

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): March 27, 2018

**CLEARSIDE BIOMEDICAL, INC.**  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-37783  
(Commission  
File Number)

45-2437375  
(IRS Employer  
Identification No.)

900 North Point Parkway, Suite 200  
Alpharetta, Georgia 30005  
(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (678) 270-3631

Not Applicable  
Former name or former address, if changed since last report

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))

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 March 27, 2018, members of management of Clearside Biomedical, Inc. (the “Company”), will hold meetings to review, among other things, the Company’s product candidate pipeline and recent clinical results. A copy of the presentation that will accompany the meetings is available on the Company’s website, and is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing 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 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Company Presentation.</a>

**SIGNATURES**

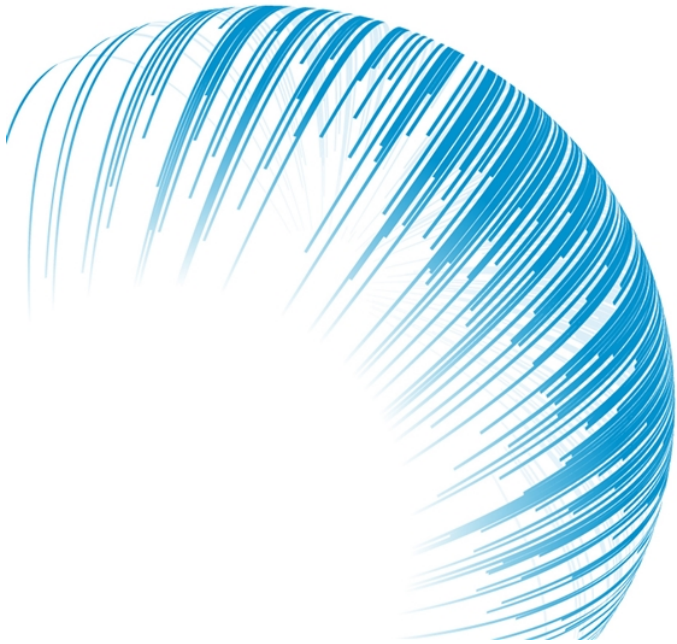
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 27, 2018

**CLEARSIDE BIOMEDICAL, INC.**

By: /s/ Charles A. Deignan  
Name: Charles A. Deignan  
Title: Chief Financial Officer

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CLEARSIDE®  
BIOMEDICAL

Corporate Presentation | March 2018



# Forward-Looking Statements

This presentation contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Clearside Biomedical, Inc.'s views as of the date of this presentation about future events and are subject to risks, uncertainties, assumptions, and changes in circumstances that may cause Clearside's actual results, performance, or achievements to differ significantly from those expressed or implied in any forward looking statement. Although Clearside believes that the expectations reflected in the forward looking statements are reasonable, Clearside cannot guarantee future events, results, performance, or achievements. Some of the key factors that could cause actual results to differ from Clearside's expectations include its plans to develop and potentially commercialize its product candidates; Clearside's planned clinical trials and preclinical studies for its product candidates; the timing of and Clearside's ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Clearside's product candidates; the clinical utility and market acceptance of Clearside's product candidates; Clearside's commercialization, marketing and manufacturing capabilities and strategy; Clearside's intellectual property position; and Clearside's ability to identify additional product candidates with significant commercial potential that are consistent with its commercial objectives. For further information regarding these risks, uncertainties and other factors you should read the "Risk Factors" section of Clearside's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 16, 2018 and Clearside's other Periodic Reports filed with the SEC. Clearside expressly disclaims any obligation to update or revise the information herein, including the forward-looking statements, except as required by law.

This presentation also contains estimates and other statistical data made by independent parties and by Clearside relating to market size and growth and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of Clearside's future performance and the future performance of the markets in which Clearside operates are necessarily subject to a high degree of uncertainty and risk.

## A World Without Blindness

We see a world without blindness; relentlessly pursuing transformative, elegant, precise solutions to **restore and preserve vision**

**Developing advanced clinical and preclinical product candidates, using a proprietary suprachoroidal treatment approach:**

- Unmet or underserved blinding eye diseases
- Pathologies manifest in the choroid and retina



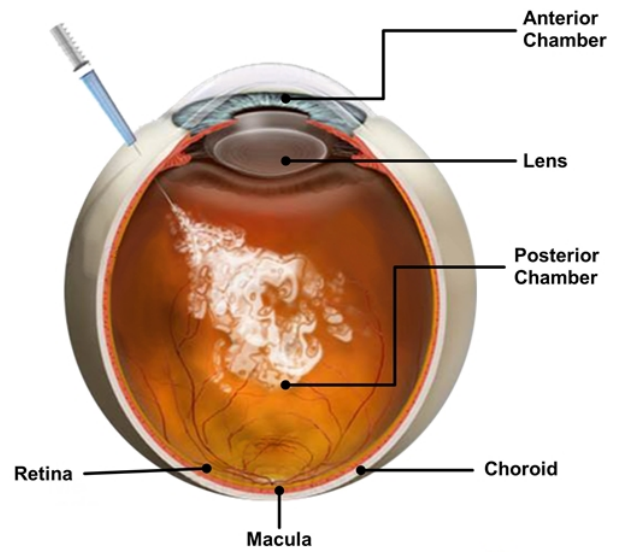
## Retinal Diseases

~5 M patients in the U.S. with target indications treated by approx. 1,900 uveitis and retinal specialists

### Privileged Organ Requiring Local Therapy

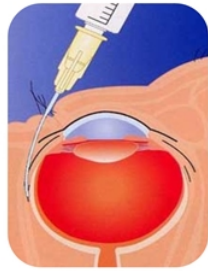
### Limitations of Current Approaches to Local Administration Include:

- Corticosteroids reach unintended tissues, causing cataracts and glaucoma
- Multi-kinase inhibitors and gene therapies require precise placement at diseased tissue
- Certain drugs like complement inhibitors require improved exposure to the choroid



## Exclusive and Proprietary Access to the Back of the Eye Through the Suprachoroidal Space (“SCS”)

### Intravitreal & Periocular

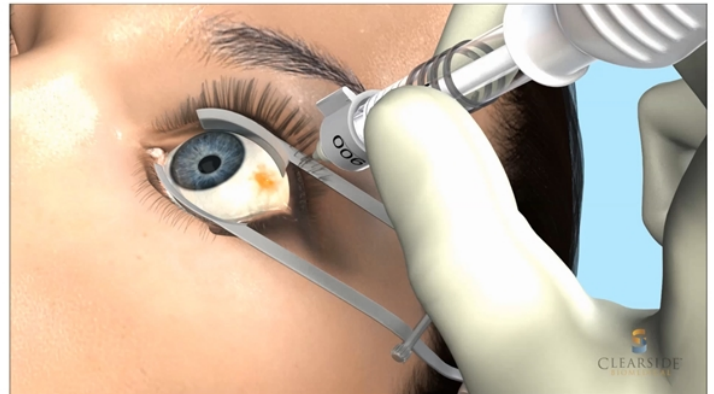


VS

- 50  $\mu$ L bolus at injection site
- Drug diffuses to all areas of the eye including the anterior chamber and lens

- 0.5 mL–1 mL injected into periocular space
- Highly variable drug diffusion across the sclera into the eye

### Suprachoroidal

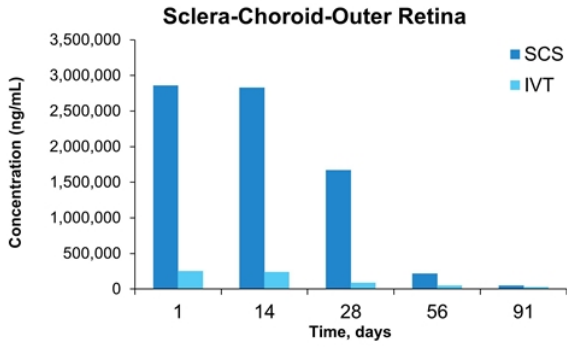


- Fluid flows instantaneously and posteriorly
- Designed consistent suprachoroidal injection procedure
- Fluid with drug is absorbed into the choroid, RPE and retina

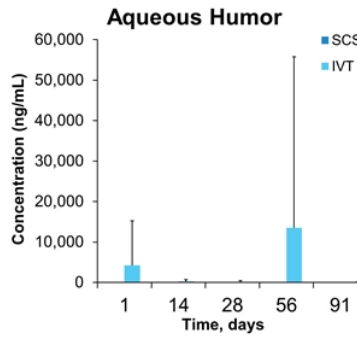


# SUPRACHOROIDAL CLS-TA

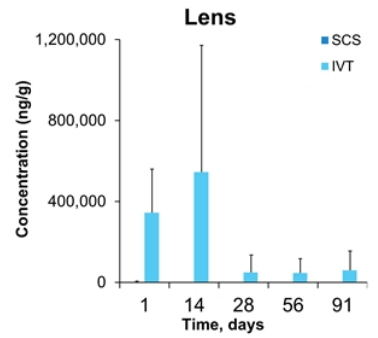
Designed to Improve Ocular Distribution of Triamcinolone Acetonide (TA)



Over 10X the amount of TA remaining in the choroid and RPE following suprachoroidal administration compared to intravitreal injection



The anterior segment is relatively spared following suprachoroidal dosing when compared to intravitreal dosing



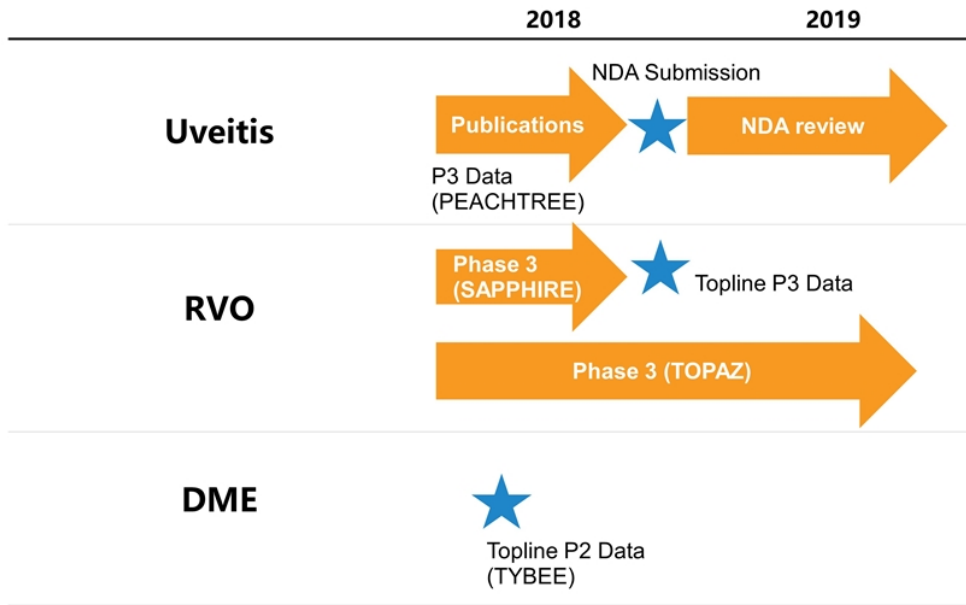
Potentially providing improved **visual outcomes**, increased **durability**, reduced **treatment burden** that can lead to improved **benefit to risk**

## Focused Pipeline of SCS Treatments For Multiple Blinding Eye Diseases

INDICATION	STUDY DRUG	CURRENT STATUS				
Uveitis (macular edema associated with non-infectious uveitis)	Suprachoroidal CLS-TA (corticosteroid triamcinolone acetonide)	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
RVO (retinal vein occlusion)	Suprachoroidal CLS-TA with anti-VEGF (Intravitreal Eylea®)	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
DME (diabetic macular edema)	Suprachoroidal CLS-TA alone or with anti-VEGF (Intravitreal Eylea®)	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
Retinal Vascular Disease	Proprietary Compound(s)	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
Orphan Diseases	Gene Therapy	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA

# Major Near-Term Anticipated Milestones

Provide Multiple Potential Value-Inflection Points



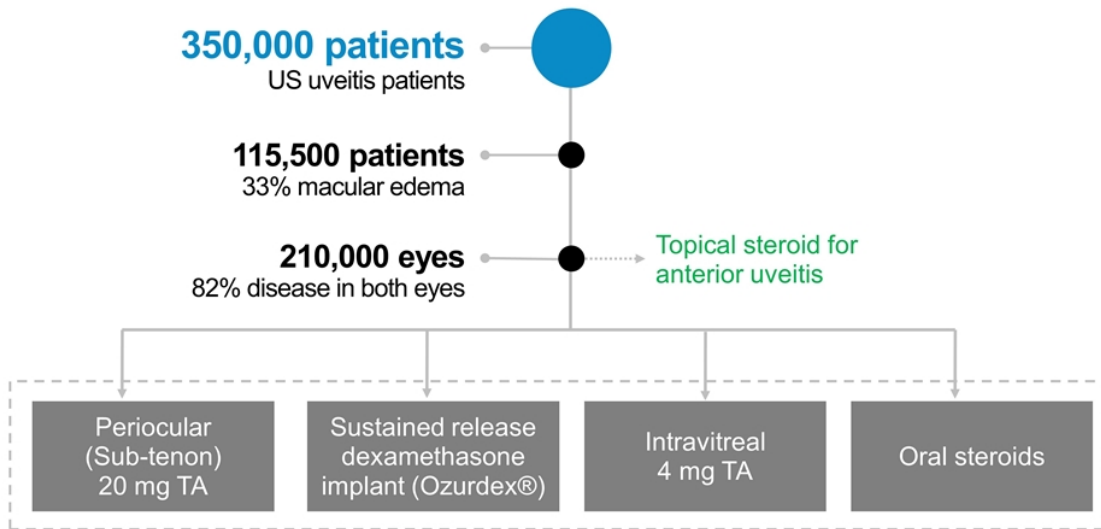


# UVEITIS

One of the World's Leading Causes of Blindness

# Current Treatment Paradigm

**Corticosteroids = most common treatment**  
for all uveitis complications, including macular edema



Current treatments

Note: TA = triamcinolone acetonide.



## The Opportunity

In Treating Macular Edema with Uveitis

### Primary Need

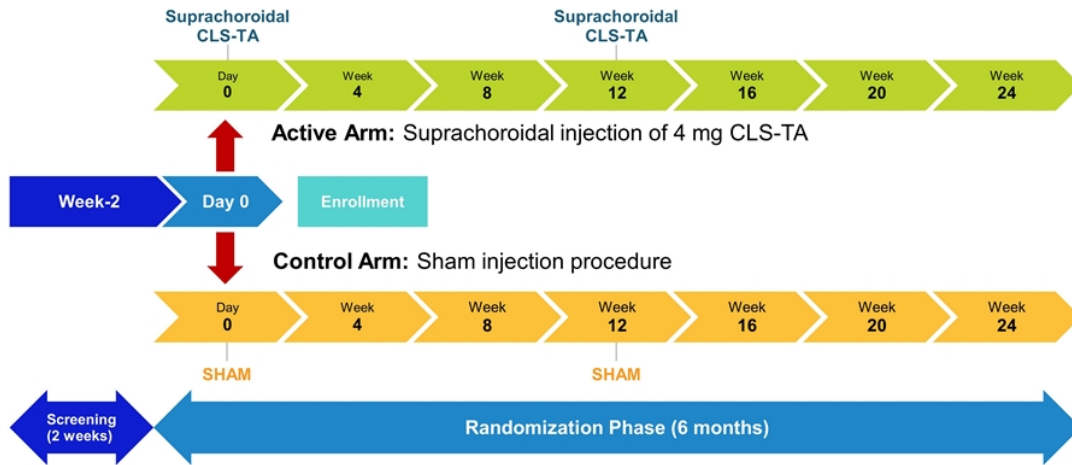
- 1) An approved therapy that targets vision impairment due to the underlying macular edema associated with all non-infectious uveitis

### The Problem

- 1) Inflammation creates sight threatening macular edema
- 2) No approved treatment for macular edema associated with uveitis
- 3) No new local treatments for uveitis since 2009
- 4) Oral corticosteroids often prescribed when disease is local to the eye

# PEACHTREE

## Design for Pivotal Phase 3 Clinical Trial



Two-arm, randomized, controlled, double-masked, multi-center trial at ~60 clinical sites

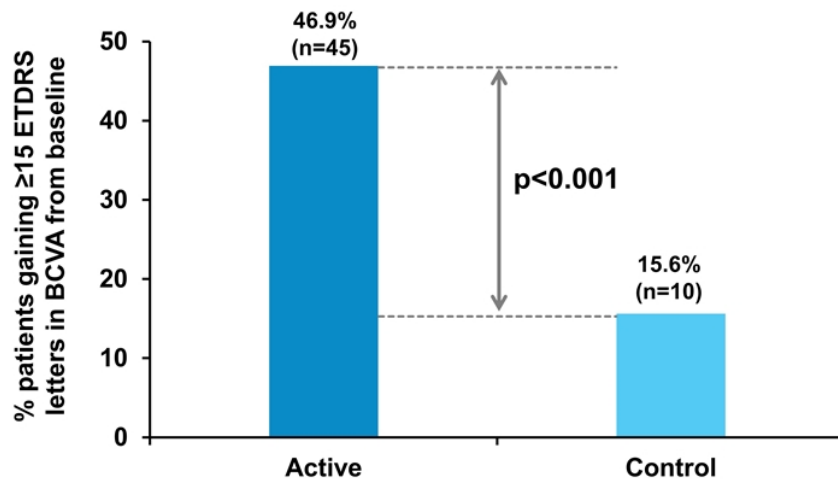
3:2 randomization of suprachoroidal CLS-TA vs. sham injection; 160 patients total

Primary endpoint at 6 months; superiority of best corrected visual acuity outcome from treatment

# Primary Endpoint

## ETDRS BCVA

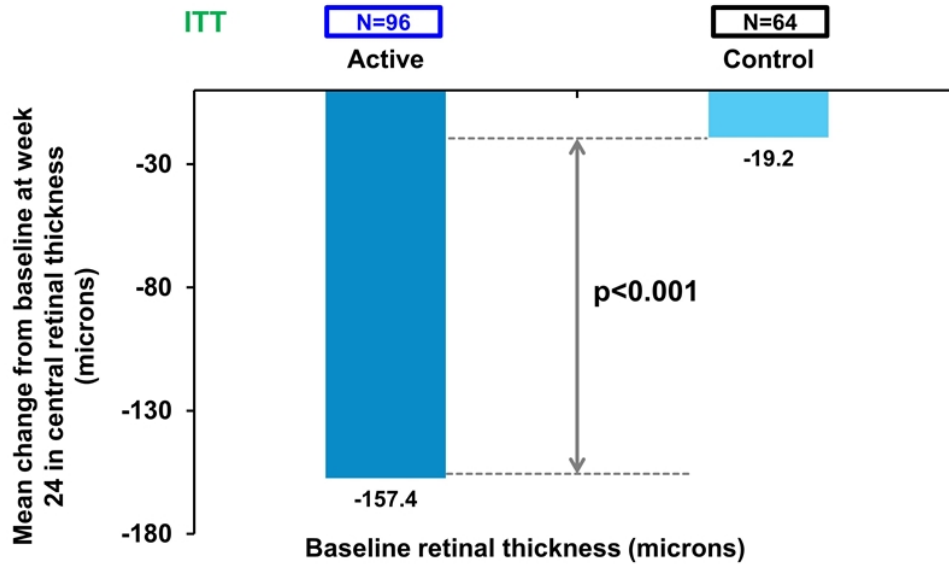
Proportion of patients in each arm gaining  $\geq 15$  ETDRS letters in BCVA from baseline at Week 24





## Secondary Endpoint

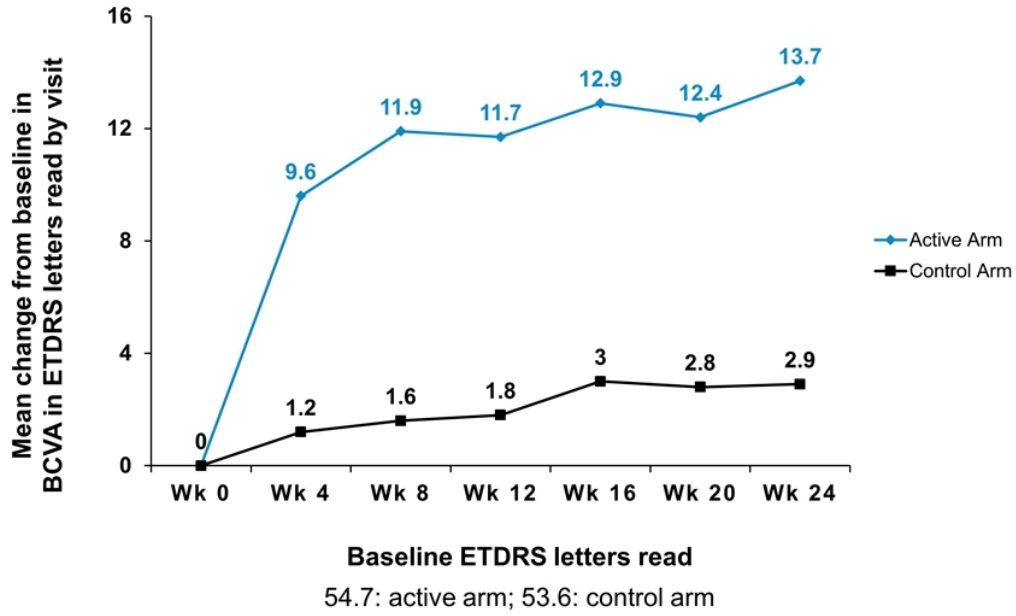
Mean Change from Baseline in CRT at Week 24 in microns



479.8  $\mu\text{m}$ : active arm; 518.0  $\mu\text{m}$ : control arm

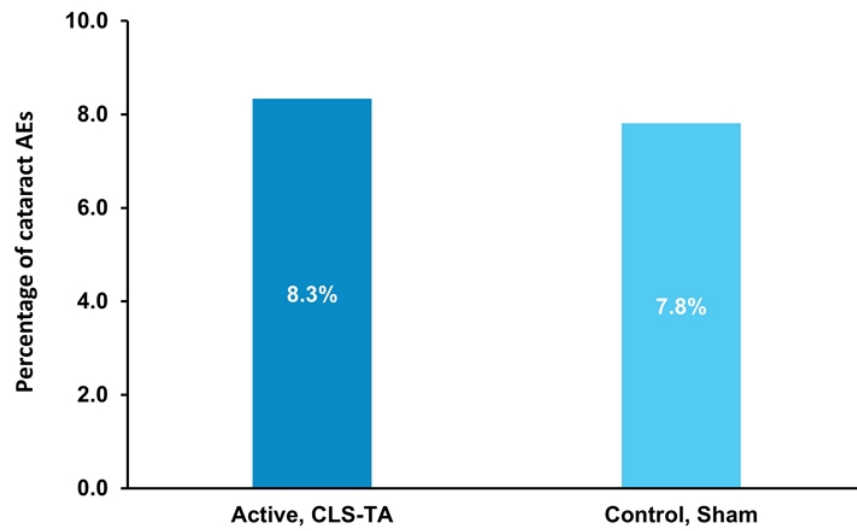
## Secondary Endpoint

Mean Change in BCVA in ETDRS Letters by Visit



## AE: Cataracts in CLS-TA and Sham Arms

% Cataract AEs in Each Arm



There were **no treatments (i.e. surgeries)** because of cataract AEs



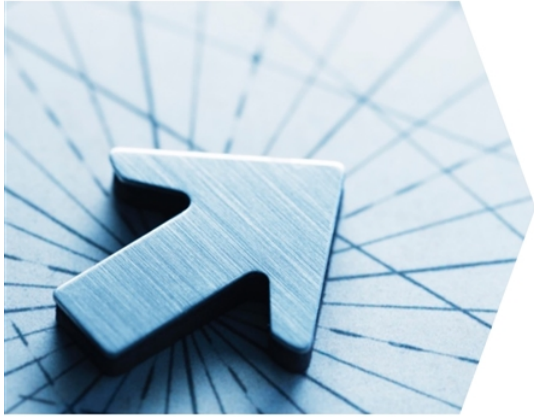
## PEACHTREE

### Safety Summary

- 97% of the randomized patients completed the trial
- No serious adverse events related to treatment
- Through 24 weeks, steroid-related elevated IOP adverse events were reported for 11.5% of patients in the CLS-TA treatment group, compared to no patients in the sham group

## Next Steps

Based on feedback from end-of-Phase 2 meeting with the FDA, we believe PEACHTREE will be the **only Phase 3 clinical trial required** to support the filing of a New Drug Application (NDA)



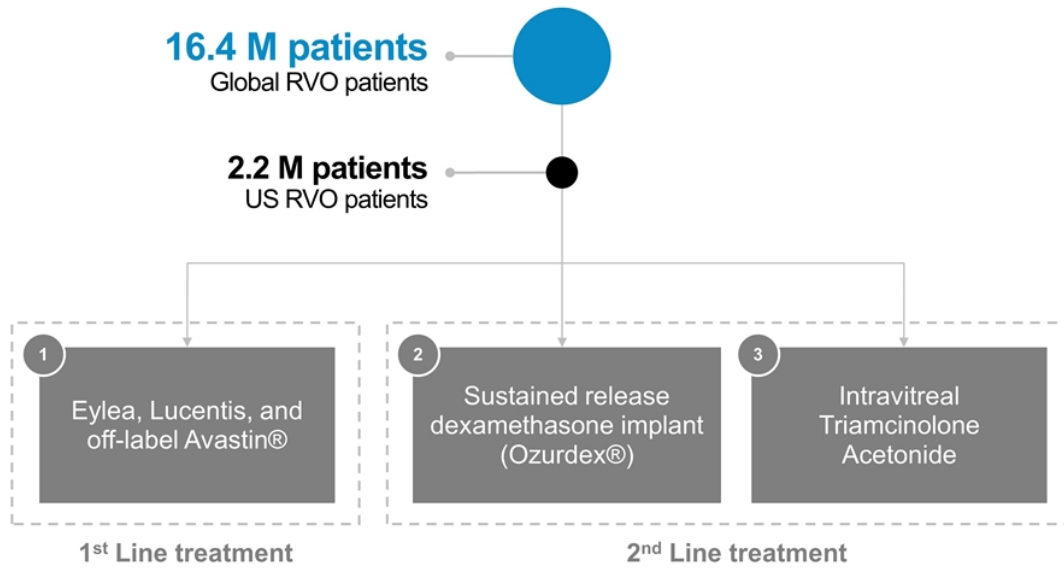
- Detailed results from PEACHTREE will be presented at an upcoming medical conference
- Positioning the company for potential transition to commercial-stage
  - Hired new Chief Commercial Officer
  - Changed Chairman of Board
- Currently expect to submit NDA to FDA in Q4 2018



# RVO

New Approach with CLS-TA + anti-VEGF

# Current Treatment Paradigm





## The Opportunity

In Treating RVO

### Primary Needs

- 1) More rapid and fuller resolution of macular edema to allow patients to recover as much vision as soon as possible

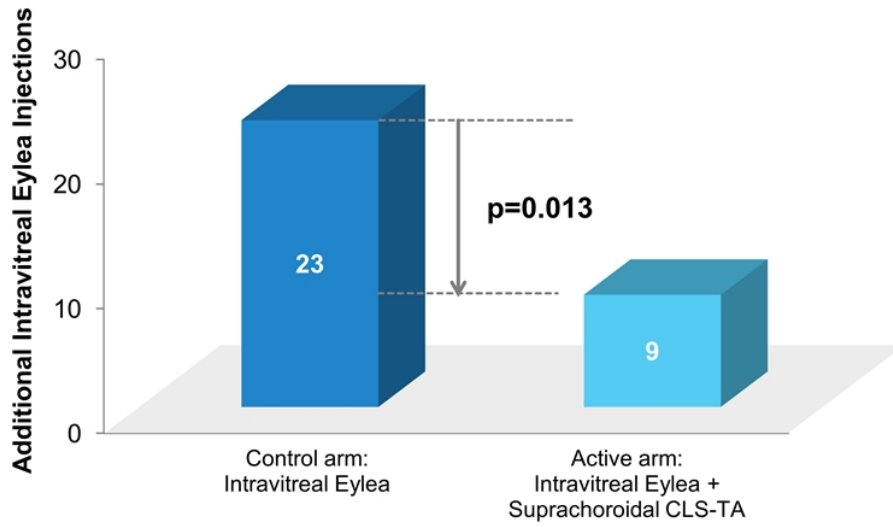
### The Problem

- 1) Compared to uveitis and DME, macular edema following RVO is more severe, as is the attendant vision loss / potential vision gain
- 2) Multiple inflammatory cytokines are involved in addition to VEGF being upregulated
- 3) Chronic, monthly anti-VEGF injections are necessary for many patients



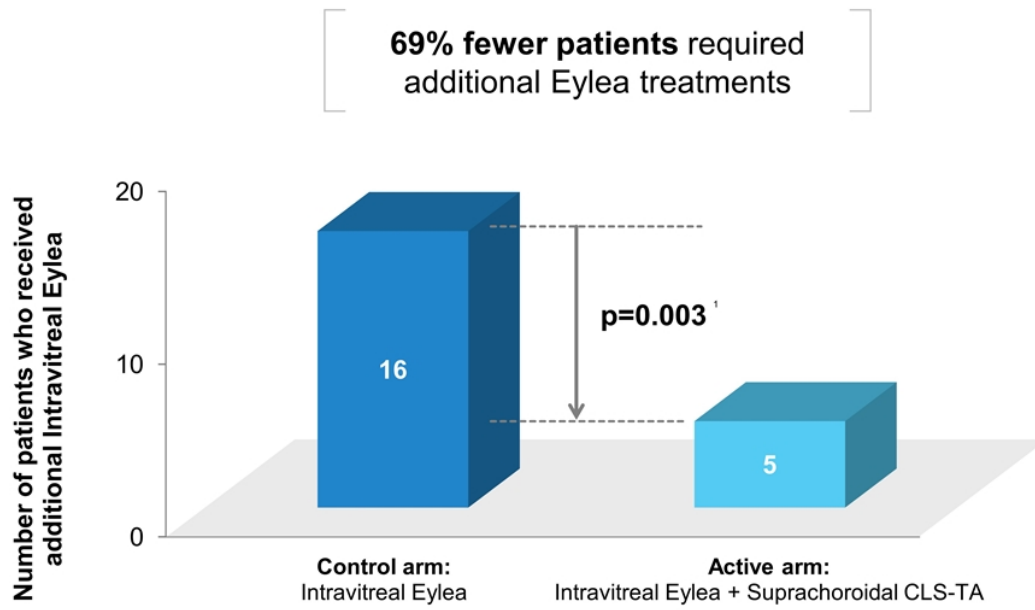
## Number of Additional Injections

**60% fewer additional intravitreal Eylea injections** in the suprachoroidal CLS-TA + intravitreal Eylea arm versus control over 3 months



**Intent-to-treat (ITT) population: N = 46 (23:23)**

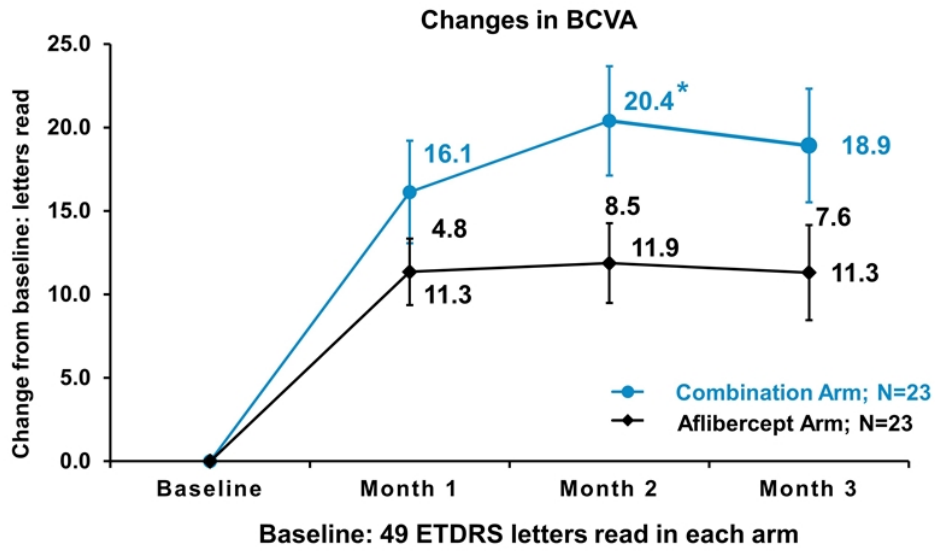
## Number of Patients Requiring Additional Treatment Reduced



Intent-to-treat (ITT) population: N = 46 (23:23)

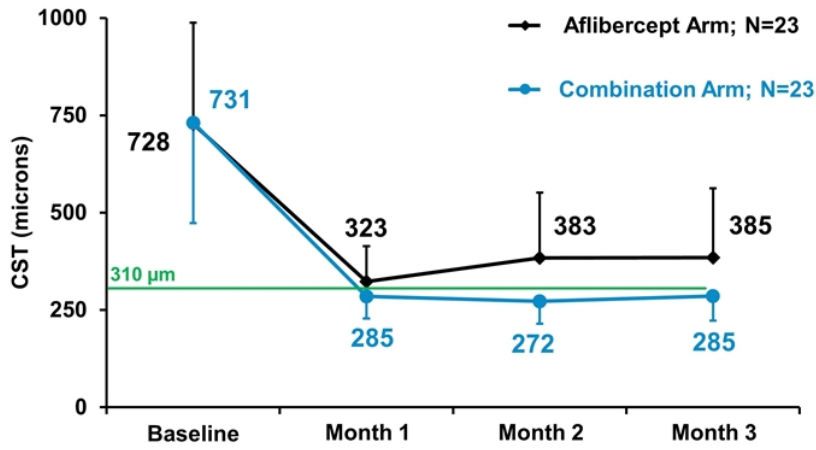
## Improved Visual Acuity

Suprachoroidal CLS-TA + intravitreal Eylea resulted in **improved visual acuity** at months 1, 2, 3 vs. intravitreal Eylea alone



## Retinal Thickness Reductions

Suprachoroidal CLS-TA + intravitreal Eylea resulted in **sustained retinal thickness reductions** at months 1, 2, 3 vs. intravitreal Eylea alone



**Baseline**  
728  $\mu\text{m}$  and 731  $\mu\text{m}$  in the Aflibercept and Combination arms

## Post-TANZANITE Evaluation

**74% of patients** who received combination therapy did not receive additional treatment through a minimum 9 months

**Monotherapy** (n=11)  
6 (55%) re-treated

**Combination** (n=20)  
3 (15%) including Month 3  
patients re-treated

■ Eylea arm: 17% (n=4/23)

■ Combination arm: 74% (n=17/23)

# SAPPHIRE

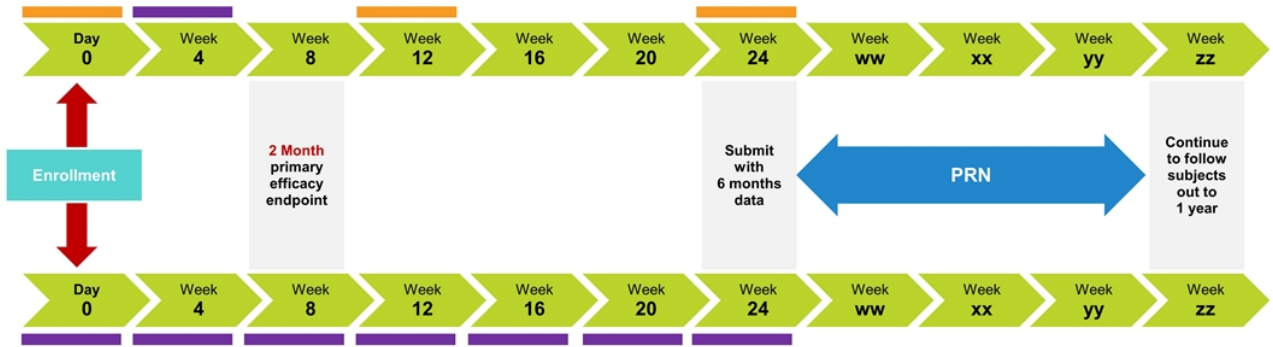
## Design for First Phase 3 RVO Clinical Trial

**Intravitreal Eylea**

**Suprachoroidal CLS-TA + Intravitreal Eylea**

### Combination arm

Suprachoroidal CLS-TA + Intravitreal Eylea; Q12Wk



### Control arm

Intravitreal Eylea; Q4Wk

- Two-arm, randomized, controlled, double-masked, multi-center trial at ~150 clinical sites
- 1:1 randomization of suprachoroidal CLS-TA + intravitreal Eylea vs. intravitreal Eylea alone; 230 per arm
- One year study with primary outcome at 2 months; superiority of best corrected visual acuity

# TOPAZ

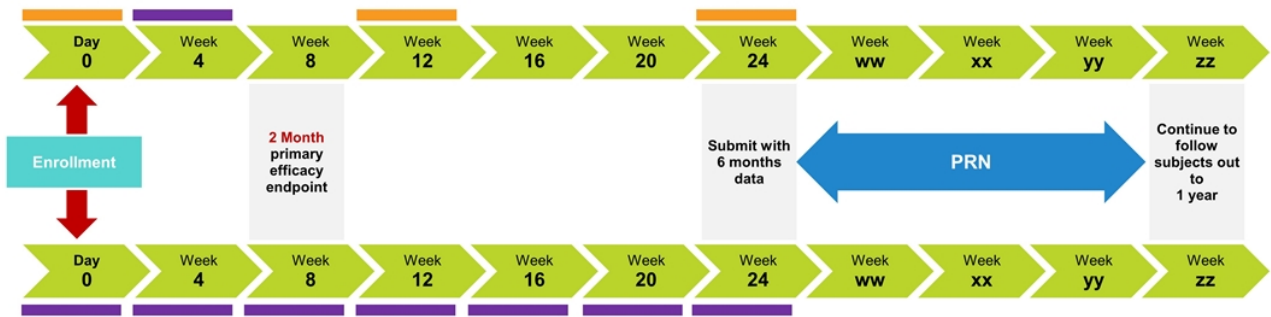
Second Phase 3 Clinical Trial in RVO Designed to Support a Potential anti-VEGF Class Label

**Intravitreal anti-VEGF**

**Suprachoroidal CLS-TA + Intravitreal anti-VEGF**

## Combination arm

Suprachoroidal CLS-TA + Intravitreal anti-VEGF<sup>1</sup>; Q12Wk



## Control arm

Intravitreal anti-VEGF<sup>1</sup>; Q4Wk

<sup>1</sup> Lucentis or Avastin

- Two-arm, randomized, controlled, double-masked, multi-center global trial; 460 patients
- 1:1 randomization of suprachoroidal CLS-TA + intravitreal anti-VEGF<sup>1</sup> vs. intravitreal anti-VEGF<sup>1</sup> alone
- Primary outcome at 2 months; superiority of best corrected visual acuity

If the primary endpoint is met in SAPPHIRE and TOPAZ, where CLS-TA has been used in combination with one of three anti-VEGF agents - Eylea, Lucentis and Avastin - **the objective will be to seek a class label in the US** where suprachoroidal CLS-TA can be used with any intravitreal anti-VEGF agent for the treatment of macular edema associated with RVO

A photograph of a male doctor in blue scrubs with a stethoscope around his neck, examining a female patient's eye. The patient is lying back, and the doctor is leaning over her, using a hand to stabilize her head. The scene is brightly lit, suggesting a clinical or hospital environment.

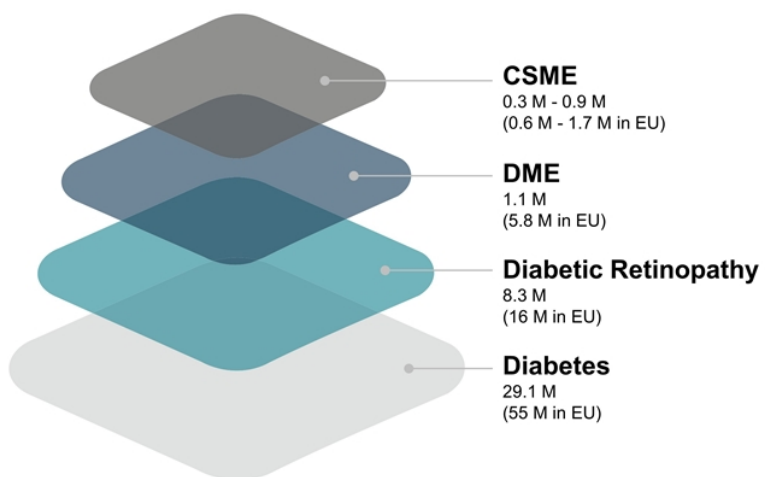
# DME

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Suprachoroidal CLS-TA Alone or in Combination  
with an Anti-VEGF Agent



# Steroids Given Frequently to Treat DME



## Current Treatments

- Anti-VEGF
- Steroids: Ozurdex, Iluvien or TA
- LASER

CSME = Clinically significantly macular edema  
DME = diabetic macular edema

National Center for Chronic Disease Preventions and Health Promotion: Division of Diabetes Translation. National Diabetes Statistical Report, 2014  
International Diabetes Federation. *IDF Diabetes Atlas: 5th Edition*. 2011; 2. International Diabetes Federation. *IDF Diabetes Atlas: 6th Edition*. 2013; 3. IDF Europe.  
[www.idf.org/sites/default/files/idf-europe/IDF%20Toolkit\\_Backgrounder\\_FINAL.pdf](http://www.idf.org/sites/default/files/idf-europe/IDF%20Toolkit_Backgrounder_FINAL.pdf)



## The Opportunity

In Treating DME

### Primary Need

- 1) Rapid reduction of edema to maximize vision gain early in course of treatment

### The Problem

- 1) Protocol T demonstrated that greater visual gains in the first three months result in improved long-term outcome in DME patients
- 2) DME is response to anti-VEGF injection is largely variable
- 3) Some patients do not respond well to anti-VEGF

# Background

## Anti-VEGF Therapy

Lucentis, Eylea are approved for treatment of patients with DME; Avastin is used off-label

- Protocol T indicates Eylea provides the greatest benefit in patients with vision 20/50 or worse
- 40% and 55% of subjects have continued macular edema at the 2 and 3 year visits, respectively, even after monthly intravitreal anti-VEGF injections
- Ongoing monthly intravitreal anti-VEGF therapy results in continued improvements

## Corticosteroid Therapy

Iluvien and Ozurdex are approved for treatment of patients with DME

- Results appear to be better in subjects with pseudo-phakic eyes vs. phakic eyes
- Adverse events, especially in phakic eyes, often appear to compromise visual gains seen within the first few months
- Implants can be used for longer periods of time



## HULK

Data Presented at AAO 2017

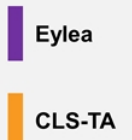
- First trial with CLS-TA in DME patients to obtain exploratory information
- Encouraging preliminary safety and efficacy data from both Tx naïve and previous Tx arms support continued clinical development

### Tx Naïve Arm

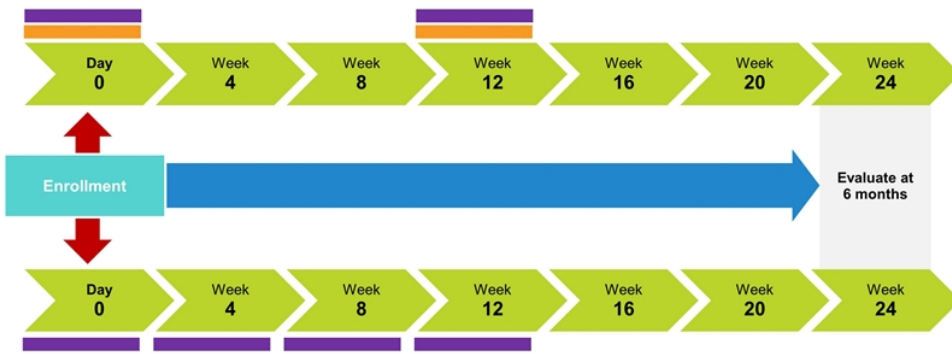
- Four (4) of 10 (40%) patients required NO additional treatment through the entire study
- One (1) patient (10%) required the first additional treatment at Month 4
- Three (3) patients (30%) required the first additional treatment at Month 3

# TYBEE

## Design for Phase 2 DME Clinical Trial



**Arm 1:** Intravitreal Eylea + Suprachoroidal CLS-TA (combo/active)



**Arm 2:** Intravitreal Eylea only (mono/control)

Any additional treatment based on *PRN* criteria will be intravitreal aflibercept

- Controlled, masked, randomized study of combination CLS-TA + intravitreal Eylea vs. intravitreal Eylea alone
- Evaluation at Month 6; treatment is based on PRN criteria from Month 3
- BCVA will be the primary outcome measure



# A WORLD WITHOUT BLINDNESS

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In Summary

## Opportunity is Well Protected

Patent No.	Significance	Expiration
U.S. 7,918,814	Provides exclusivity for the administration of any drug to the eye by inserting a microinjector into the sclera or corneal stroma of a patient's eye, and infusing the drug into the sclera or cornea	2029
U.S. 8,197,435	Provides exclusivity for administration of any drug to the suprachoroidal space, when the drug is administered through a microinjector that is inserted into the patient's sclera	2027
U.S. 8,636,713	Provides exclusivity for all hollow microinjector ocular delivery methods of anti-inflammatory drugs, so long as the anti-inflammatory drug is infused into the suprachoroidal space	2027
U.S. 8,808,225	Provides exclusivity for all hollow microinjector ocular delivery methods of drug, so long as the drug is infused into the suprachoroidal space	2027
U.S. 9,788,995	Provides exclusivity for all microinjector ocular delivery methods of drug at any ocular insertion site for controlled release	2027
U.S. 9,180,047	Provides exclusivity for methods for delivering a substance to a region of the eye (e.g., SCS, sclera, choroid) via loss of resistance injection technology	2034
U.S. 9,539,139	Provides exclusivity for apparatus with actuation rod configured to operate via loss of resistance injection technology	2034
U.S. 9,636,253	Provides exclusivity for methods for delivery a substance to a region of the eye (e.g., SCS, sclera, choroid) via an adjustable needle and loss of resistance injection technology	2034
U.S. 9,770,361	Provides exclusivity for apparatus with adjustable needle configured to operate via loss of resistance injection technology	2034
U.S. 9,572,800	Provides exclusivity for methods of treating a posterior ocular disorder in a human via non-surgical administration of axitinib to the SCS	2033
U.S. 9,636,332	Provides exclusivity for methods of treating a posterior ocular disorder in a human via non-surgical administration of triamcinolone to the SCS	2033
U.S. Appl. No. 15/673,073 (allowed)	Provides exclusivity for methods of treating macular edema (e.g., secondary to RVO) in a human via non-surgical administration of an anti-inflammatory drug to the SCS and non-surgical administration of a VEGF antagonist to the eye	2033
U.S. Appl. No. 15/714,441 (allowed)	Provides exclusivity for apparatus with an adjustable needle configured to operate via loss of resistance injection technology and a medicament container containing triamcinolone	2034
U.S. Appl. No. 15/383,582 (allowed)	Provides exclusivity for methods of delivering a substance to a target tissue using loss of resistance injection technology	2035

## Leadership

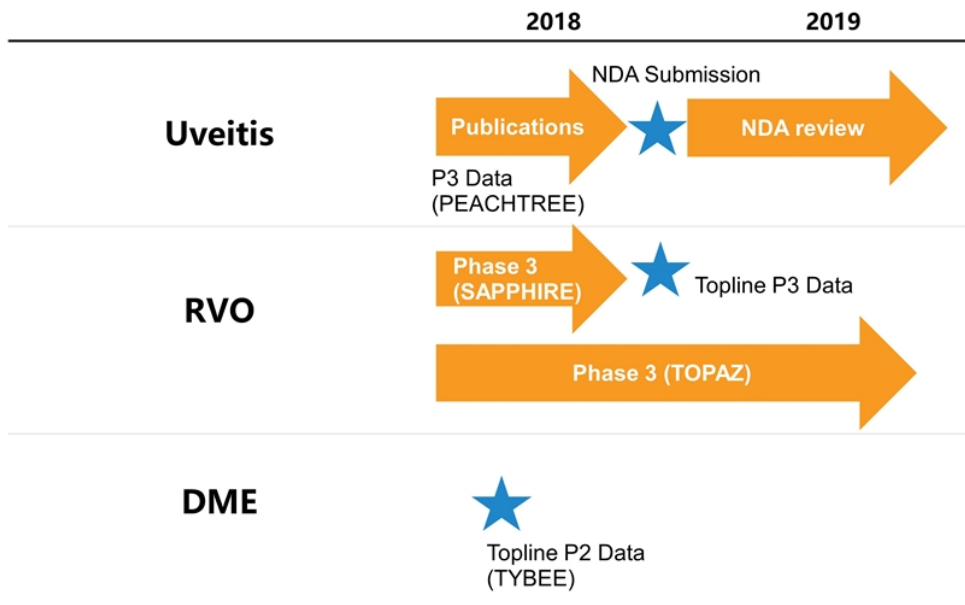
### Accomplished Team with Deep Ophthalmic Experience

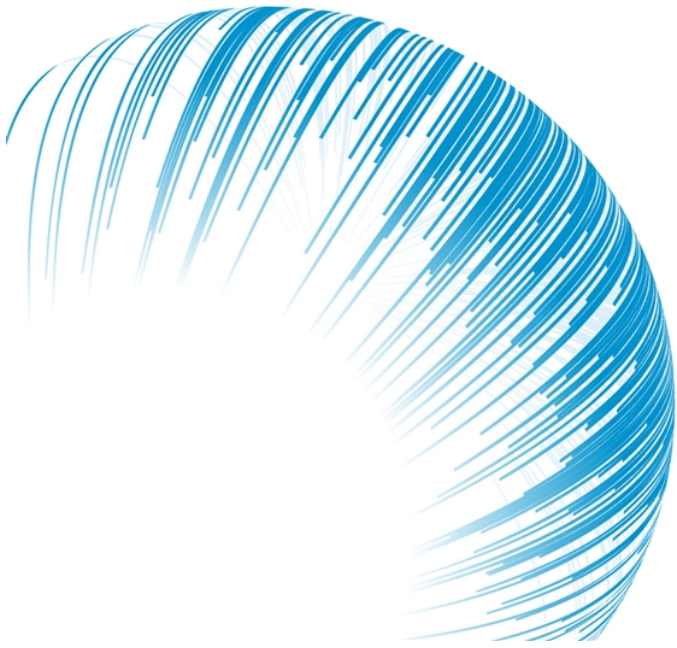
	Experience	Years	Ophthalmic Experience
<b>DANIEL WHITE</b> President, CEO and Director	GSK, Stiefel, CIBA Vision, Alimera	25	        
<b>CHARLES DEIGNAN</b> Chief Financial Officer	AtheroGenics, AAI Pharma, Schering-Plough	27	
<b>GLENN NORONHA, Ph.D.</b> Chief Scientific Officer	Alcon, Sucampo, TargeGen	17	
<b>BRION RAYMOND</b> Chief Commercial Officer	Genentech, Carl Zeiss Meditec, Xoma	14	
<b>RAFAEL ANDINO</b> VP, Engineering & Manufacturing	CR Bard, CIBA Vision, Dupont, GE, IBM	26	
<b>JENNIFER KISSNER, Ph.D.</b> VP, Clinical Development	Alcon, Acucela, Vanderbilt	12	
<b>RICK MCELHENY</b> VP, Business Development	Sanofi, MEDA, Vidara	18	



# Major Near-Term Anticipated Milestones

Provide Multiple Potential Value-Inflection Points





# THANK YOU!



*We see a world without blindness;  
relentlessly pursuing transformative,  
elegant, precise solutions to restore  
and preserve vision.*