

## TRANSFORMING DRUG DELIVERY LEVERAGING A NOVEL TECHNOLOGY PLATFORM

JEFFERIES LONDON HC CONFERENCE

DONALD NOTMAN | CFO | NOVEMBER 21, 2019





## 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, including the impact of and restructuring costs and potential future savings associated with the Company's operational restructuring, workforce reduction and development program deferrals; the commercial launch of and effectiveness of reimbursement codes for DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of, and the prospects of approveability for, DEXTENZA for any additional indications including allergic conjunctivitis, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT 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 potential utility or commercial potential 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; 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 implementation of the operational restructuring, 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 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 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 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.



## POSITIONED TO DEVELOP BREAKTHROUGH TREATMENTS

## WE BELIEVE THE APPROVAL OF DEXTENZA® IS ONLY THE BEGINNING

Provide unique drug delivery to the surface and anterior segment of the eye.

Obsolete drop therapies

Obsolete immediate release injections

Develop sustained release injections for the posterior segment of the eye.

Leverage the hydrogel platform

Enable new delivery modalities for breakthrough technologies.



## PIPELINE AT A GLANCE

PRODUCT/PROGRAM	DISEASE STATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	REGULATORY APPROVAL	
INTRACANALICULAR INSERTS							
Dextenza® (dexamethasone ophthalmic insert) 0.4 mg	Post-surgical ocular inflammation and pain					$\Diamond$	
Dextenza® (dexamethasone ophthalmic insert) 0.4 mg	Allergic conjunctivitis						
OTX-TP (travoprost insert)	Glaucoma and ocular hypertension						
INTRACAMERAL IMPLANT							
OTX-TIC (travoprost implant)	Glaucoma and ocular hypertension						
INTRAVITREAL IMPLANTS							
OTX-TKI (tyrosine kinase inhibitor implant)	Wet AMD, DME and RVO <sup>†</sup>						
OTX-IVT* (anti-VEGF antibody implant)	Wet AMD, DME and RVO <sup>†</sup>						

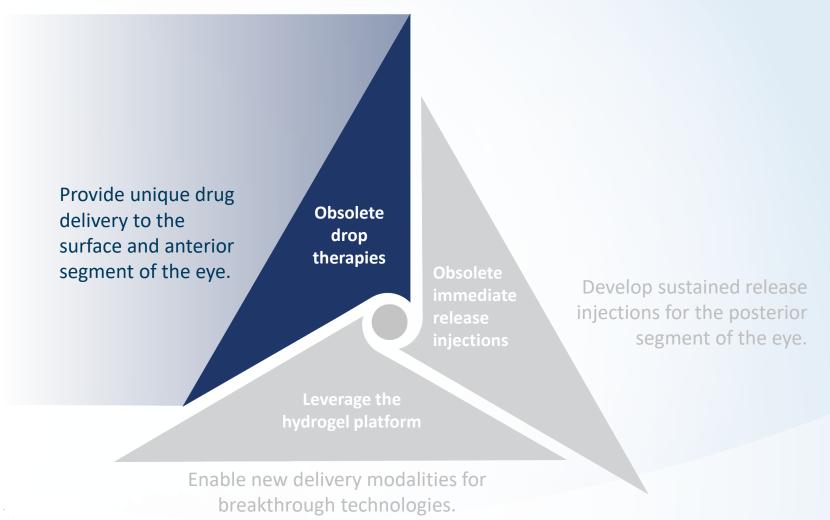
<sup>\*</sup> In Partnership with REGENERON

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





## POSITIONED TO DEVELOP BREAKTHROUGH TREATMENTS





## **Dextenza**®

(dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use

# BIGTIME INNOVATION

THE FIRST AND ONLY OPHTHALMIC STEROID INSERT

PRESERVATIVE-FREE INTRACANALICULAR INSERT<sup>2</sup> SUSTAINED DELIVERY FOR UP TO 30 DAYS<sup>2</sup>

## INTRACANALICULAR ADMINISTRATION AVOIDS THE BURDEN OF EYE DROPS

## CORTICOSTEROID DROP REGIMENS ARE COMPLEX AND ARE DEPENDENT ON PATIENT COMPLIANCE

## **Dextenza**°

(dexamethasone ophthalmic insert) 0.4 mg



### **DEXTENZA INSERTION**

1 insert provides a full course of therapy

### **OPHTHALMIC DROPS**



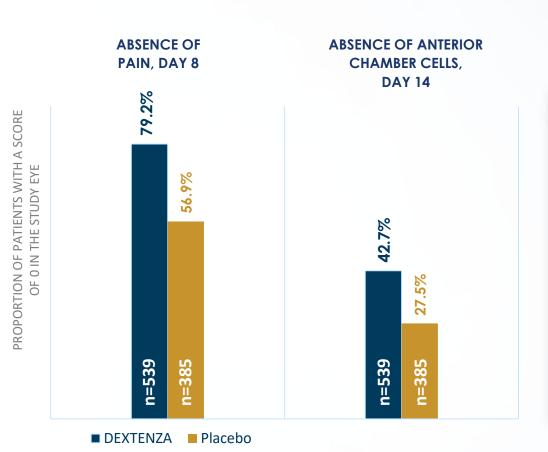
## **DROP ADMINISTRATION**

70 applications over 1 month with a different frequency every week



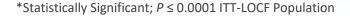
## THE SAFETY & EFFICACY OF DEXTENZA® HAS BEEN DEMONSTRATED IN AN EXTENSIVE CLINICAL PROGRAM

## POOLED RESULTS OF THREE PHASE 3 CLINICAL TRIALS FOR THE TREATMENT OF POST-OPERATIVE PAIN AND INFLAMMATION



### TREATMENT-RELATED OCULAR ADVERSE EVENTS

Phase 3 Trials						
# of Subjects, n (%)	DEXTENZA n=539	Placebo n=385				
Any Ocular AEs	4 (0.7%)	2 (0.5%)				
Conjunctivitis	0	1 (0.3%)				
Eyelid Irritation	1 (0.2%)	0				
Increased Lacrimation	2 (0.4%)	0				
Dacryocanaliculitis	0	1 (0.3%)				
Increased Intraocular Pressure	1 (0.2%)	0				





## DEXTENZA® STATUS

## **FDA APPROVED**

DEXTENZA® is a corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery.



## REIMBURSEMENT AND CODING

- J-code 1096 became effective October 1, 2019
  - ✓ Replaces C-code 9048
  - ✓ Maintains 3 year pass-through payment status
  - ✓ Allows for billing in the office setting
- Procedure CPT code 0356T (currently in place)
- DEXTENZA 360 external reimbursement HUB (active)

## FORMALLY LAUNCHED JULY ~ Q3 FIRST QUARTER

- 29 Key Account Managers in place supported by 6 Field Reimbursement Managers and 3 Medical Science Liaisons
- Active with "DEXTENZA Days" since mid-May
- Over 7,000 patients treated at over 350 ASCs to date

## POSITIVE MARKET RECEPTION

- Surgeons report they are finding easy to adopt
- Favorable patient feedback
- Of initial centers ordering to date:
  - √ ½ of centers re-ordering
  - ✓ More than 1/3<sup>rd</sup> of centers re-ordering three or more times

### LIFECYCLE MANAGEMENT

- 80 patient confirmatory P3 allergic conjunctivitis trial enrolling
  - ✓ U.S.-based, multi-center, 1:1 randomized, double-masked, placebocontrolled trial
  - ✓ DEXTENZA vs. a placebo in conjunctival allergen challenge model
  - ✓ Primary efficacy endpoint is ocular itching at multiple time points over 30 days
  - ✓ Topline data anticipated in first half of 2020
- Active investigator-initiated trials (IIT) program



## SURGICAL SALE OF A PHARMACEUTICAL PRODUCT

4 million cataract procedures per year in the US, 50% are performed under Medicare Part B, where DEXTENZA has full coverage<sup>1</sup>



~60% of the annual 2 million Medicare Part B surgeries are done in ~900 surgical centers<sup>2</sup>



## DEXTENZA INVOLVES A DETAILED SALE, INCLUDES MANY STAKEHOLDERS AND HAS THE POTENTIAL FOR A SIGNIFICANT PAYOFF





## DEXTENZA® OPENS NEW POTENTIAL REIMBURSEMENT PATHWAYS

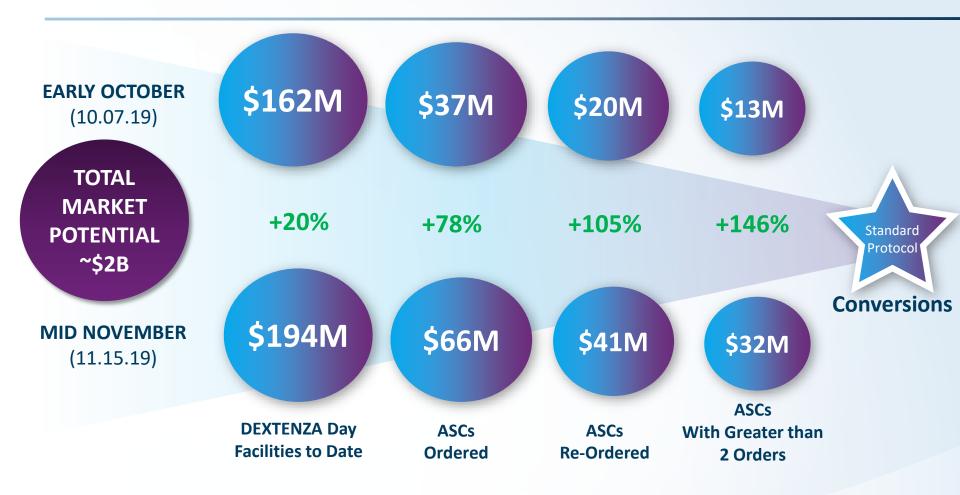
Permanent separate drug payment provides the flexibility to price DEXTENZA based on the clinical value, while enhancing provider revenues and spurring adoption







## ASSESSING THE ADDRESSABLE MARKET - ALL CATARACT VOLUME



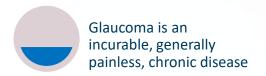
Addressable market potential at each stage based on actual cumulative value of <a href="total">total</a> cataract volume of each ambulatory surgery center

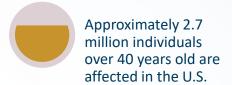
CMS, Medicare Provider Utilization and Payment Data, 2017



## GLAUCOMA: PATIENT ADHERENCE IS PROBLEMATIC

## POOR ADHERENCE HAS BEEN SHOWN TO BE ASSOCIATED WITH DISEASE PROGRESSION AND BLINDNESS





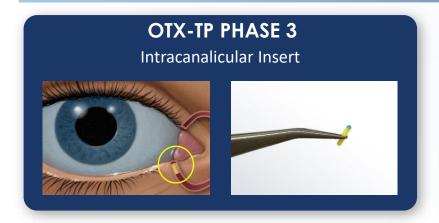


- The primary goal of glaucoma treatment is to reduce intraocular pressure
- Various medications can significantly lower intraocular pressure and reduce the progression of glaucoma, but these are almost always life-long medications that must be taken on a daily basis
- Adherence to glaucoma therapies is particularly poor, with reported rates of non-adherence ranging from 30–80%<sup>2,3,4</sup>
- Poor adherence has been shown to be associated with disease progression and blindness<sup>5,6</sup>





## NON-COMPLIANCE IS A SIGNIFICANT PROBLEM IN THE TREATMENT OF GLAUCOMA





### **DESCRIPTION**

- Up to 90 days of sustained release of travoprost
- Can be visualized and is preservative-free
- Little to no eye redness

### **STATUS**

- First Phase 3 trial complete, top-line readout May 2019
- Met with FDA on October 30, 2019
  - Data did not meet standard of clinical meaningfulness
  - Discussed potential pathways forward in patient populations for whom drops are problematic
  - No immediate plans to bring forward without a partner

### **DESCRIPTION**

- Up to 6 months of sustained release of travoprost
- Can be visualized and is preservative-free
- Consistent resorption
- Minimal effect on endothelial cells

## **STATUS**

- Phase 1 study is ongoing
  - First, therapeutic-dose cohort fully enrolled
    - Continuing long-term evaluation of low-dose cohort
  - Second, higher-dose cohort fully enrolled
  - Third, therapeutic-dose cohort with fast-degrading hydrogel has begun enrollment
  - Fourth, smaller implant cohort anticipated in the future

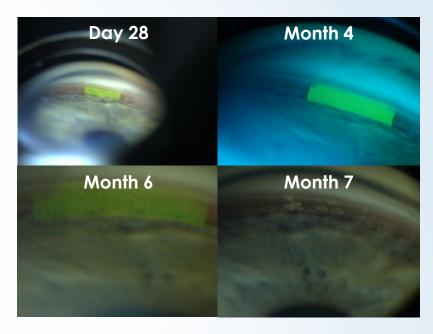


## OTX-TIC PHASE 1 INTERIM FINDINGS

## SUMMARY FROM LOW-DOSE COHORT

- Clinically-meaningful decrease in IOP IOP values were decreased as early as two days
- Duration of therapy
   IOP-lowering out to 13 months
- Bioresorbable
   Implant biodegraded by 7 months
- Implant location and movement
  Implant did not move and was visualized in all patients
- Corneal health
   No changes from baseline observed; preservative-free

## IMPLANTS VISUALIZED IN ALL SUBJECTS AT ALL VISITS THROUGH 7 MONTHS



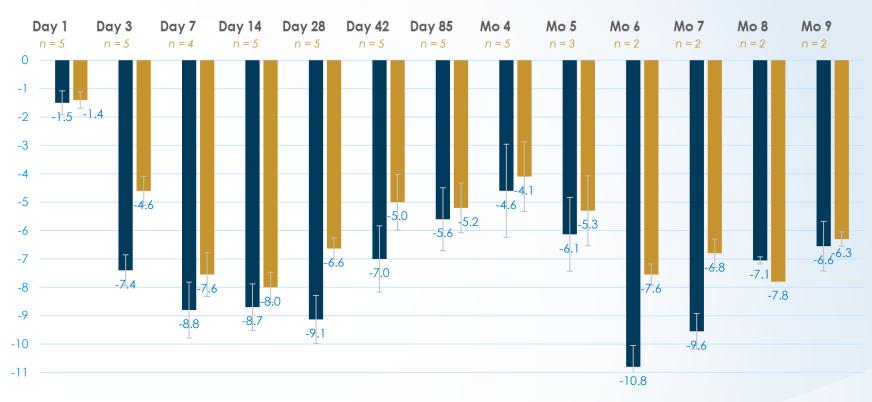






## OTX-TIC EFFICACY RESULTS: MEAN IOP CHANGE FROM BASELINE, COHORT 1

## Measurements taken at 8 AM



Study Eye: OTX-TIC Implant

Non-Study Eye: Topical Travaprost (QD Nightly)





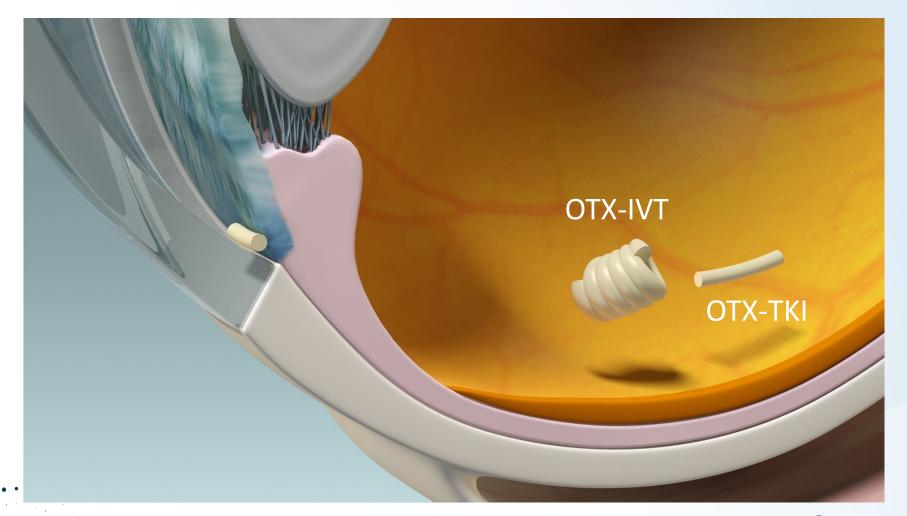
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Provide unique drug delivery to the surface and anterior segment of the eye. Develop sustained release **Obsolete** immediate injections for the posterior release segment of the eye. injections Enable new delivery modalities for breakthrough technologies.



## SUSTAINED RELEASE INJECTIONS

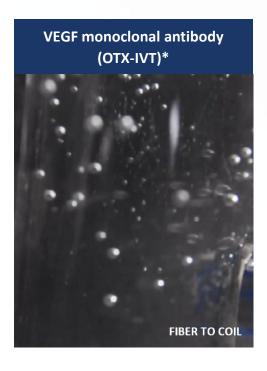
## **INTRAVITREAL IMPLANTS**





## IMPROVING TREATMENT TO THE BACK OF THE EYE

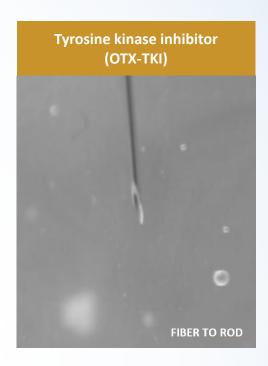
## SHAPE-CHANGING IMPLANTS WITH UP TO 6 MONTHS OF DRUG DELIVERY



### **HIGH DRUG LOAD**

### **STATUS**

Ongoing discussions with Regeneron regarding potential additional formulations and next steps



### **LOW DRUG LOAD**

### **STATUS**

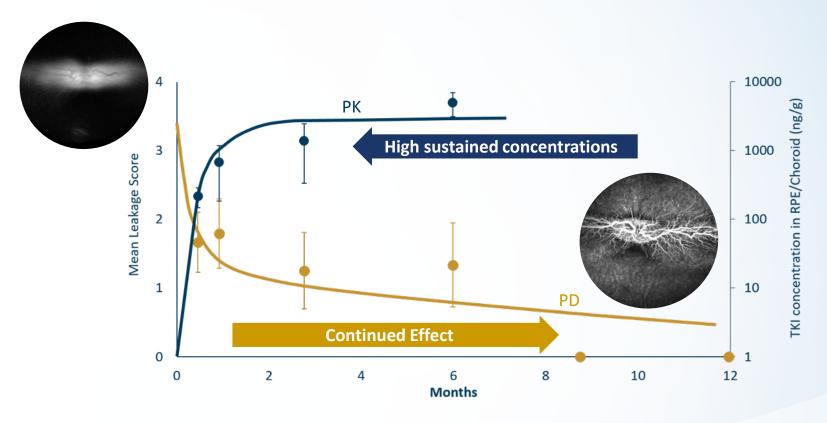
Phase 1 clinical trial in Australia
- cohort 1 complete
- cohort 2 dose escalation enrolling





## OTX-TKI HAS DEMONSTRATED SUSTAINED PK/PD EFFECT IN PRECLINICAL TRIALS

## DEMONSTRATED ABILITY TO DELIVER TKI TO THE POSTERIOR SEGMENT FOR UP TO 12 MONTHS USING AN INTRAVITREAL BIORESORBABLE HYDROGEL IMPLANT



Completed in vivo evaluations through 12 months

 PK, PD and tolerability with no negative safety signals reported to date



## RECENT AND ANTICIPATED NEAR-TERM MILESTONES

US launch of DEXTENZA® in 2019 with reimbursement using J-code 1096 effective October 1, 2019 and CPT code 0356T

• J1096 offers the potential to broaden the commercial opportunity of DEXTENZA to the estimated 8.0 million steroid prescriptions written each year in the U.S.

## Progress of pipeline programs

- DEXTENZA AC Phase 3 trial expected to read out first half of 2020
- OTX-TIC third cohort underway, fourth cohort expected to begin in the near future
- OTX-TKI second therapeutic dose cohort has begun enrollment

## Corporate restructuring implemented November 8th:

- Estimated to generate \$11M in annualized savings and \$14M of savings in one-time program deferrals
- Expanded Key Account Managers by 50% as of the end of November
- Company estimates that existing cash plus anticipated inflows from DEXTENZA product sales and expected cost savings generated from the restructuring extend cash runway through the end of Q4 2020

Actively seeking new business development opportunities



(NASDAQ: OCUL)

## TRANSFORMING DRUG DELIVERY LEVERAGING A NOVEL TECHNOLOGY PLATFORM



**THANK YOU** 

