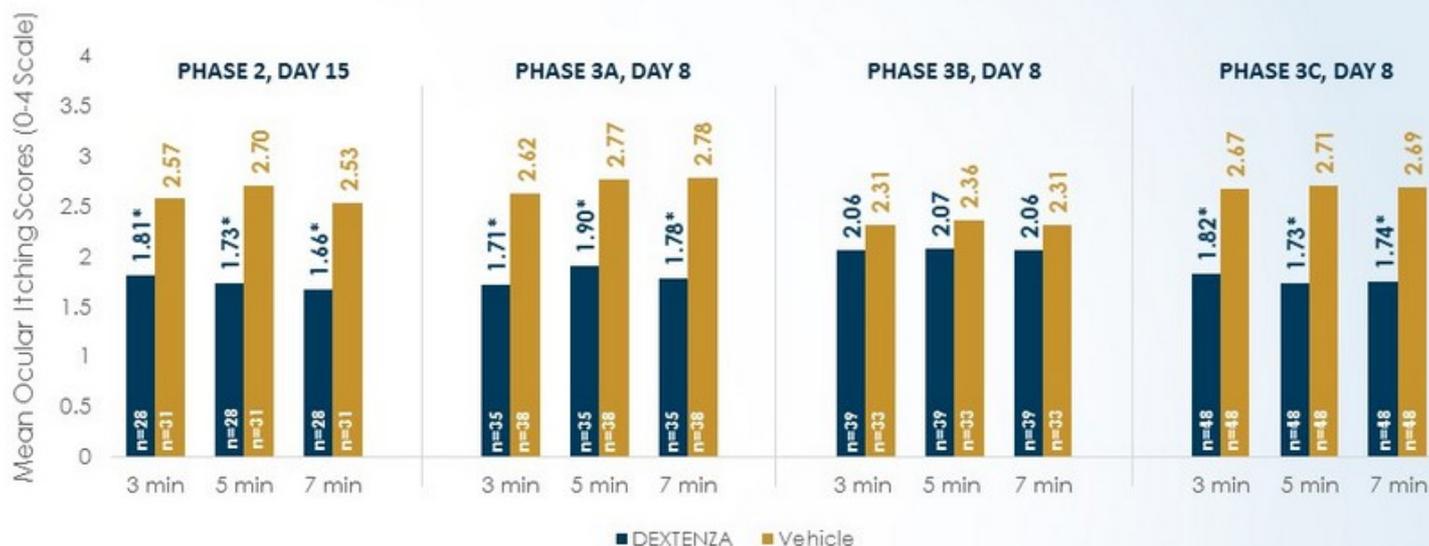
Dextenza[®]
(dexamethasone ophthalmic insert) 0.4 mg
for intracanalicular use



sNDA filed in December 2020 for the treatment of
ocular itching associated with allergic conjunctivitis



RESULTS: PRIMARY EFFICACY ENDPOINT MEAN OCULAR ITCHING SCORES ACROSS ALL STUDIES



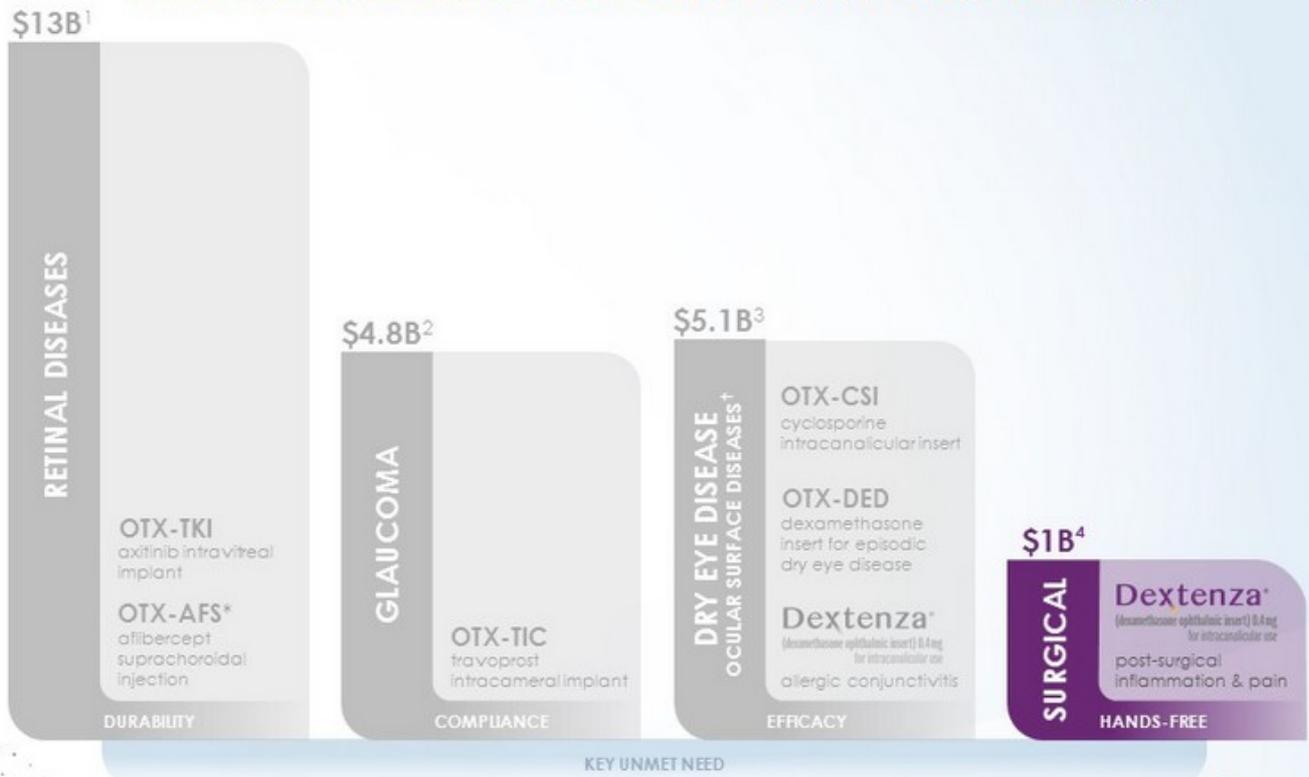
*Statistically Significant; $P < 0.0025$; Population: ITT + LOCF (Phase 2) & ITT + MCMC (subject level imputation, Phase 3)



Milaurin E, et al. Evaluating the Safety and Efficacy of DEXTENZA, a Dexamethasone Insert (0.4 mg) for the Treatment of Ocular Itching. Presented at the American Society of Cataract and Refractive Surgery Annual Meeting; San Diego, CA, May 3-7, 2019.

GLOBAL MARKET VALUES

DEVELOPING PRODUCTS WITH THE POTENTIAL TO BECOME A STANDARD OF CARE FOR SELECT INDICATIONS IN SEVERAL OF THE LARGEST SEGMENTS IN OPHTHALMOLOGY



KEY UNMET NEED

These data reflect the total global market for the respective indications. Our market opportunity for such indications reflects a portion of this market.

* in collaboration with REGENERON; †Data shown here is only representative of Dry Eye and not other Ocular Surface Diseases

1. 2019 Retina Pharma Market Scope Report 2. 2019 Glaucoma Pharma Market Scope Report 3. 2019 Dry Eye Market Scope Report 4. Estimated using historical costs of topical eye drops (not DEXTENZA) and the total addressable market based on the total US ocular surgical steroid market value 2019

THE UNMET NEED IN TREATMENT OF PAIN AND INFLAMMATION FOLLOWING SURGERY

EYE DROPS HAVE POOR CORNEAL RESIDENCE TIME^{3,4}



STEROID DROPS ARE THE MOST COMPLEX POST-OP CATARACT TREATMENT REGIMEN

Common clinical approach: 4 weeks with taper¹

	SUN	MON	TUES	WED	THURS	FRI	SAT	TAPER
Week 1	3 drops	~ 28 drops						
Week 2	2 drops	~ 21 drops						
Week 3	1 drop	~ 14 drops						
Week 4	1 drop	~ 7 drops						



Ocular rebound inflammation may develop secondary to rapid tapering or abrupt discontinuation of steroids³



1. Kessel L et al. Ophthalmology. 2014;121(10):1915-24. 2. Data on file 00663. Ocular Therapeutix Inc. 3. Renfro L, Snow JS. Dermatol Clin. 1992;10(3):505-512 3. Kushwaha SK et al. Int J Pharm Investig. 2012;2(2):54-60. 4. Geuzens R, et al. AAPS Journal. 2010;12 (3):348-360.

DEXTENZA® (DEXAMETHASONE OPHTHALMIC INSERT)

A HANDS-FREE ALTERNATIVE TO EYE DROPS

FDA approved for the treatment of ocular inflammation and pain following ophthalmic surgery

REIMBURSEMENT AND CODING

Product Code: J1096 **Procedure Code:** 0356T

- Medicare Administrative Contractor coverage provides physician reimbursement for procedure of ~\$100
- AMA granted permanent Category 1 CPT code effective Jan 2022 (applies to DEXTENZA and all future products in canaliculus)

1

**INNOVATIVE
INSERT**

VS

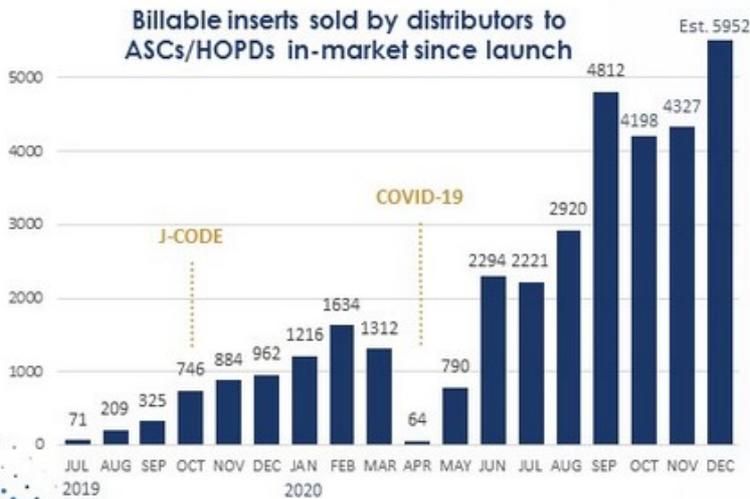
~70

DROPS^{1,2}

Provides a tapered delivery of preservative-free steroid onto the ocular surface for 30 days



2020 growth indicates strong momentum into 2021



1. DEXTENZA (package insert), Bedford, MA: Ocular Therapeutix Inc 2019.
 2. Data on file 00663, Ocular Therapeutix Inc.

2020 MILESTONES AND NEAR-TERM ACHIEVEMENTS



OTX-TKI (wet AMD)

- Provided Phase 1 clinical update at AAO (Nov 2020)
- FDA acceptance of eIND



OTX-TIC (glaucoma) – Completed P1 enrollment of all 4 cohorts



OTX-CSI (dry eye) – Initiated Phase 2 Clinical Trial (Sept 2020)



OTX-DED (episodic dry eye) – Submitted Phase 2 enabling IND



DEXTENZA® (inflammation and pain) – Goal of more than 5,000 billable inserts per month by year-end (Est. 5,952 inserts in December 2020)



DEXTENZA® (allergic conjunctivitis) – Filed sNDA in Q4 2020



ANTICIPATED 2021-2022 MILESTONES



OTX-TKI (wet AMD) – Plan to initiate US Phase 1 clinical trial and ex-US Phase 2 clinical trial mid-2021



OTX-TIC (glaucoma) – Plan to initiate Phase 2 clinical trial in mid-2021



OTX-CSI (dry eye) – Expect topline data from Phase 2 trial 1H 2022



OTX-DED (episodic dry eye) – Plan to initiate Phase 2 clinical trial in Q1 2021



DEXTENZA® (inflammation and pain) – Expect to continue strong growth of in-market sales



DEXTENZA® (allergic conjunctivitis) – Expected PDUFA date October 2021



(NASDAQ: OCUL)

TRANSFORMING
DRUG DELIVERY
LEVERAGING A NOVEL
TECHNOLOGY PLATFORM

THANK YOU

Ocular
Therapeutix™

