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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): June 6, 2016**

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

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-36554**  
(Commission  
File Number)

**20-5560161**  
(IRS Employer  
Identification No.)

**34 Crosby Drive, Suite 105  
Bedford, MA 01730**  
(Address of Principal Executive Offices) (Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

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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 (see General Instruction A.2. below):

- 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))
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**Item 7.01 Regulation FD Disclosure.**

On June 6, 2016, Ocular Therapeutix, Inc. (the “Company”) issued a press release announcing the top-line results of its second Phase 3 clinical trial of DEXTENZA™ for the treatment of allergic conjunctivitis. A copy of the press release announcing the results of this trial is attached as Exhibit 99.1 hereto and is incorporated by reference into this Item 7.01.

In addition, as stated in the press release, on June 6, 2016, at 8:30 am Eastern Time, representatives of the Company will present by conference call and webcast information about the results of the Company’s second Phase 3 clinical trial of DEXTENZA™ for the treatment of allergic conjunctivitis. The slides to be presented at this conference call and webcast are attached as Exhibit 99.2 hereto and are incorporated by reference into this Item 7.01.

The information in this Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

- 99.1 Press Release of Ocular Therapeutix, Inc., dated June 6, 2016
- 99.2 Ocular Therapeutix, Inc. slide presentation, dated June 6, 2016

**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: June 6, 2016

By: /s/ W. Bradford Smith  
W. Bradford Smith  
Chief Financial Officer

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press Release of Ocular Therapeutix, Inc., dated June 6, 2016.
99.2	Ocular Therapeutix, Inc. slide presentation, dated June 6, 2016.

**Ocular Therapeutix™ Announces Topline Results of Second Phase 3 Clinical Trial of DEXTENZA™ for the Treatment of Allergic Conjunctivitis**

*Primary endpoint for ocular itching not achieved*

*Conference call today at 8:30 am Eastern Time*

**BEDFORD, Mass, June 6, 2016 (BUSINESS WIRE):** Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced topline results from its second Phase 3 clinical trial to evaluate the safety and efficacy of DEXTENZA™ (sustained release dexamethasone) Intracanalicular Depot for the treatment of ocular itching associated with chronic allergic conjunctivitis. DEXTENZA is a product candidate administered by a physician as a bioresorbable intracanalicular depot and designed for drug release to the ocular surface for up to 30 days.

The single primary endpoint of the trial, defined as the difference in the mean scores in ocular itching between the treatment group and the placebo comparator group at three time points 7 days following insertion of the depots, was not achieved. While mean ocular itching was seen to be numerically lower (more favorable) in the DEXTENZA treatment group compared to the placebo group measured 7 days following insertion of the depots, at 3, 5, and 7 minutes by -0.18, -0.29, and -0.29 units, respectively, on a five point scale, this difference did not reach statistical significance. In addition, the trial did not achieve the requirement of at least a 0.5 unit difference at all three time points 7 days following insertion of the depots and at least a 1.0 unit difference at the majority of the three time points between the treatment group and the placebo group 7 days following insertion of the depots.

The trial also assessed conjunctival redness as a secondary endpoint. The differences in the mean scores in conjunctival redness between the DEXTENZA treatment group and the placebo group 7 days following insertion of the depots at 7, 15 and 20 minutes were -0.35, -0.39 and -0.42, respectively, compared with values of -0.26, -0.32 and -0.41, respectively, at the same time points 7 days following insertion of the depots in the first Phase 3 trial.

The results from the second Phase 3 trial contrast with those achieved in the first Phase 3 clinical trial of DEXTENZA for the treatment of allergic conjunctivitis announced in October 2015, in which the primary endpoint of treatment of ocular itching associated with allergic conjunctivitis was successfully achieved, with mean ocular itching scores being lower in the DEXTENZA group at 3, 5, and 7 minutes by -1.02, -0.87, and -1.04 units, respectively ( $p < 0.0001$ ), 7 days following insertion of the depots.

In the second Phase 3 clinical trial, as well as other DEXTENZA clinical trials completed to date regardless of indication, DEXTENZA has exhibited a strong safety profile and has been generally well-tolerated. There were no serious adverse events observed in the second Phase 3 clinical trial.

“We are disappointed that the primary endpoint of ocular itching associated with allergic conjunctivitis was not achieved in our second Phase 3 trial in these patients, and this result is inconsistent with what we saw in our first Phase 3 trial,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “We are currently in the process of conducting a thorough analysis of the data from the second Phase 3 trial to fully understand the difference in efficacy between the two Phase 3 trials. There was a greater variability in ocular itching exhibited by patients in the second Phase 3 trial over the multiple allergen challenges 7, 14 and 28 days following insertion of the depots, compared to the first Phase 3 trial. In a post hoc analysis, when ocular itching scores were averaged over these multiple visits, a statistically significant reduction of symptoms over the entire 1 month intended duration of sustained release, single dose therapy was observed in the DEXTENZA treatment group relative to the placebo vehicle group. Since this analysis was not part of the original end points, we plan to meet with the FDA to discuss the results and chart an appropriate path forward for the development of DEXTENZA for the treatment of allergic conjunctivitis.”

Dr. Sawhney continued, “We remain confident in the potential of our innovative sustained release platform to address diverse applications in ophthalmology. We look forward to the July 2016 PDUFA date for DEXTENZA for the treatment of post-surgical ocular pain.”

### **Second Phase 3 Study Design**

This Phase 3 prospective, U.S.-based multicenter, 1:1 randomized, double-masked, vehicle-controlled trial in 86 patients was designed to evaluate the safety and efficacy of DEXTENZA™ (sustained release dexamethasone), Intracanalicular Depot for the treatment of signs and symptoms of chronic allergic conjunctivitis. This was the second Phase 3 trial which evaluated DEXTENZA versus a placebo vehicle punctum plug using Ophthalmic Research Associate’s modified Conjunctival Allergen Challenge (Ora-CAC®) Model (Ora, Inc., Andover, MA), which accommodates for the longer therapeutic effect of a seasonal one-time administered drug product.

The trial was designed to assess the effect of DEXTENZA compared with placebo on allergic reactions. DEXTENZA or placebo was administered 48 to 72 hours after the first set of allergen challenges confirming the appropriate allergen and dose exposure to incite an allergic response, followed by three series of successive allergen challenges over a 30 day period. The primary efficacy endpoint evaluated was the difference in mean scores in ocular itching between the treatment group and the placebo vehicle group at three time points 7 days

following insertion of the depots. The trial also included a secondary efficacy endpoint for conjunctival redness which evaluated the difference in mean scores in conjunctival redness between the treatment group and the placebo vehicle group at three time points 7 days following insertion of the depots.

Ocular Therapeutix reported topline results of its first Phase 3 allergic conjunctivitis clinical trial with DEXTENZA in October 2015, where the primary endpoint for ocular itching associated with allergic conjunctivitis was successfully achieved and the primary endpoint for conjunctival redness was not achieved.

#### **About Allergic Conjunctivitis**

Allergic conjunctivitis is an inflammatory disease of the conjunctiva resulting primarily from a reaction to allergy-causing substances such as pollen or pet dander. The primary symptom of this inflammation is acute ocular itching and the primary sign is conjunctival redness. Allergic conjunctivitis ranges in clinical severity from relatively mild, common forms to more severe forms that can cause impaired vision. According to a study on the management of seasonal allergic conjunctivitis published in 2012 in the peer-reviewed journal *Acta Ophthalmologica*, allergic conjunctivitis affects 15% to 40% of the U.S. population. For patients with chronic or more severe forms of allergic conjunctivitis, antihistamines and mast cell stabilizers are often not sufficient to treat their signs and symptoms. Many ocular allergy sufferers are not responsive to the conventional dual-acting antihistamine/mast cell stabilizers. These refractory patients are frequently treated with topical corticosteroids administered by eye drops.

#### **About the Modified Conjunctival Allergen Challenge (Ora-CAC®) Model**

The modified Ora-CAC® model used in the recently completed clinical trial has been developed to study the interactions between the early and late phases of the allergic response in the eye, and to evaluate the effects of pharmaceutical intervention. The modified Ora-CAC® model utilizes four challenges conducted over a 2-day interval to evaluate the effectiveness of a test agent to prevent an acute ocular allergic reaction, as well as evaluate the test agent's ability to prevent an acute ocular allergic reaction in the presence of subclinical late phase inflammation.

#### **Conference Call & Webcast Information**

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am Eastern Time to discuss these results.

The live webcast can be accessed by visiting the investor section of the Company's website at [investors.ocutx.com](http://investors.ocutx.com). Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast.

Alternatively, please call 844-464-3934 (U.S.) or 765-507-2620 (International) to listen to the conference call. The conference ID number for the live call will be 27710660. An archive of the webcast will be available until June 20, 2016 on the company's website.

#### **About Ocular Therapeutix, Inc.**

Ocular Therapeutix, Inc. (NASDAQ: OCUL) is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix's lead product candidate, DEXTENZA™ (sustained release dexamethasone) Intracanalicular Depot, is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for dry eye disease. A New Drug Application (NDA) for the post-operative ocular pain indication has been filed with FDA and has a Prescription Drug User Fee Act (PDUFA) target action date of July 24, 2016. A third Phase 3 clinical trial is being conducted for post-surgical ocular inflammation and pain. For glaucoma and ocular hypertension, the Company has completed its End-of-Phase 2 review with the FDA, and the first of two planned OTX-TP (sustained release travoprost) Phase 3 clinical trials is expected to be initiated in the third quarter of 2016. Ocular Therapeutix is also evaluating sustained-release injectable anti-VEGF drug depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery.

#### **Forward Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the development and regulatory status of the Company's product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for the treatment of allergic conjunctivitis, DEXTENZA for post-surgical ocular inflammation and pain, including our expectations regarding the pending PDUFA date for the NDA filed with the FDA, DEXTENZA for dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel depot technology and the advancement of the Company's other product candidates, the potential utility of any of the Company's product candidates, 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, those related to the timing and costs involved in commercializing ReSure® Sealant or any product candidate that receives regulatory approval, the initiation 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 sufficiency of cash resources and need for additional financing 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 press release represent the Company's views as of the date of this release. 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. 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 release.

**Contact:**

**Investors**

Ocular Therapeutix, Inc.  
Brad Smith  
Chief Financial Officer  
[bsmith@ocutx.com](mailto:bsmith@ocutx.com)  
or

Burns McClellan on behalf of Ocular Therapeutix  
Steve Klass, 212-213-0006  
[sklass@burnsmc.com](mailto:sklass@burnsmc.com)  
or

**Media**

Ocular Therapeutix, Inc.  
Scott Corning  
Vice President of Sales and Marketing  
[scorning@ocutx.com](mailto:scorning@ocutx.com)



**A Multi-Center, Randomized, Double-Masked, Vehicle Controlled  
Phase 3 Study Evaluating the Efficacy and Safety of OTX-DP for  
the Treatment of Chronic Allergic Conjunctivitis Using a Modified  
Conjunctival Allergen Challenge Model (Ora-CAC®)**

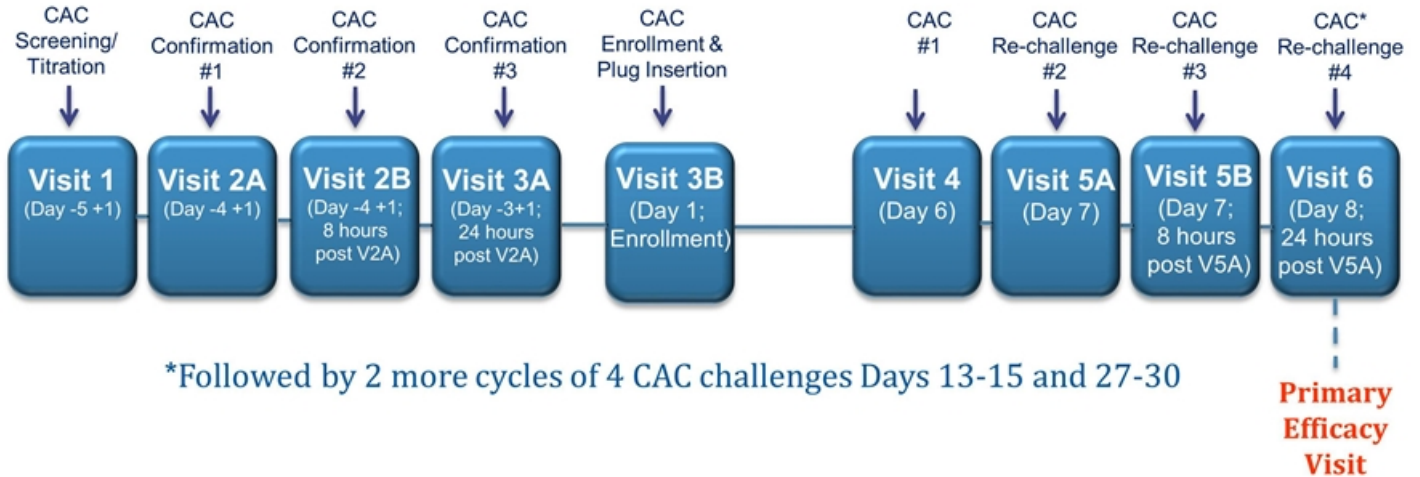
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*This presentation contains forward-looking statements about future expectations, plans and prospects for the Company, including statements about the development and regulatory status of the Company's product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA for post-surgical inflammation and pain, DEXTENZA for allergic conjunctivitis, DEXTENZA for dry eye disease and OTX-TP for glaucoma and ocular hypertension, the ongoing development of the Company's sustained released hydrogel depot technology, pre-commercial activities, the potential commercialization of DEXTENZA, the potential utility of any of the Company's product candidates, the advancement of the Company's other product candidates and earlier stage pipeline, future sales of ReSure® Sealant, 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 Ocular Therapeutix'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, those related to the timing and costs involved in commercializing ReSure® Sealant and DEXTENZA, the initiation 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 sufficiency of cash resources and need for additional financing or other actions and other factors discussed in the "Risk Factors" section of the Company's filings with the Securities and Exchange Commission, including the Company's most recent Quarterly Report on Form 10-Q. 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. 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.*

- Prospective/Randomized/Double-Masked/Vehicle-Controlled
  - OTX-DP (DEXTENZA™, sustained release dexamethasone, 0.4mg)
  - Placebo Drug Delivery Vehicle (PV)
  - N=86: Intent to Treat (ITT) population; N=78: Per Protocol (PP) population\*
- Treatment Duration: 30 days, or until OTX-DP or PV absorbed/removed
- Method: modified Ora-CAC<sup>®</sup> model
- Primary Endpoint = Ocular Itching
- Secondary Endpoint = Conjunctival Redness

\* 3 (6.8%) subjects in the OTX-DP arm, randomized not treated due to unsuccessful depot insertion  
2 (4.8%) subjects in the PV arm, consent withdrawn  
1 (2.3%) subject in the OTX-DP arm did not complete through Visit 6  
2 (4.8%) subjects in the PV arm did not complete through Visit 6

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The modified Ora-CAC<sup>®</sup> model utilizes 4 allergen challenges conducted over 2-day intervals to evaluate the effectiveness of a test agent to: 1) prevent an acute ocular allergic reaction (the initial Ora-CAC<sup>®</sup>), and 2) evaluate the test agent's ability to prevent an acute ocular allergic reaction in the presence of subclinical late phase inflammation (the latter is the re-challenge Ora-CAC<sup>®</sup>).



***Based on previous guidance from FDA on the Ora-CAC<sup>®</sup> model***

**To demonstrate efficacy for ocular itching (Primary Endpoint), OTX-DP needs to show statistical significance ( $p < 0.05$ ) at all three post-CAC time points: 3 ( $\pm 1$ ), 5 ( $\pm 1$ ), 7 ( $\pm 1$ ) minutes at 7 days post-treatment and clinical superiority over Vehicle by:**

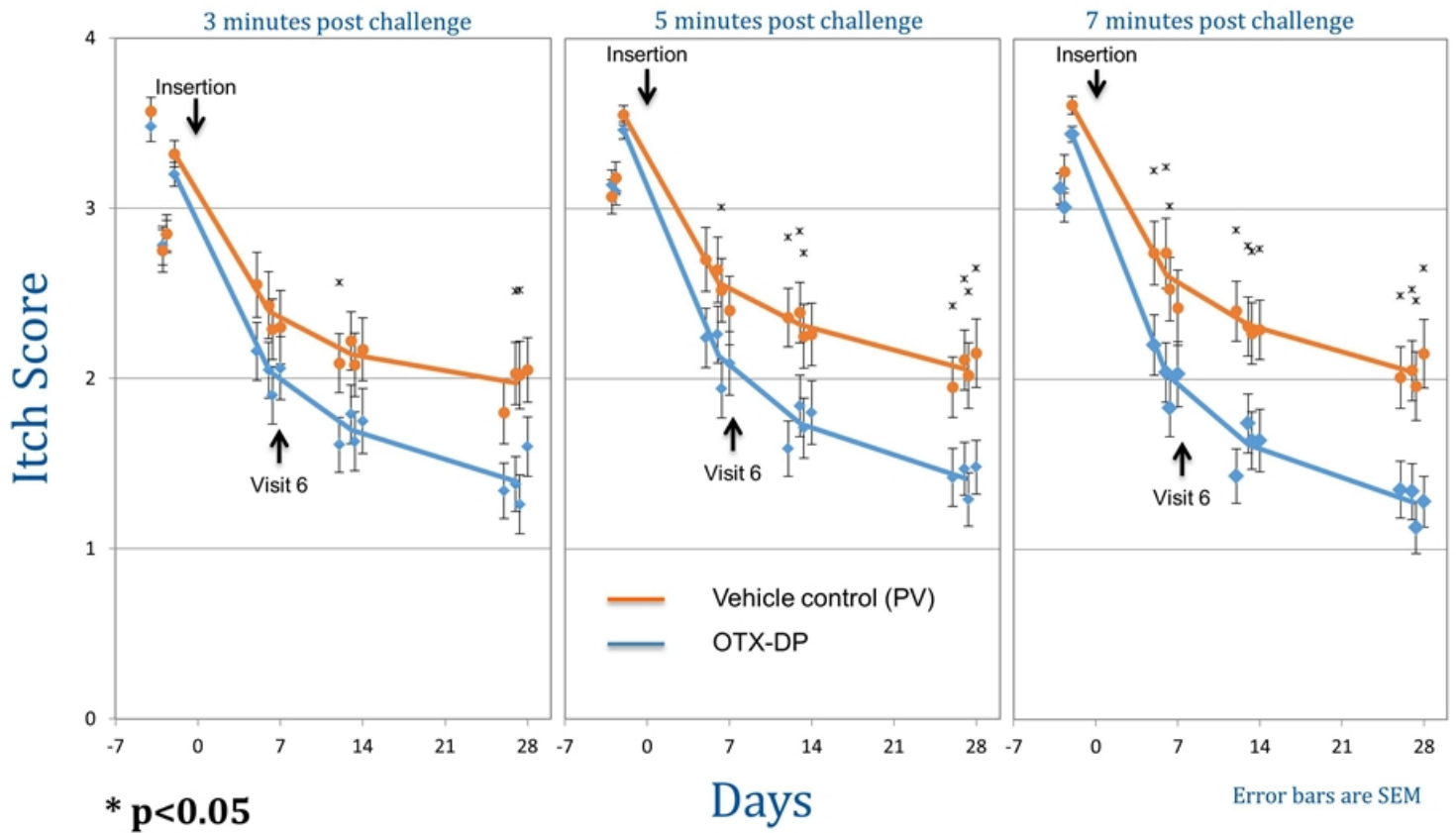
- At least 0.5 units for all 3 post-CAC time points

AND

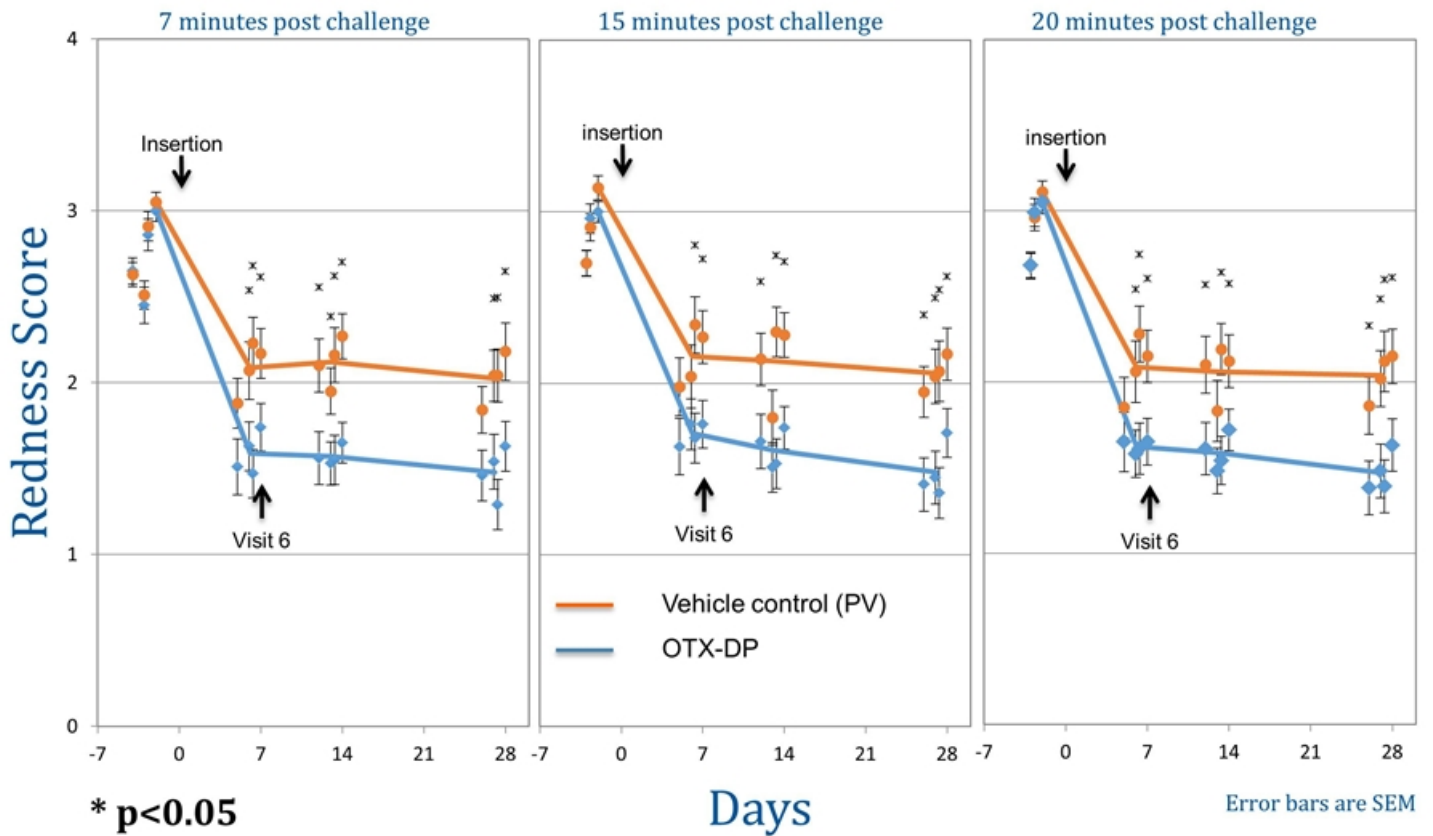
- At least 1 unit for the majority of post-CAC time points
-

Parameter	Time point	OTX-DP	Vehicle	ANCOVA LS Means Treatment Difference (P value)	Meets Success Criteria
<b>Ocular Itching</b>	3 min	2.08	2.26	-0.18 (0.4400)	<b>NO</b>
	5 min	2.09	2.39	-0.29 (0.2230)	
	7 min	2.05	2.33	-0.29 (0.2611)	

- No statistically significant treatment difference ( $p > 0.05$ ) was observed in Ocular Itching between OTX-DP and Vehicle for any of the 3 time points, 3( $\pm 1$ ), 5( $\pm 1$ ), 7( $\pm 1$ ) minutes post-Ora-CAC<sup>®</sup>, at Visit 6 (Day 8, 7 days post-insertion) in the ITT population with MCMC.
- Criteria for Efficacy in Ocular Itching were not met as follows:
  - Treatment differences were less than 0.5 units at all 3 post-CAC<sup>®</sup> time points (-0.18, -0.29 and -0.29 units, respectively)







## ITT observed data, LS Means and Differences

Time (post-Ora-CAC™)	2 <sup>nd</sup> Phase 3 Study			2 <sup>nd</sup> Phase 3 Study Excluding 5000 Allergen Units (AU)		
	OTX-DP	PV	Difference	OTX-DP	PV	Difference (% excluded)
n	39	33		22	22	39.7%
3 min	2.08	2.26	-0.18	1.98	2.61	-0.63
5 min	2.09	2.39	-0.29	1.99	2.74	-0.75
7 min	2.05	2.33	-0.29	1.95	2.75	-0.80

\*Preliminary Post-Hoc Analysis, review of full data ongoing

Observed Data Only, unadjusted differences  
Excluding Subjects requiring allergen dose of 5000 AU  
OTX-DP (N=26), PV (N=28)

Visit	OTX-DP n	PV n	Minutes Post-CAC					
			3		5		7	
			Mean Difference	t-test p-value	Mean Difference	t-test p-value	Mean Difference	t-test p-value
4	22	25	-0.74	0.0166	-0.80	0.0090	-0.86	0.0055
5a	22	24	-0.58	0.0575	-0.70	0.0216	-1.10	0.0010
5b	22	24	-0.66	0.0488	-0.95	0.0049	-1.05	0.0013
<b>6</b>	<b>22</b>	<b>22</b>	<b>-0.70</b>	<b>0.0443</b>	<b>-0.80</b>	<b>0.0191</b>	<b>-0.89</b>	<b>0.0130</b>
7	21	22	-0.80	0.0105	-1.15	0.0003	-1.30	<.0001
8a	20	22	-0.65	0.0341	-0.96	0.0022	-0.99	0.0011
8b	20	22	-0.73	0.0290	-0.88	0.0104	-1.00	0.0018
9	20	22	-0.74	0.0326	-0.77	0.0146	-1.06	0.0009
10	19	22	-0.86	0.0110	-0.83	0.0120	-0.99	0.0038
11a	18	22	-1.08	0.0007	-1.11	0.0003	-1.14	0.0004
11b	18	22	-1.08	0.0015	-1.17	0.0002	-1.24	0.0002
12	18	22	-0.69	0.0494	-0.92	0.0080	-1.15	0.0007

\*Preliminary Post-Hoc Analysis, review of full data ongoing

### Area Under the Curve

Visit	OTX-DP	Vehicle	Post-CAC	
			Average of 3, 5, 7 minute time-points	
	n	n	Mean Difference	t-test p-value
V4 - V6 (5-7 days post insertion)	39	36	-0.96	0.0766
V7 - V9 (12-14 days post insertion)	38	33	-1.38	0.0096
V10 - V12 (25-30 days post insertion)	36	33	-1.51	0.0041

\*Preliminary Post-Hoc Analysis, unadjusted differences, review of full data ongoing

**Area Under the Curve  
excluding subjects requiring allergen dose of 5000  
Allergen Units (AU)**

Visit	OTX-DP	Vehicle	Post-CAC	
			Average of 3, 5, 7 minute time-points	
	n	n	Mean Difference	t-test p-value
V4 - V6 (5-7 days post insertion)	22	25	-1.71	0.0123
V7 - V9 (12-14 days post insertion)	21	22	-2.21	0.0009
V10 - V12 (25-30 days post insertion)	19	22	-2.35	0.0004

\*Preliminary Post-Hoc Analysis, unadjusted differences, review of full data ongoing

	OTX-DP (N=41)	Vehicle (N=42)
Total- Ocular AEs	6	9
Number of subjects with at least one ocular AE	5 (12.2%)	6 (14.3%)
Eye Pruritus	0	2 (4.8%)
Dacryostenosis Acquired	0	1 (2.4%)
Eye Discharge	0	1 (2.4%)
Eyelid Oedema	1 (2.4%)	0
Lacrimal Structure Disorder	0	1 (2.4%)
Visual Acuity Reduced	1 (2.4%)	0
Dacryocanalculitis	0	2 (4.8%)
Abscess of Eyelid	1 (2.4%)	0
Conjunctivitis	0	1 (2.4%)
Medical Device Complication*	0	1 (2.4%)
Intraocular Pressure Increased**	2 (4.9%)	0
Aura	1 (2.4%)	0

\*Unsuccessful removal leading to a piece of the hydrogel carrier lodged in the canaliculus, rated as mild. Unexpected, suspected to be related to product; recovering/resolving at exit.

\*\* Transient IOP increase by 8mmHg and 9mmHg from Baseline; rated as mild. Expected, suspected to be related to product; resolved with temporary use (2-4 wks) of medication (brimonidine).



- **OTX-DP did not meet primary endpoint for itching at Visit 6 (7 days post-insertion).**
  - **While trial design was otherwise identical to first Phase 3 trial a much higher proportion (~40% vs. ~19%) of subjects received maximal allergen challenge dosing (5000 Allergen Units), which may have impacted results.**
  - **Presentation of primary endpoint efficacy and all other results and post-hoc analyses to be discussed with FDA during meeting scheduled late July.**
-