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): June 20, 2018

Clearside Biomedical, Inc.

(Exact name of registrant as specified in its charter)

<u>001-37783</u>

<u>Delaware</u> (State or other jurisdiction of incorporation)

(Commission File Number)

45-2437375 (IRS Employer Identification No.)

900 North Point Parkway, Suite 200 Alpharetta, GA 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))

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 account standards provided pursuant to Section 13(a) of the Exchange Act. 🖂

Item 7.01 Regulation FD Disclosure.

On June 21, 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 presentation that will be used in the meetings contains new topline clinical data from the Company's TYBEE Phase 2 clinical trial evaluating suprachoroidal CLS-TA used with intravitreally administered EYLEA® (aflibercept) in patients with diabetic macular edema.

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

Exhibit No.	Description
99.1	Company Presentation.

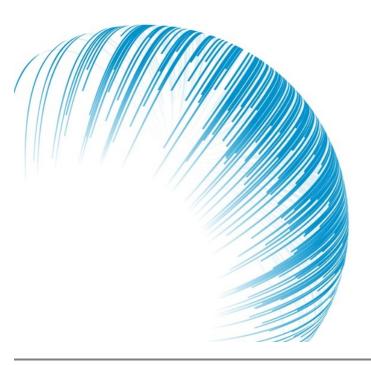
SIGNATURES

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: June 20, 2018

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





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'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 product candidates; to clearside's planned of Clearside's product candidates; Clearside's commercialize its product candidates; Clearside's product candidates; the timing of and Clearside's product candidates; Clearside's product candidates; the extent of clinical trials potentially required for Clearside's product candidates; 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

Dedicated to developing treatments that **restore and preserve vision** for people with serious eye disease

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

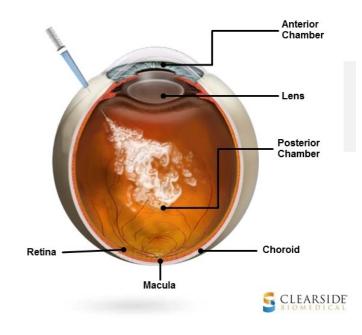
~5 M patients in the U.S. with target indications treated by approx. 1,900 uveitis and retinal specialists

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

4



Exclusive and Proprietary Access to the Back of the Eye Through the Suprachoroidal Space ("SCS")

VS

Intravitreal & Periocular

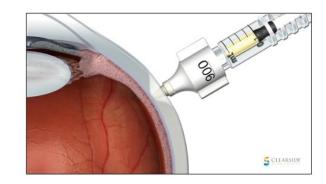


- 50 µL bolus at injection site
- Drug diffuses to all areas of the eye including the anterior chamber and lens



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

Suprachoroidal

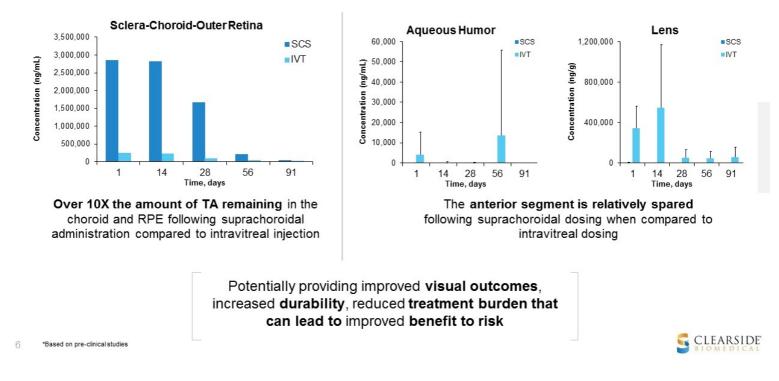


- Fluid flows instantaneously and posteriorly
- · Designed consistent suprachoroidal injection procedure
- · Fluid with drug is absorbed into the choroid, RPE and retina



5

Suprachoroidal CLS-TA Designed to Improve Ocular Distribution of Triamcinolone Acetonide (TA)

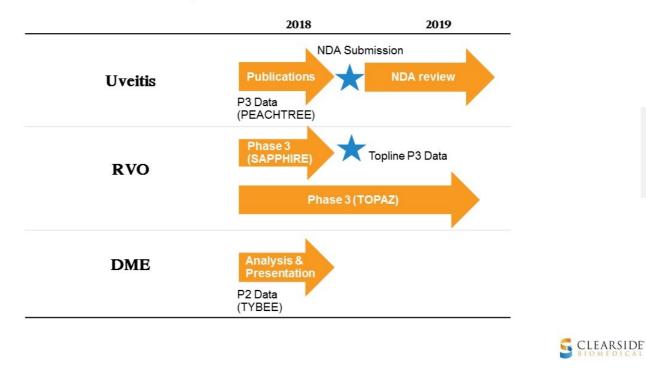


Focused Pipeline of SCS Treatments For Multiple Blinding Eye Diseases

INDICATION STUDY DRUG		CURRENT STATUS				
Uveitis (macular edema associated with non-infectious uveitis)	Suprachoroidal CLS-TA (corticosteroid triamcinolone acetonide)					
with non-infectious uveits)	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

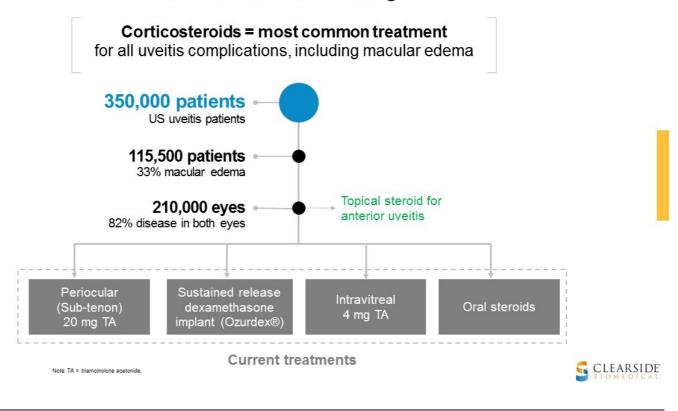


8

UVEITIS

One of the World's Leading Causes of Blindness

Current Treatment Paradigm





The Opportunity

In Treating Macular Edema with Uveitis

Primary Need

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

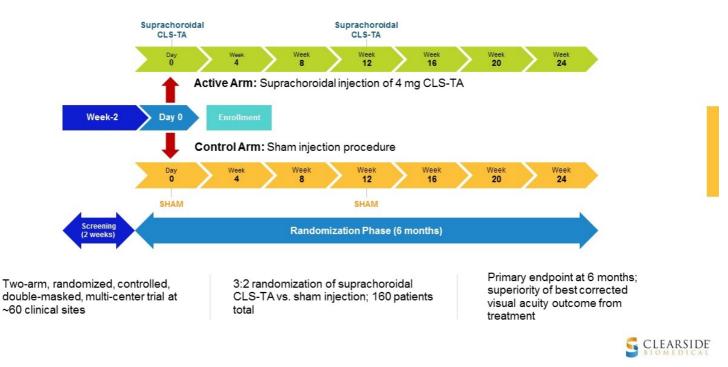
The Problem

- 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



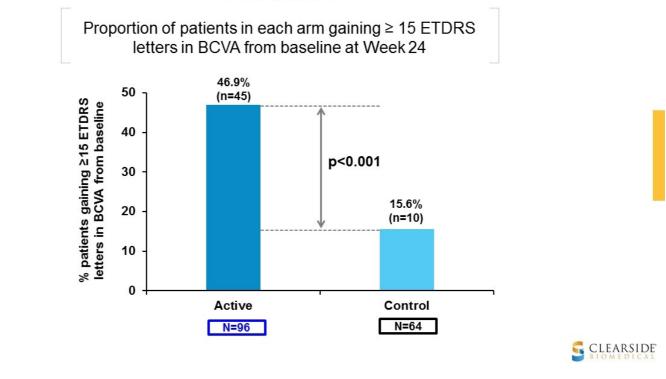
PEACHTREE

Design for Pivotal Phase 3 Clinical Trial



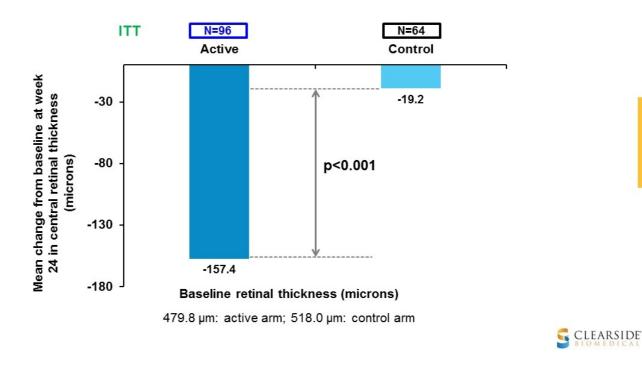
Primary Endpoint

ETDRS BCVA

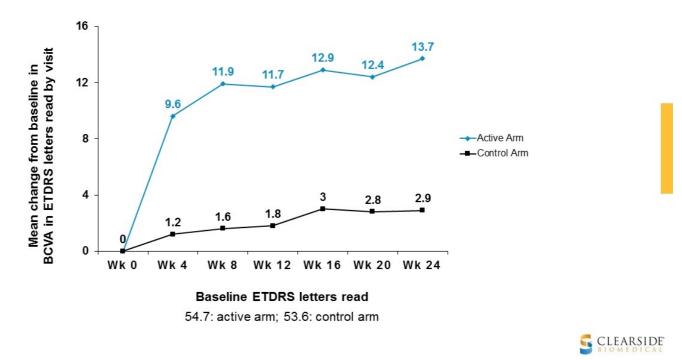


Secondary Endpoint

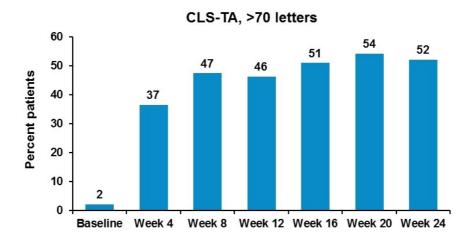
Mean Change from Baseline in CRT at Week 24 in Microns



Secondary Endpoint Mean Change in BCVA in ETDRS Letters by Visit



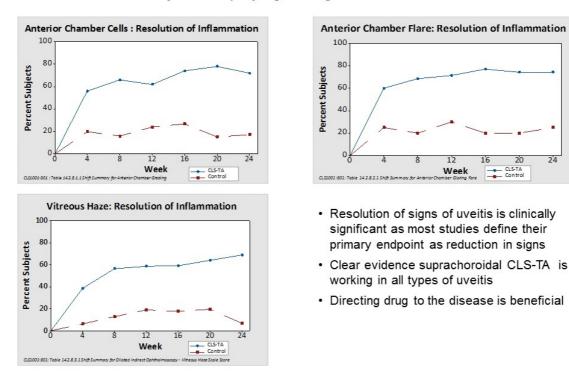
% Subjects Reading ≥70 ETDRS Letters (20/40)



- Starting at week 8, approximately 50% of the suprachoroidal CLS-TA patients could read 70 or more ETDRS letters
- · This improvement was sustained through the 24 weeks of the trial

CLEARSIDE

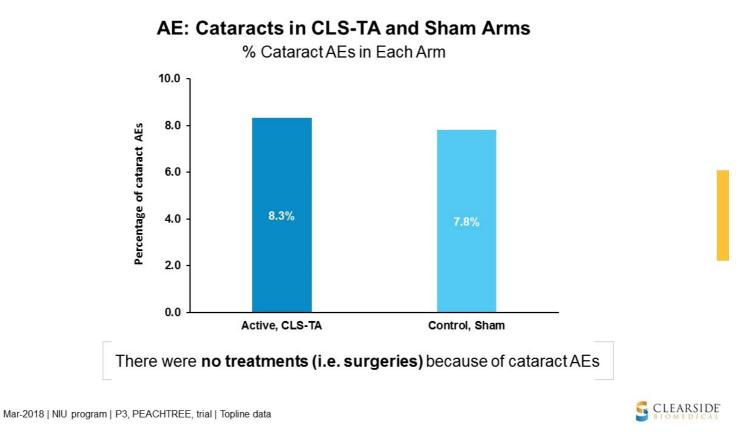
Resolution to Zero % Subjects Displaying Change to Zero at Week 24

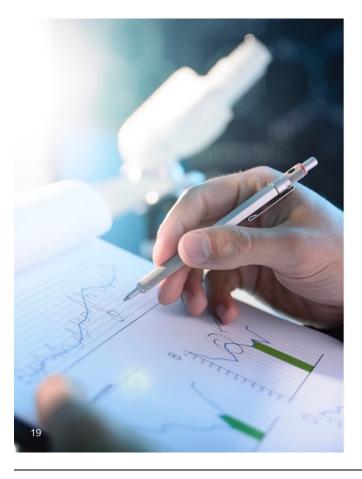


16

20

CLS-TA





PEACHTREE

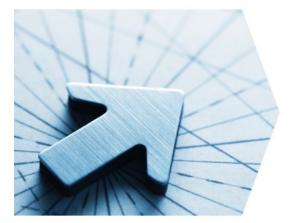
Safety Summary

- 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
- 85-90% of subjects in the CLS-TA arm were not rescued, while a majority of subjects in the control arm were rescued, before the end of the study



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

CLEARSIDE

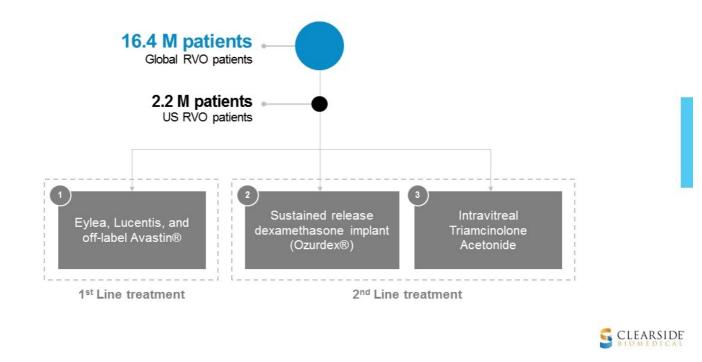
Currently expect to submit NDA to FDA in Q4 2018

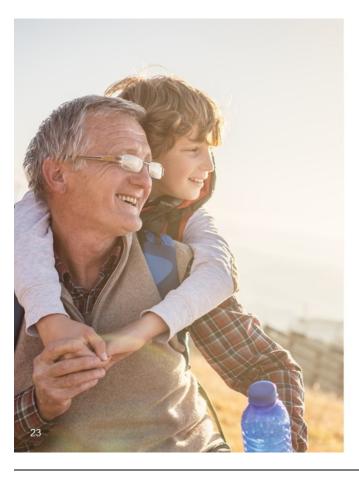


RVO

New Approach with CLS-TA + anti-VEGF

Current Treatment Paradigm





The Opportunity

In Treating RVO

Primary Needs

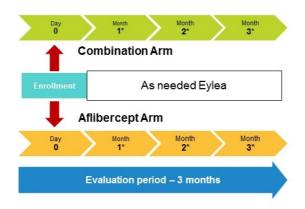
 More rapid and fuller resolution of macular edema to allow patients to recover as much vision as soon as possible

The Problem

- 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



TANZANITE Design for Phase 2 TANZANITE Trial



Controlled, masked, randomized (1:1) study

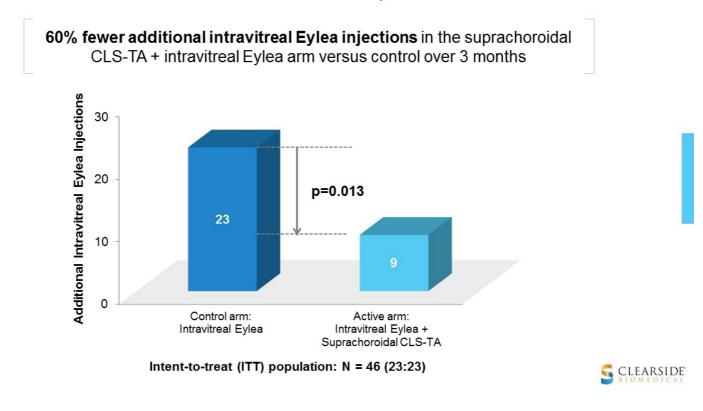
- Patients RVO; Treatment naïve
 - BCVA worse than 70 letters read; macular edema >310 μm on SD-OCT
- Single treatment at Baseline of either CLS-TA + Eylea (combination arm) or Eylea only (Control/Eylea only arm)

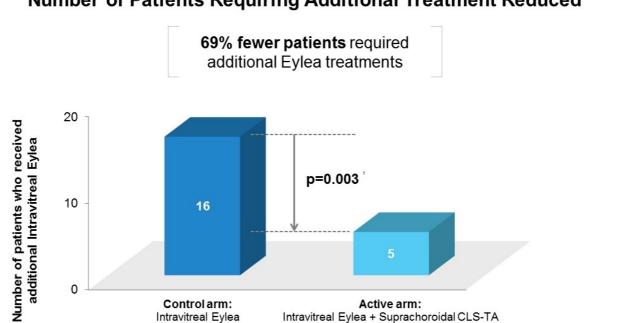
CLEARSIDE

- Subjects were observed for 3 months post treatment; 46 patients enrolled: 23 per arm



Number of Additional Injections





Intravitreal Eylea + Suprachoroidal CLS-TA

CLEARSIDE

G

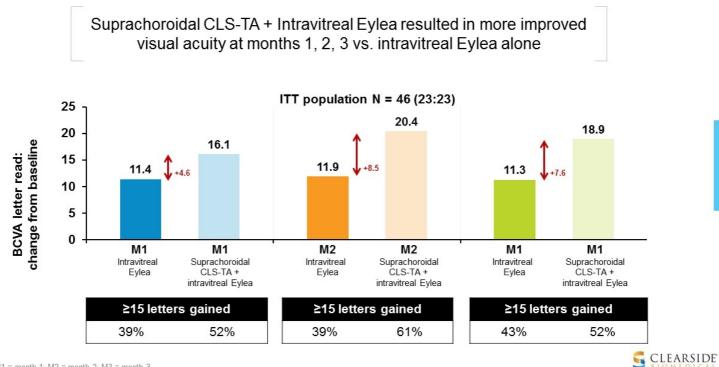
Number of Patients Requiring Additional Treatment Reduced

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

Intravitreal Eylea

26 ¹ Based on post-hoc analysis

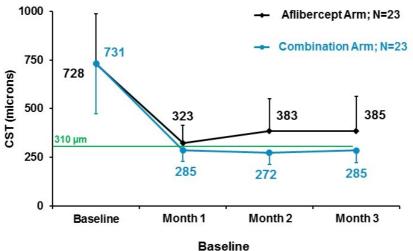
Improved Visual Acuity

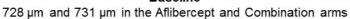


27 M1 = month 1; M2 = month 2; M3 = month 3

Retinal Thickness Reductions

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





28 Note: Bars are one-sided standard deviations



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)



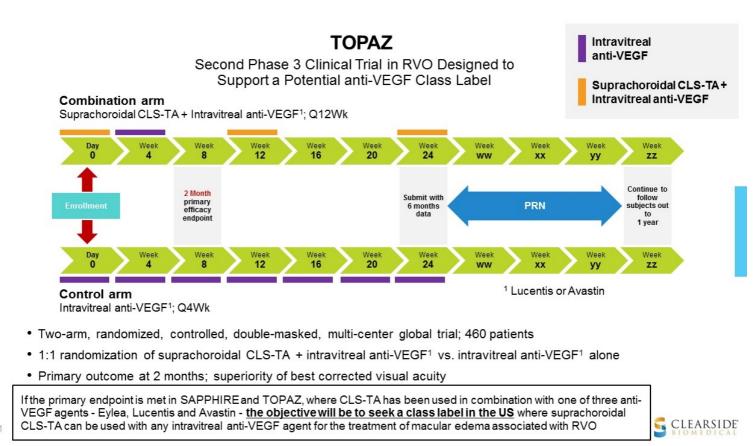
SAPPHIRE Design for First Phase 3 RVO Clinical Trial



CLEARSIDE



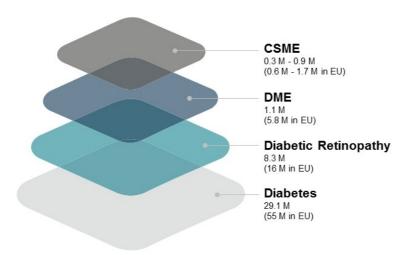
- Two-arm, randomized, controlled, double-masked, multi-center trial at ~150 clinical sites
- 1:1 randomization of suprachoroidal CLS-TA + intravitreal Eylea vs. intravitreal Eylea alone; 230 per arm
- One year study with primary outcome at 2 months; superiority of best corrected visual acuity





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

Steroids Given Frequently to Treat DME



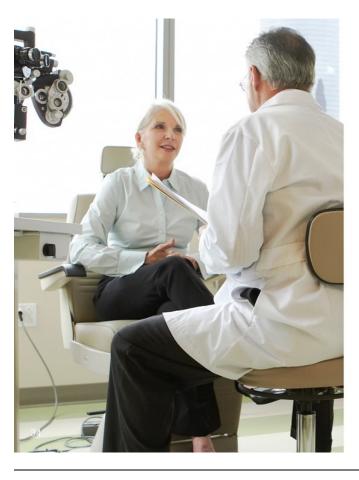
Current Treatments

- 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





The Opportunity

In Treating DME

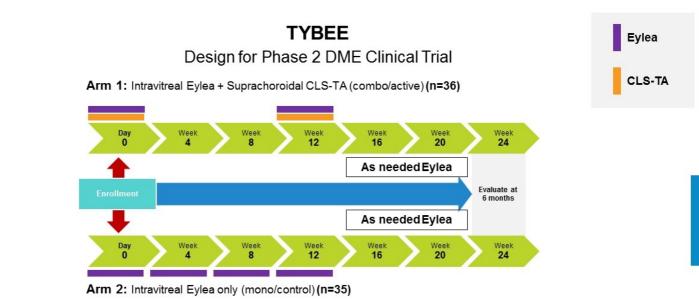
Anti-VEGF Therapy

- 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

The Problem

- 1. DME response to anti-VEGF injection is largely variable
- 2. Need for ongoing monthly intravitreal anti-VEGF therapy results in high burden for DME patients





Any additional treatment based on as needed criteria at Week 16 and Week 20 will be intravitreal Eylea

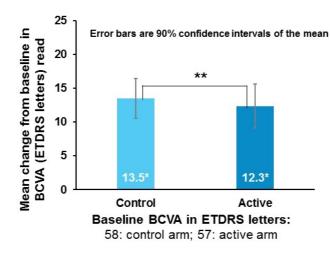
CLEARSIDE

- 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
- Primary outcome measure is comparison of mean change from baseline in BCVA at 24 weeks between the combination arm and the control arm. The study was powered and designed to show that the mean change in BCVA is not different between the two arms.

35

TYBEE Met Its Primary Endpoint

Mean Change in BCVA from baseline at Week 24; the data¹ are tested for equivalence by comparing the 90% confidence intervals

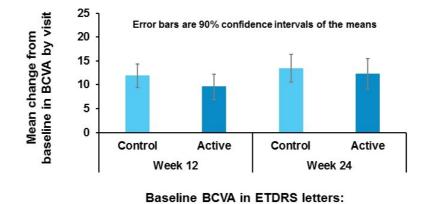


• Each arm shows a statistically equivalent improvement in BCVA from baseline (*p<0.001)

36 **p=0.664; p>0.05 implies equivalence | Table 14.2.1.1.1; Listing 16.2.6.1 | 1. Data without major deviations; data with major deviations shows similar result



Similar Visual Acuity Data Observed Through Month 6

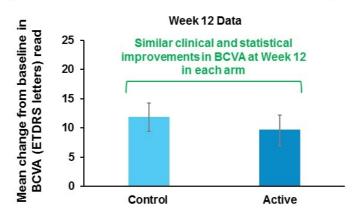


• Data at each visit starting from Week 4 (week 12 and Week 24 displayed) show similar outcomes with no statistically or clinically meaningful difference when comparing data from each arm

58: control arm; 57: active arm



1/3 as Many Treatments in the Active (Combination) Arm Resulted in Efficacy Similar to that Seen in the Monthly Eylea Arm



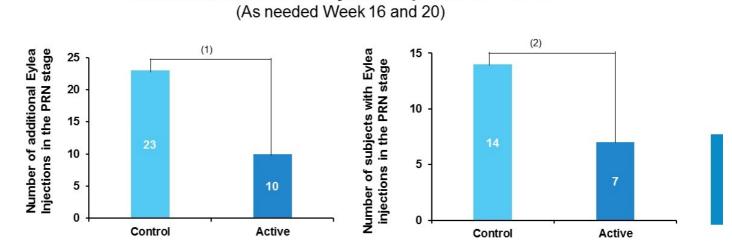
CONTROL (Eylea only) arm: Treatments given at Baseline, Month 1 and Month 2 **ACTIVE** (Combination) arm: Treatment given at Baseline only

For the first three months of the trial with similar visual acuity outcomes, significantly fewer treatments given in the Active (combination) arm compared to those given in the Control (Eylea only) arm

CONTROL (Eylea only) arm (n=35): 105 treatments ACTIVE (combination) arm (n=36): 36 treatments

CLEARSIDE

Additional Intravitreal Eylea Required in TYBEE



CLEARSIDE

- Significantly fewer additional Eylea injections in the Combination (Active) arm than in the Eylea only (Control) arm in the as needed period (p=0.03)
- Fewer patients receiving additional Eylea injections in the combination (Active) arm than in the Eylea only (Control) arm in the as needed period

(2) p=0.1; although numerically this shows that half the number of patients required intravitreal Eylea in the Active arm, this difference does not achieve statistical significance

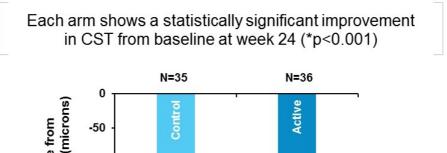
• 49% fewer treatments required in the Active arm versus the Control

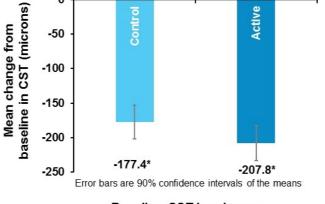
39

(1) p=0.03

Secondary Endpoint

Mean change from baseline in CST at week 24 in microns





Baseline CST in microns: 513: control arm; 501: active arm

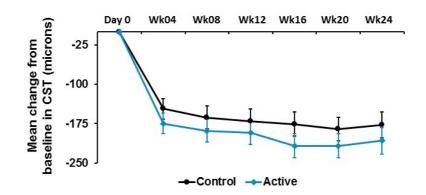
CLEARSIDE

40 Table 14.2.2.2.1; Listing 16.2.6.2

Central Retinal Thickness (CST)

Mean change from baseline in CST by visit

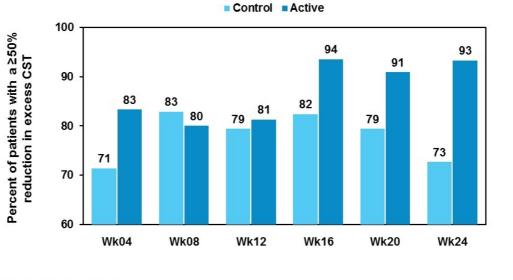
Apparent additional improvement in retinal thickness reduction is seen from week 4 in the combination arm, and sustained through the end of the study (week 24)





50% or Greater Reduction in Excess CST

Proportion of patients demonstrating response by retinal thickness reduction is seen from week 4 in the combination arm, and maintained through the end of the study



CLEARSIDE

42 CST: central subfield thickness | Table 14.2.2.5.1; Listing 16.2.6.1

TYBEE Trial High Level Summary

Efficacy

This Phase 2 trial met its primary endpoint. Suprachoroidal CLS-TA used together with intravitreal Eylea showed equivalent vision improvement to Eylea alone with fewer treatments at week 24

- Each arm shows a statistically significant improvement in BCVA from baseline (p<0.001)
- Equivalent improvements in mean changes from baseline in BCVA (p>0.05 indicating outcomes are not different) when comparing the 90% confidence intervals
- · Apparent additional improvements in reduction of CST seen in the combination arm

Safety

Adverse events in the trial were generally consistent with other trials involving CLS-TA and Eylea

- These low rates of typical steroid-related events are consistent with our previous trials and continue to support the hypothesis that suprachoroidal injections may provide an adverse event profile similar to that seen in our previously completed trials and similar to the Eylea only (control) arm
 - Elevated IOP 8.3 % (3/36) in the combo arm and 2.9% (1/35) in the control arm
 - Cataracts 5.6% (2/36) in the combo arm and 2.9 % (1/35) in the control am
 - Elevated IOP events were consistent with previous trials with CLS-TA and resolved with eye drops

4.3 ETDRS: early treatment of diabetic retinopathy study; BCVA: best corrected visual acuity; CST: central subfield thickness



A WORLD WITHOUT BLINDNESS

In Summary

Opportunity is Well Protected

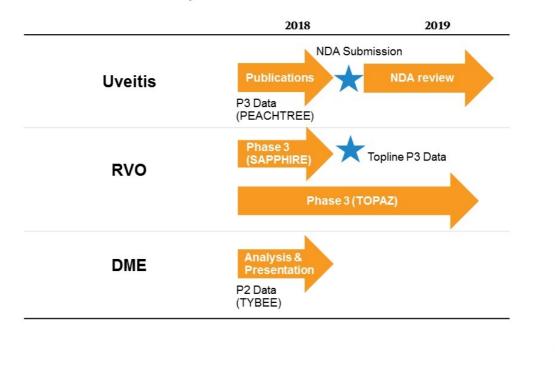
Patent No.	Significance	Expiration
U.S. 7,918,814	Provides exclusivity for the administration of any drug to the eye by inserting a microinjector into the sclera or corneal stroma of a patient's eye, and infusing the drug into the sclera or cornea	2029
U.S. 8,197,435	Provides exclusivity for administration 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
J.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	
DANIEL WHITE President, CEO and Director	GSK, Stiefel, CIBA Vision, Alimera	25	Experience	
CHARLES DEIGNAN Chief Financial Officer	AtheroGenics, AAIPharma, Schering- Plough	27	Alcon	
GLENN NORONHA, Ph.D. Chief Scientific Officer	Alcon, Sucampo, TargeGen	19	CIBA OVISION.	
BRION RAYMOND Chief Commercial Officer	Genentech, Carl Zeiss Meditec, Xoma	14	U NOVARTIS	
RAFAEL ANDINO VP, Engineering & Manufacturing	CR Bard, CIBA Vision, Dupont, GE, IBM	26	ALIMERA	
JENNIFER KISSNER, Ph.D. VP, Clinical Development	Alcon, Acucela, Vanderbilt	17	SCIENCES	
RICK MCELHENY VP, Business Development	Sanofi, MEDA, Vidara	18	Genentech	

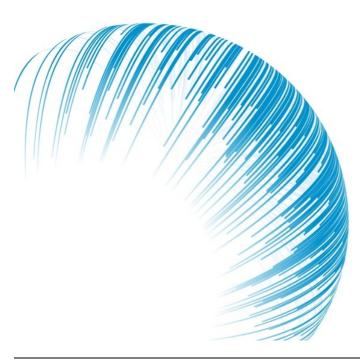
Major Near-Term Anticipated Milestones

Provide Multiple Potential Value-Inflection Points



CLEARSIDE

47



THANK YOU!



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