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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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 8, 2017**

**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.)

**1220 Old Alpharetta Road, Suite 300  
Alpharetta, Georgia 30005**  
(Address of principal executive offices, including zip code)

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

**N/A**  
(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:

- 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 March 8, 2017, Daniel H. White, president and chief executive officer of Clearside Biomedical, Inc. (the "Company"), will present at the Cowen and Company 37<sup>th</sup> Annual Health Care Conference on, among other things, the Company's product candidate pipeline. A copy of this presentation 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**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
99.1	Presentation titled "Clearside Biomedical - Cowen & Company 37 <sup>th</sup> Annual Health Care Conference" dated March 8, 2017.

**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.

**CLEARSIDE BIOMEDICAL, INC.**

Date: March 8, 2017

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

## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Exhibit Description</b>
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**CLEARSIDE**  
**BIOMEDICAL**  
(NASDAQ:CLSD)

***Cowen & Company 37<sup>th</sup> Annual Health Care Conference***  
*March 8, 2017*

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

## Forward-Looking Statements

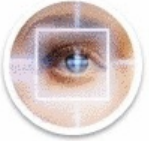
Matters discussed in this presentation may constitute forward-looking statements. The forward looking statements contained in this presentation reflect Clearside's views as of the date of this presentation about future events and are subject to risks, uncertainties, assumptions, and changes in circumstances 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 Registration Statement on Form S-1 (File No. 333-214836) declared effective by the Securities and Exchange Commission (SEC) on December 9, 2016, and Clearside's other Periodic and Current 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.

# Targeted Therapy for Retinal and Choroidal Disease



Exclusive and proprietary access to 17 square centimeters in the eye: The suprachoroidal space (SCS)



Positive Phase 2 clinical data in both retinal vascular disease (RVO) and ocular inflammatory disease (uveitis)



Phase 3 data in uveitis expected early 2018; Phase 3 in RVO initiated Q1 2017; Phase 1/2 data in DME expected H2 2017



Platform in retinal and choroidal disease: RVO, Uveitis, DME and Wet AMD



Proven, successful leadership team with deep ophthalmic expertise

# Retinal Diseases Represent Large Growth Markets with over \$7B in Global Sales in 2015

~5 M patients in the U.S. with target indications treated by approx. 1,700 retinal specialists

## Intravitreal injection



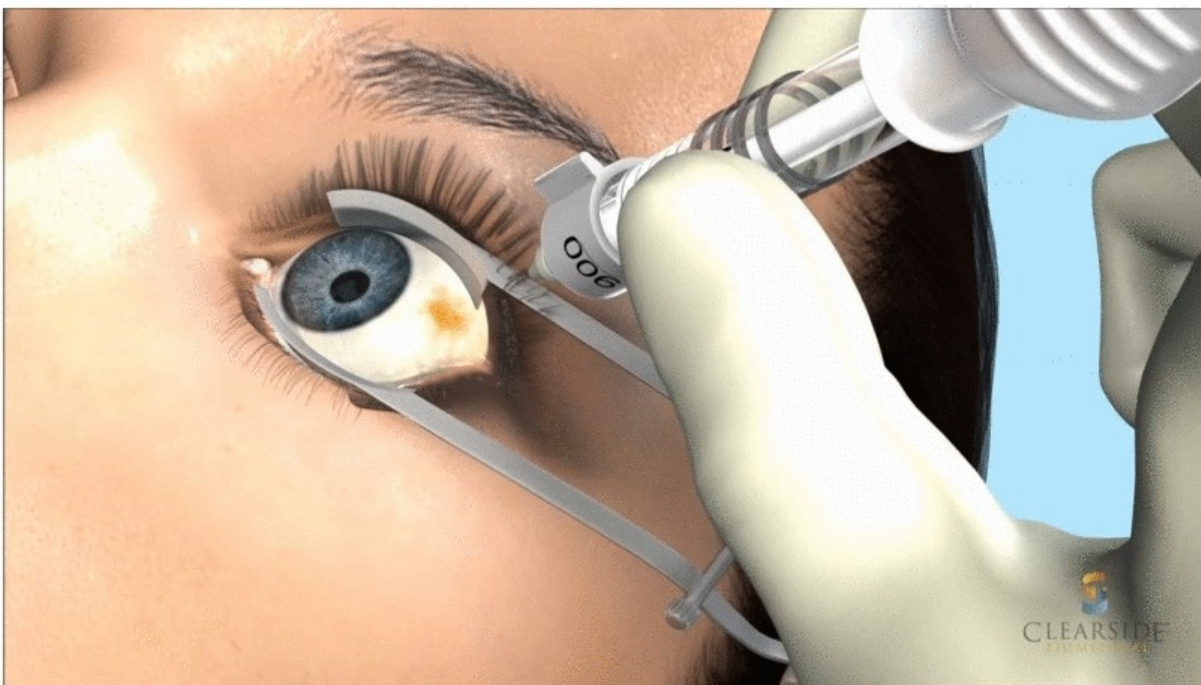
## Limitations include

- Certain drugs: steroids, multi-kinase inhibitors, gene therapy
- Lower concentrations of drug at diseased tissue
- Concentrations at unintended parts of the eye, which may lead to side effects

Drugs diffuse outward from the vitreous to all areas of the eye

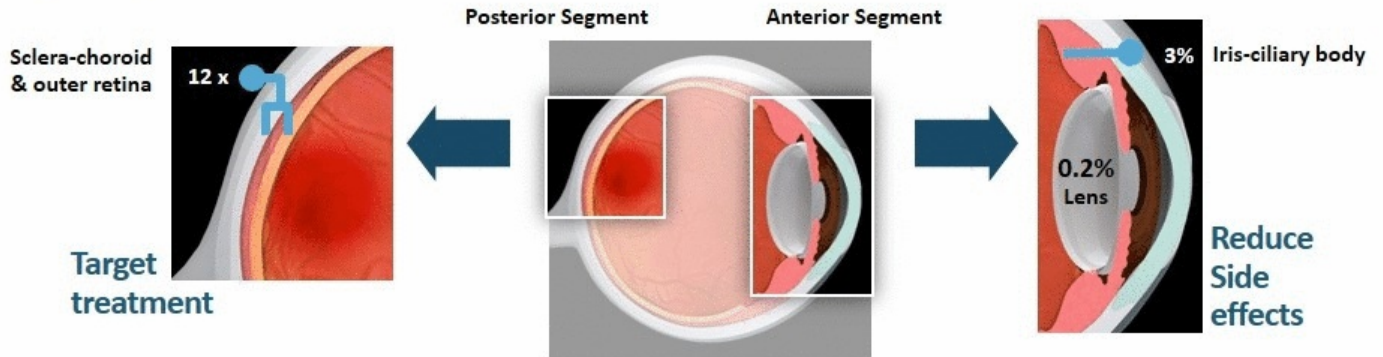


# Precise Access to the Back of the Eye Through the SCS

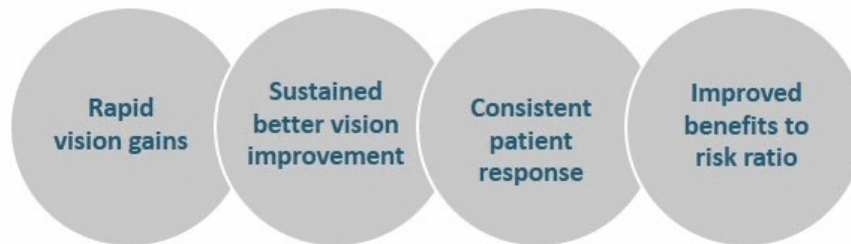


# Scientific Rationale for Novel Ocular Treatment: Suprachoroidal Injection

**When compared to intravitreal injections:  
High drug concentration at disease sites - Retains drug away from where side effects occur**



## Clearside Disease Program Objectives



Note: Percentages in the illustrations represent ratio of SCS distribution to intravitreal distribution of triamcinolone acetonide in specific tissues in an animal model.

# Focused Pipeline of SCS Treatments for Multiple Blinding Eye Diseases



	Indication	Study drug	U.S. Est. Prevalence	Current status
Clearside's Current Programs	Macular edema associated with non-infectious uveitis (Uveitis)	Suprachoroidal CLS-TA	~350K	Phase 3 data early 2018
	RVO (retinal vein occlusion)	Suprachoroidal CLS-TA with anti-VEGF (Intravitreal Eylea®)	~2.2M	Phase 3
	DME (diabetic macular edema)	Suprachoroidal CLS-TA alone or with anti-VEGF (Intravitreal Eylea)	~1.1M	Phase 1/2 data H2 2017
Clearside Collaborations	Retinal Vascular Disease	Proprietary compound(s)	~1.2M	Preclinical
	Orphan diseases	Gene therapy	<200K	Preclinical



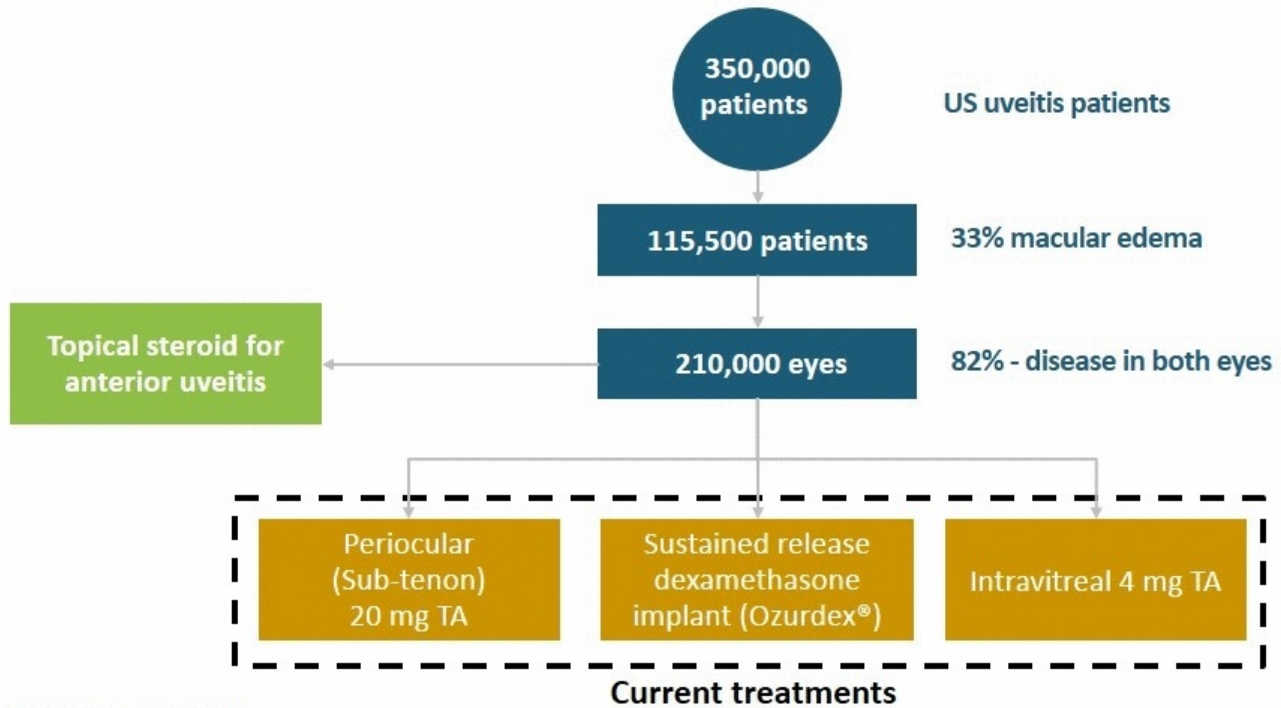
**TREATING INFLAMMATION**

# **MACULAR EDEMA ASSOCIATED WITH UVEITIS**

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# Suprachoroidal CLS-TA for Macular Edema Associated with Uveitis

Administration of corticosteroids is most common treatment for all complications of uveitis including macular edema



Note: TA = triamcinolone acetonide.

## **TREATING OCULAR INFLAMMATION** **UVEITIS PHASE 2: DOGWOOD TRIAL**

Single suprachoroidal injection of CLS-TA 4.0 mg or 0.8 mg

Randomized, controlled, masked, multi-center trial

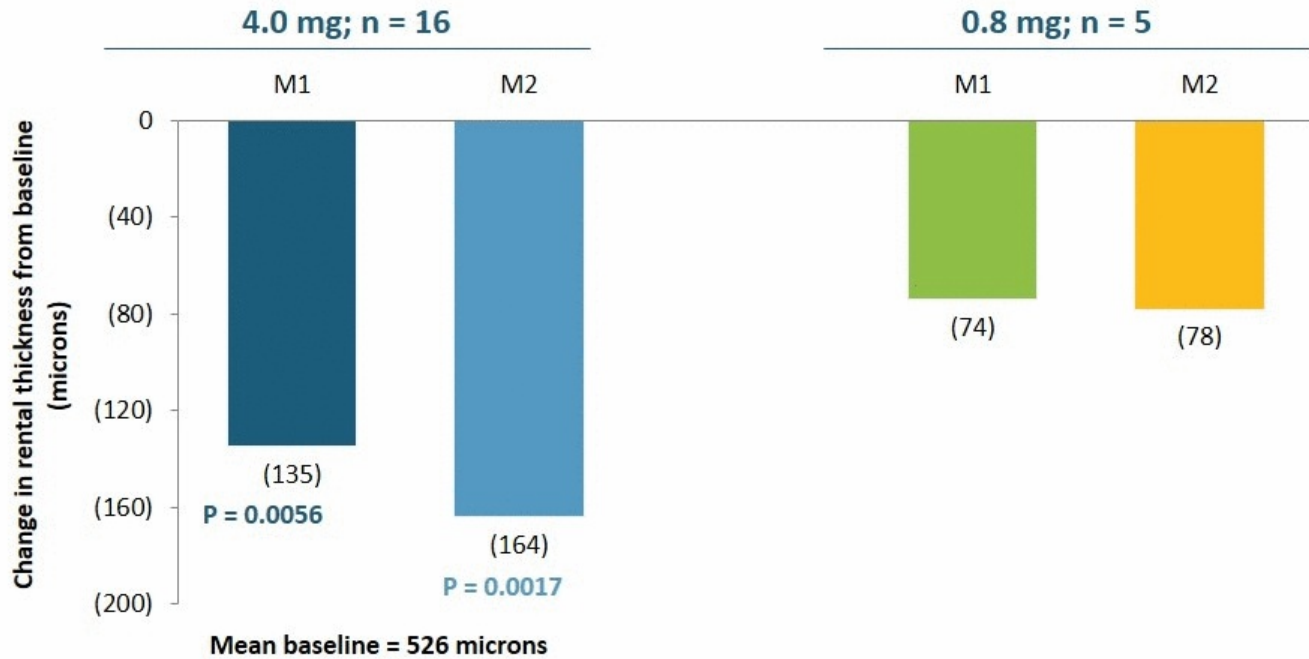
22 subjects with macular edema associated with non-infectious uveitis

Primary endpoint: reduction in retinal thickness at 2 months

# Primary Endpoint of Reducing Retinal Thickness was Successfully Achieved



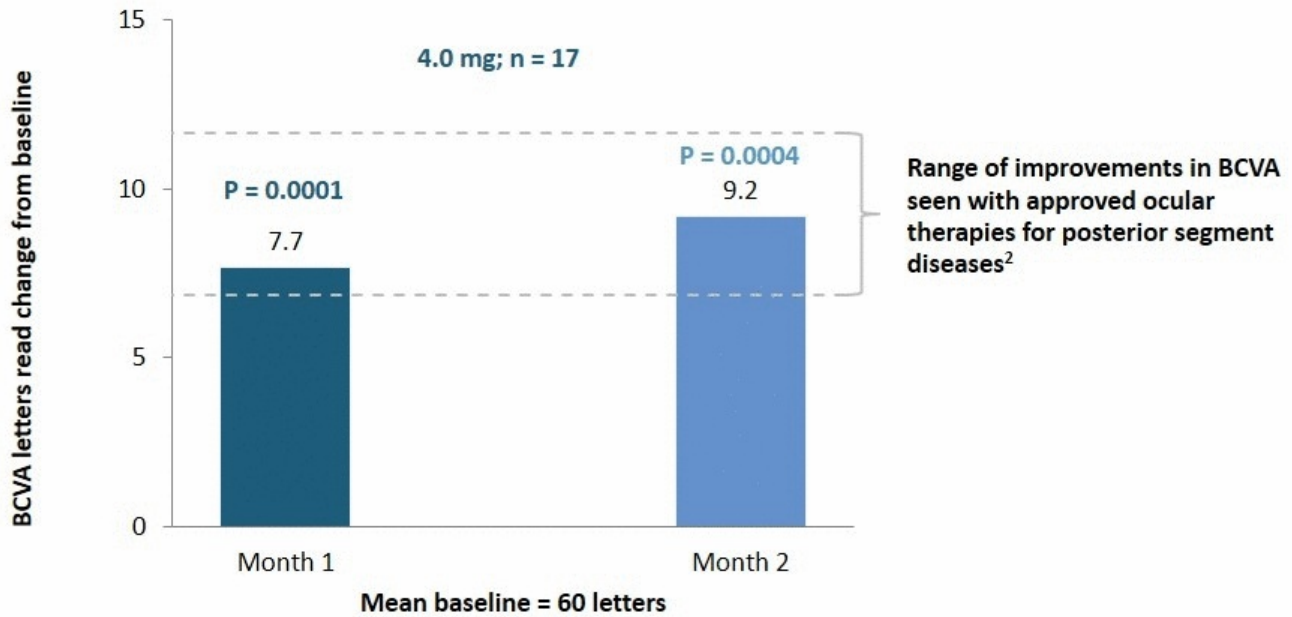
## Reduction in CST<sup>1</sup> From Baseline – ITT Population



<sup>1</sup> CST is the central retinal thickness measured using optical coherence tomography (OCT)  
M1 = Month 1; M2 = Month 2

# Secondary Endpoint of Improving Best Corrected Visual Acuity (BCVA) was Achieved

## Best Corrected Visual Acuity – ITT Population<sup>1</sup>



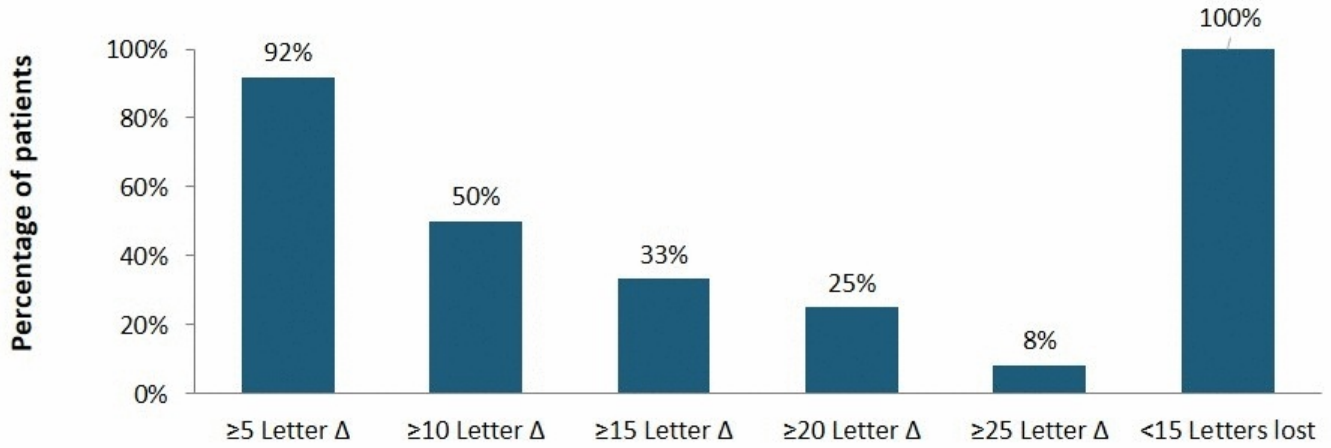
<sup>1</sup> N=17

<sup>2</sup> Eylea, Lucentis®, Ozurdex® package inserts



# BCVA and ME Improvements at Month 2

## Percent of Patients with BCVA Improvement



### Macular edema outcomes

### Percent

≥ 20% reduction in retinal thickness	69
Retinal thickness ≤ 310 microns	56

# Anterior Chamber (AC) Cells, AC Flare and Vitreous Haze – Reduced From Baseline to Month 2 (4.0 mg group; ITT)



## Anterior cell grade



## Anterior flare grade



## Vitreous haze grade



AC cells, AC flare and vitreous haze are signs of inflammation of the eye

- Each of these signs shows favorable changes from baseline
- The average in each case shows trend toward improvement; a majority of individual patients either improve or maintain low levels

## Efficacy Summary

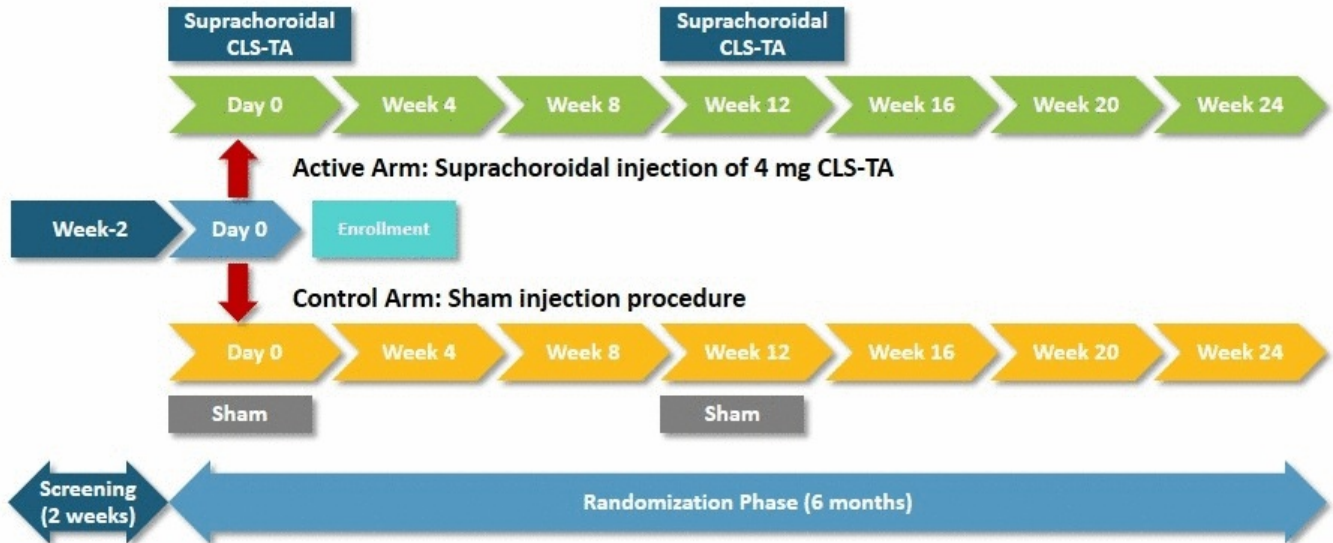
- Improvements in BCVA observed in patients treated in both trials
- Statistically significant reduction in retinal thickness in patients treated in the Phase 2 trial
- Duration of improvement in visual acuity of up to 6 months in Phase 1/2 trial

## Safety Summary

- No serious adverse events related to treatment
- No adverse events leading to discontinuation
- No steroid-related increase in IOP
- Only adverse events related to treatment in more than 5% of dosed patients were cystoid macular edema, blurred or decreased vision, and eye pain

# Suprachoroidal CLS-TA Phase 3 Trial is in Progress with Data Expected by Early 2018

- Two-arm, randomized, controlled, double-masked, multi-center trial at ~50 clinical sites
- 3:2 randomization of suprachoroidal CLS-TA vs. sham injection; 150 patients total (90:60)
- Primary at 6 months; superiority of best corrected visual acuity outcome from treatment





TREATING RETINAL VASCULAR DISEASE

# RETINAL VEIN OCCLUSION (RVO)

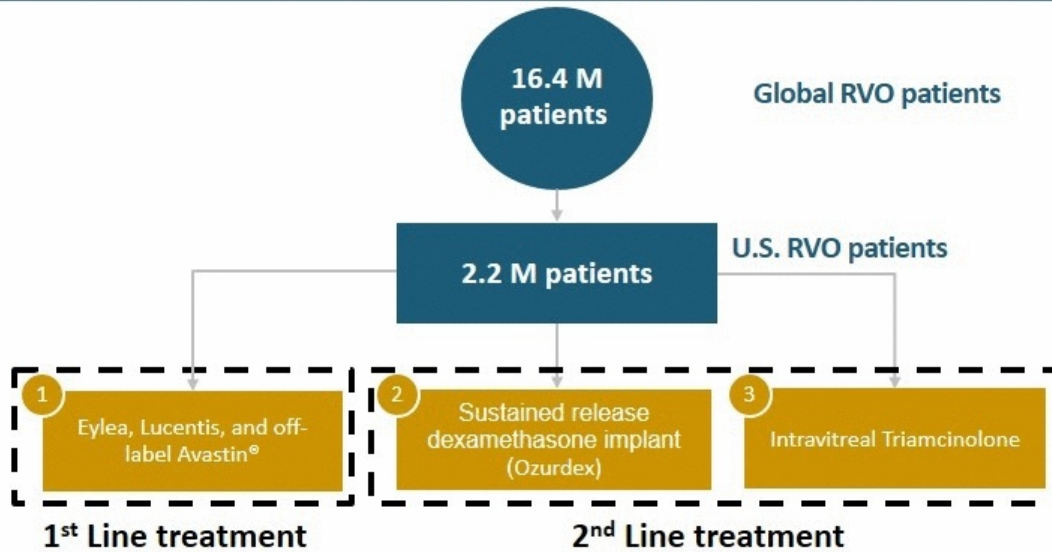
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# Suprachoroidal CLS-TA with Intravitreal Eylea for Macular Edema Associated with RVO

RVO  
(retinal vein occlusion)

Suprachoroidal CLS-TA with  
intravitreal anti-VEGF  
(Intravitreal Eylea)

Phase 2  
Data available



**Objective:** Improve the current treatment by potentially improving and sustaining visual outcomes over treatment with anti-VEGF alone, and reducing the treatment frequency

## TREATING RVO PHASE 2: TANZANITE TRIAL

Single suprachoroidal injection of CLS-TA a plus intravitreal Eylea versus intravitreal Eylea only in treatment naïve RVO patients

1:1 controlled, randomized, masked, multi-center trial

46 subjects with macular edema associated with Retinal Vein Occlusion

Treatment naïve patients randomized to treatment first day and evaluated monthly

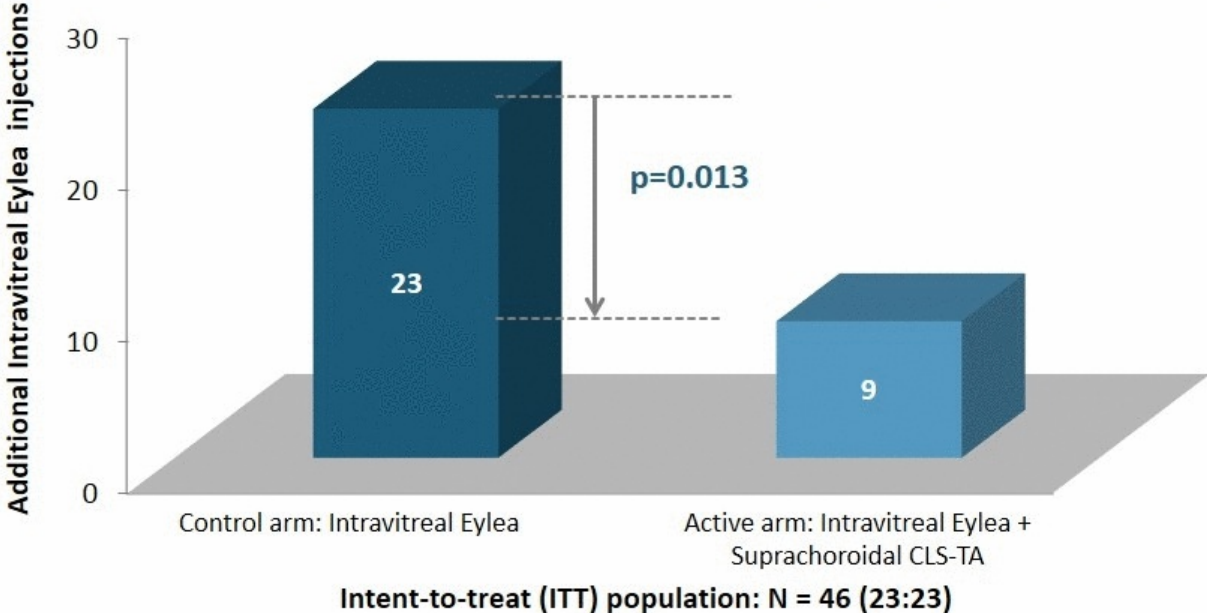
Objective: reduce number of intravitreal Eylea treatments while maintaining visual acuity improvements

Primary endpoint: the number of times patients met the criteria for additional intravitreal Eylea treatments over the three-month trial duration

**60% Fewer Additional Intravitreal Eylea Injections in the Suprachoroidal CLS-TA + Intravitreal Eylea Arm Versus Control Over 3 Months**

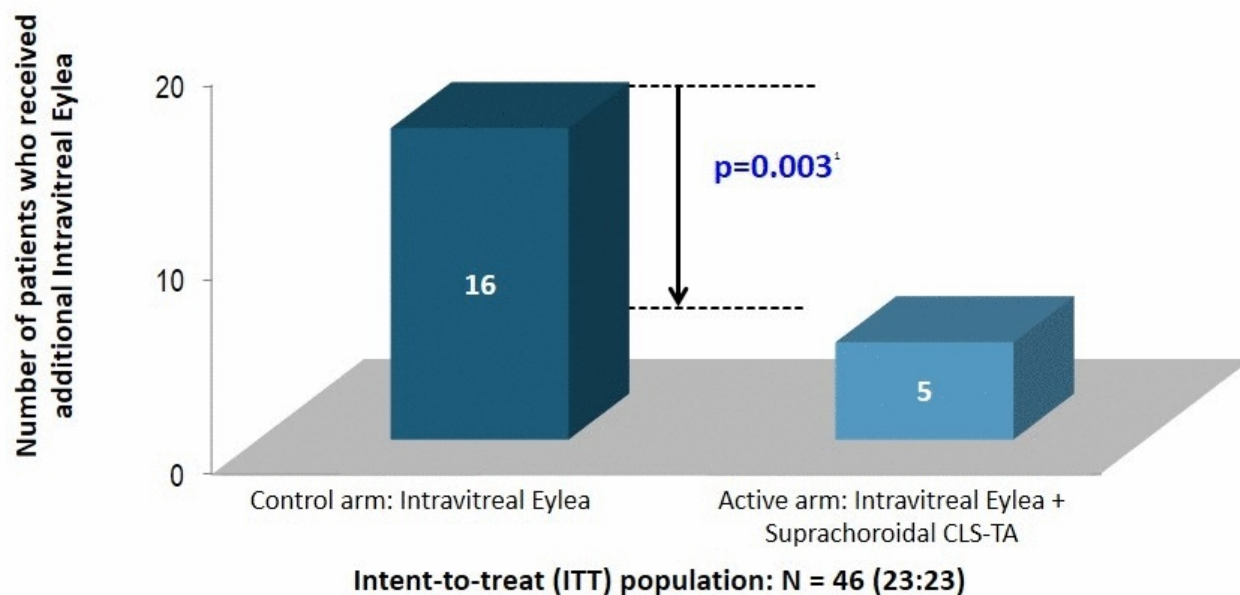


**Number of Additional Intravitreal Eylea Injections**





## Comparison of the Two Arms on a Patient Basis



### TAKE HOME MESSAGE:

There were **11 fewer patients** in the Active arm compared to the Control arm, representing a **69% reduction** in the number of patients requiring additional intravitreal Eylea

<sup>1</sup>Based on post-hoc analysis

# Suprachoroidal CLS-TA + Intravitreal Eylea resulted in More Improved Visual Acuity at Months 1, 2, 3 vs. Intravitreal Eylea Alone



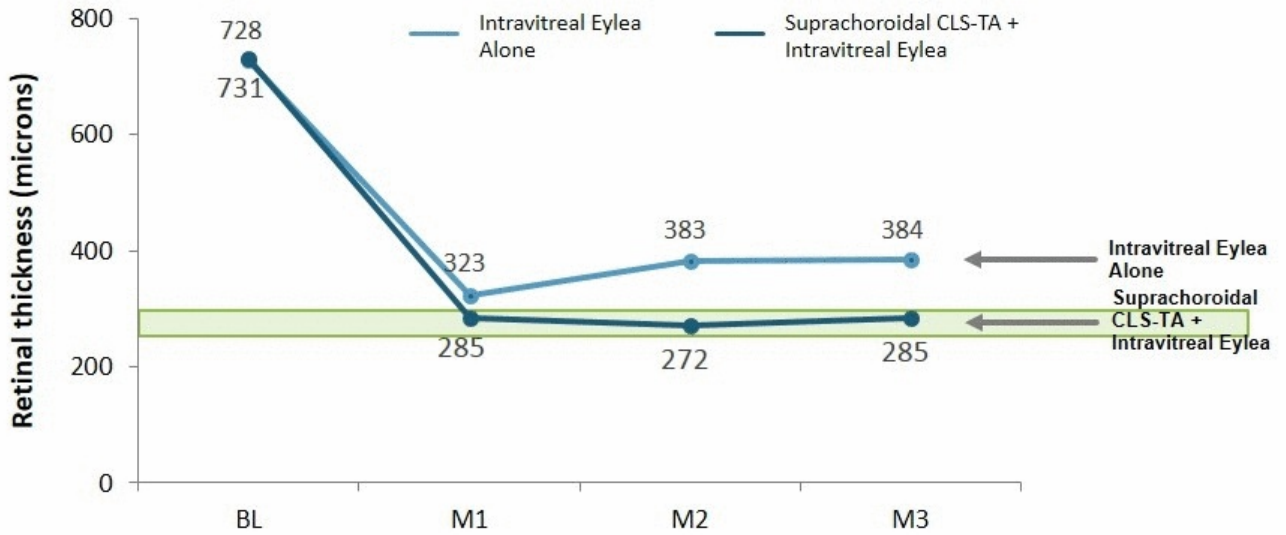
## Change in Best Corrected Visual Acuity



ITT population N = 46 (23:23)

M1 = month 1; M2 = month 2; M3 = month 3

# Suprachoroidal CLS-TA + Intravitreal Eylea Resulted in Sustained Retinal Thickness Reductions at Months 1, 2, 3 vs. Intravitreal Eylea Alone



### **Patients treated with Suprachoroidal CLS-TA and Intravitreal Eylea vs. Intravitreal Eylea alone**

- Greater improvement of vision in comparison with intravitreal Eylea alone in this phase 2 trial
- Sustained clinical benefit over the 3-month trial period
- Significantly fewer additional intravitreal Eylea treatments

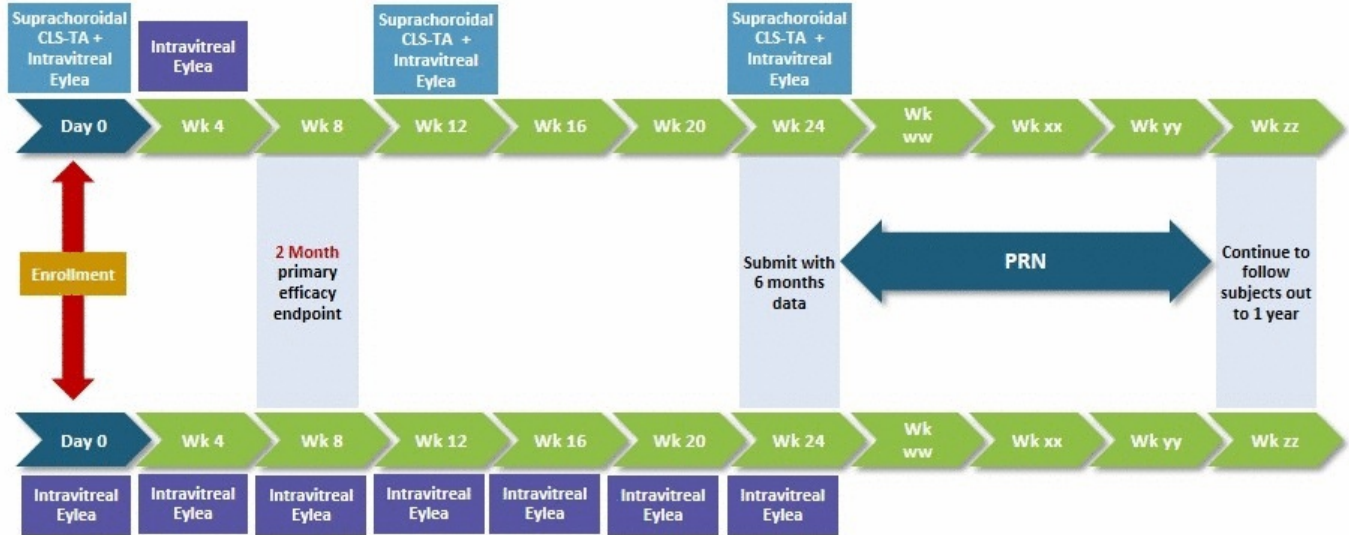
### **Safety Summary**

- No serious adverse events
- No adverse events leading to discontinuation
- Only adverse events observed in more than 5% of patients in the suprachoroidal CLS-TA + intravitreal Eylea arm were conjunctival hyperemia, eye pain, ocular hypertension and increased IOP

# Design for Phase 3 Clinical Trials

- 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; 230 per arm
- Primary outcome at 2 months; superiority of best corrected visual acuity

**Combination arm:** suprachoroidal CLS-TA + Intravitreal Eylea; Q12Wk



**Control arm:** Intravitreal Eylea; Q4Wk



**ANOTHER PROMISING MARKET IN RETINAL VASCULAR DISEASE**

# **DIABETIC MACULAR EDEMA (DME)**

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# Suprachoroidal CLS-TA Alone or in Combination with an Anti VEGF agent for DME

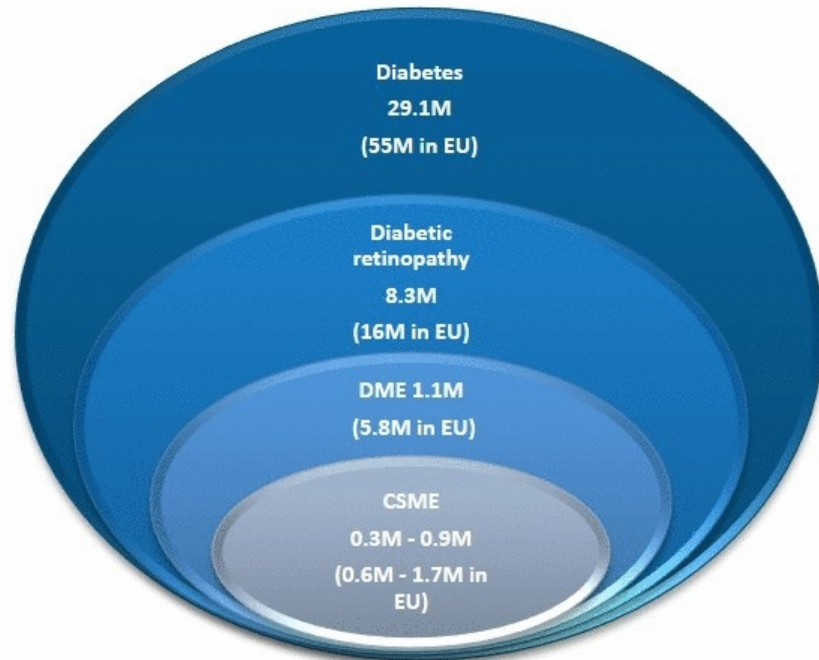
## Steroids are given frequently to treat DME

### 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)

## Anti-VEGF Therapy

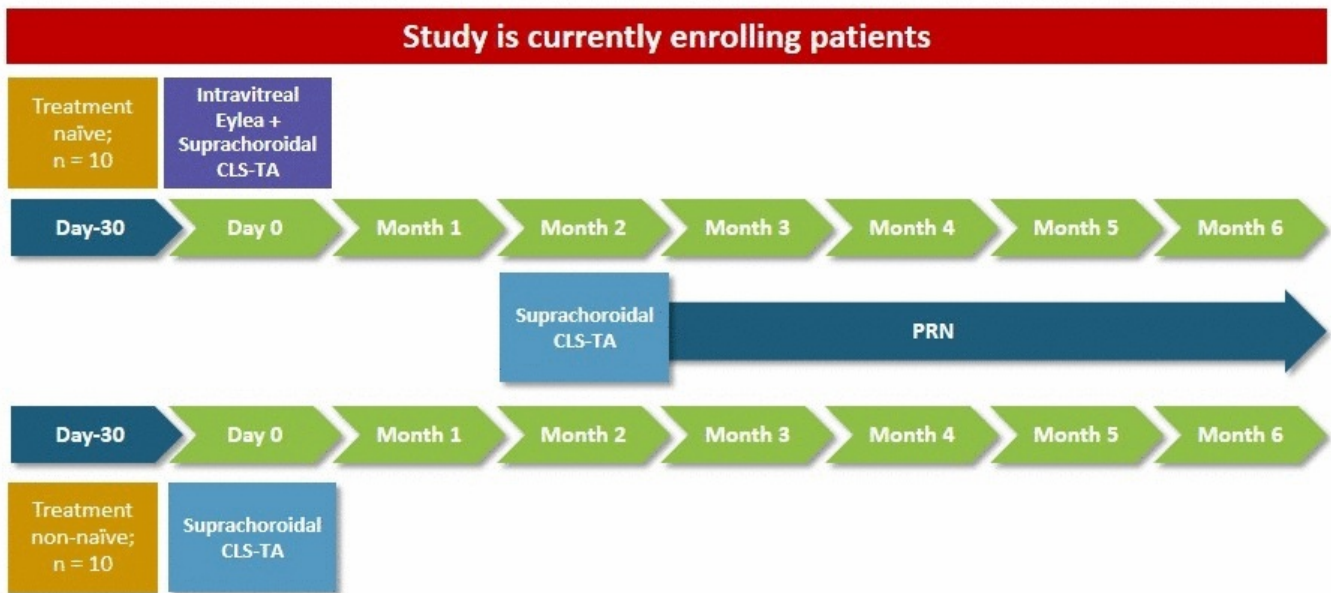
- Lucentis, Eylea and off-label Avastin have a good track record
  - Protocol T indicates Eylea, compared to the other two therapies, provides the greatest benefit in initial 12 months
  - A proportion of subjects have persistent disease with 40% and 55% having continued macular edema at the 2 and 3 year visits, even after monthly intravitreal anti-VEGF injections
  - Ongoing monthly intravitreal anti-VEGF therapy results in continued improvements

## Corticosteroid Therapy

- Fluocinolone and dexamethasone appear to have a reasonable track record for providing efficacy in DME subjects
  - 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



# DME Phase 1/2 study design



- Single suprachoroidal injection of CLS-TA alone and in combination with intravitreal Eylea
- 10 treatment naïve subjects and 10 subjects treatment non-naïve
- Safety and efficacy information will be collected through the entire time period

# Planned Phase 2 DME Trial

## Group 1: Intravitreal Eylea + suprachoroidal CLS-TA (combo/experimental)



## Group 2: Intravitreal Eylea only (mono/control)

- Controlled, masked, randomized study of combination CLS-TA + Eylea vs. monotherapy Eylea
- Evaluations at Month 3, Month 6 and Month 9; study is PRN from Month 3
- BCVA will be the primary outcome measure



**IN SUMMARY**

# **A WORLD WITHOUT BLINDNESS**

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# Proprietary Access to 17 Square Centimeters of the Human Eye



Patent No.	Significance	Expiration
U.S. 7,918,814	Provides <b>exclusivity for the administration of any drug to the eye by inserting a microinjector into the sclera</b> or corneal stroma of a patient's eye, and infusing the drug into the sclera or cornea	2029
U.S. 8,197,435	Provides <b>exclusivity for administration of any drug to the suprachoroidal space, when the drug is administered through a microinjector</b> that is inserted into the patient's sclera	2027
U.S. 8,636,713	Provides <b>exclusivity for all hollow microinjector ocular delivery methods of anti-inflammatory drugs</b> , so long as the anti-inflammatory drug is infused into the suprachoroidal space	2027
U.S. 8,808,225	Provides <b>exclusivity for all hollow microinjector ocular delivery methods of drug</b> , so long as the drug is infused into the suprachoroidal space	2027
U.S. 9,180,047	Provides exclusivity for <b>methods for delivering a substance</b> to a region of the eye ( <b>e.g., SCS, sclera, choroid</b> ) via <b>loss of resistance</b> injection technology	2034
(U.S. Application Allowed)	Provides exclusivity for methods of treating a posterior ocular disorder in a human via non-surgical administration of axitinib to the suprachoroidal space	2033
(U.S. Application Allowed)	Provides exclusivity for methods of treating a posterior ocular disorder in a human via non-surgical administration of triamcinolone to the suprachoroidal space	2033

## Accomplished Team with Deep Ophthalmic Expertise

	Experience	Years
<b>DANIEL WHITE</b> President, CEO and Director	GSK, Stiefel, CIBA Vision, Alimera	25
<b>CHARLES DEIGNAN</b> Chief Financial Officer	AtheroGenics, AAIPharma, Schering-Plough	27
<b>GLENN NORONHA, Ph.D.</b> Chief Scientific Officer	Alcon, Sucampo, TargeGen	17
<b>RICHARD BECKMAN</b> Chief Medical Officer	Ophthotech, Neurotech, Alcon, Lux, Becton-Dickinson	32
<b>RAFAEL ANDINO</b> VP, Engineering and 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

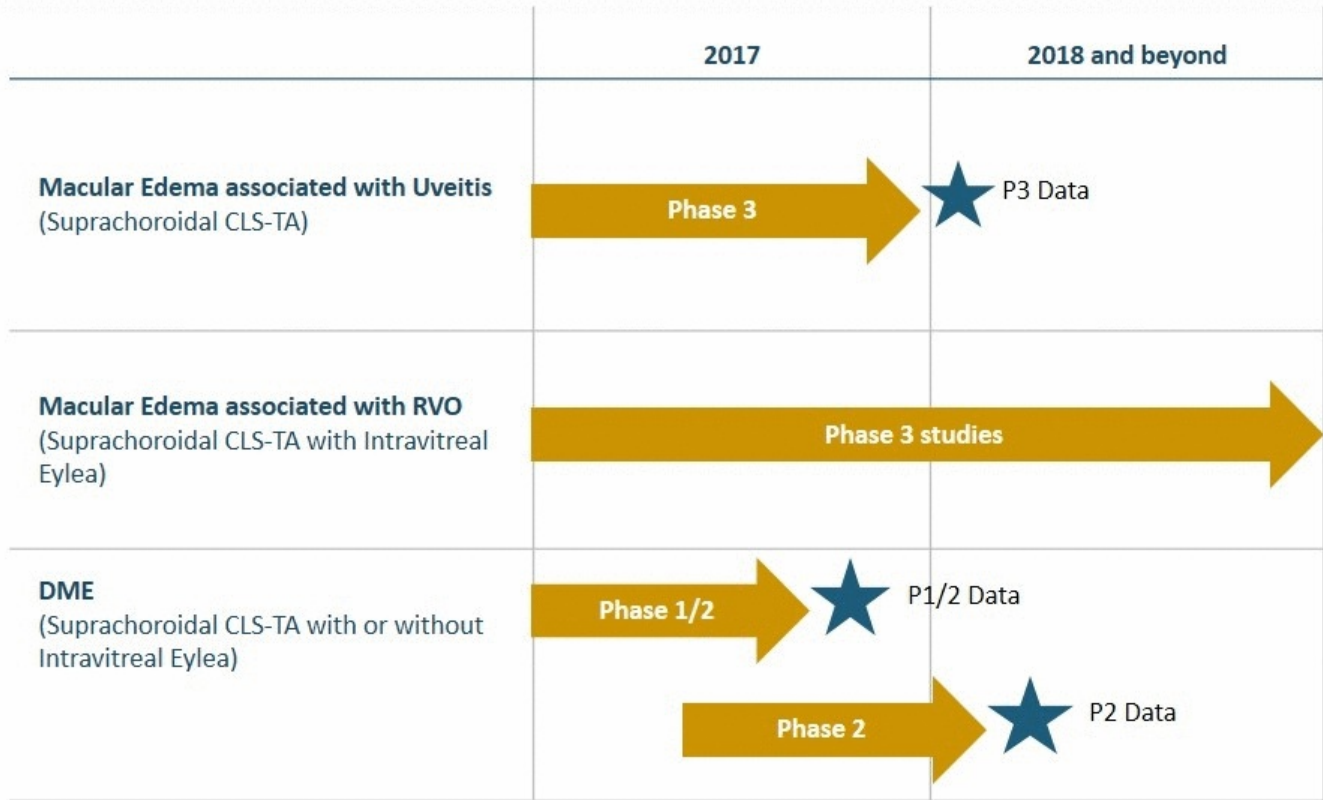
### Ophthalmic Experience







# Pipeline has Meaningful Near-Term Milestones





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