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): May 22, 2019

Clearside Biomedical, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37783**	**45-2437375**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**CLSD**	**The Nasdaq Stock Market LLC**

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 May 22, 2019, 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 business developments. A copy of the presentation that will accompany the meetings 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

Exhibit Number	Exhibit Description
99.1	Company Presentation

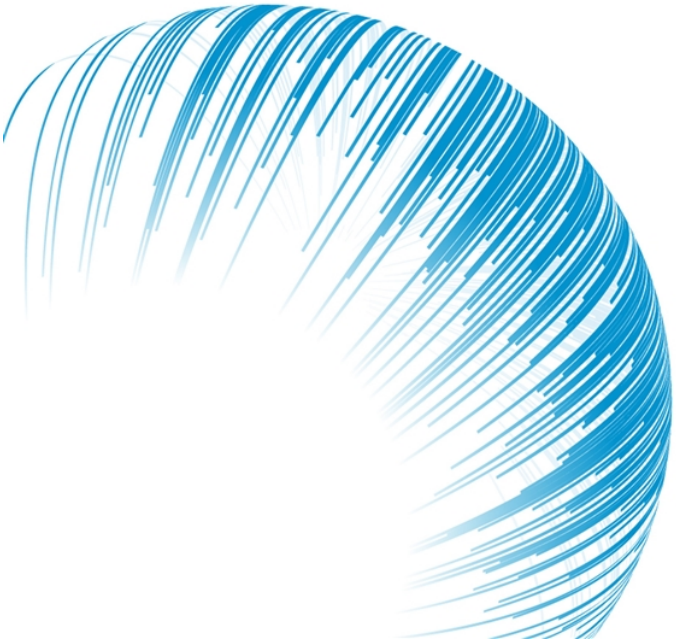
SIGNATURES

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.

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

Date: May 22, 2019



CLEARSIDE® BIOMEDICAL

Corporate Presentation | May 2019

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, 2018, filed with the SEC on March 15, 2019, 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.

Clearside Biomedical Overview

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

Novel, therapeutic platform combines patented suprachoroidal space injection technology with a proprietary drug formulation

XIPERE™
(triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

Validating platform with first potential FDA approval with October 2019 PDUFA date, for eye disease that currently has no approved therapies

XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection is an investigational product under FDA review.

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Proprietary Approach to Treating Eye Diseases

Clearside Suprachoroidal Space Injection Platform

Therapeutics:
Small Molecules
Biologics
Gene Therapy

Device:
SCS Microinjector™

Suprachoroidal Space (SCS)

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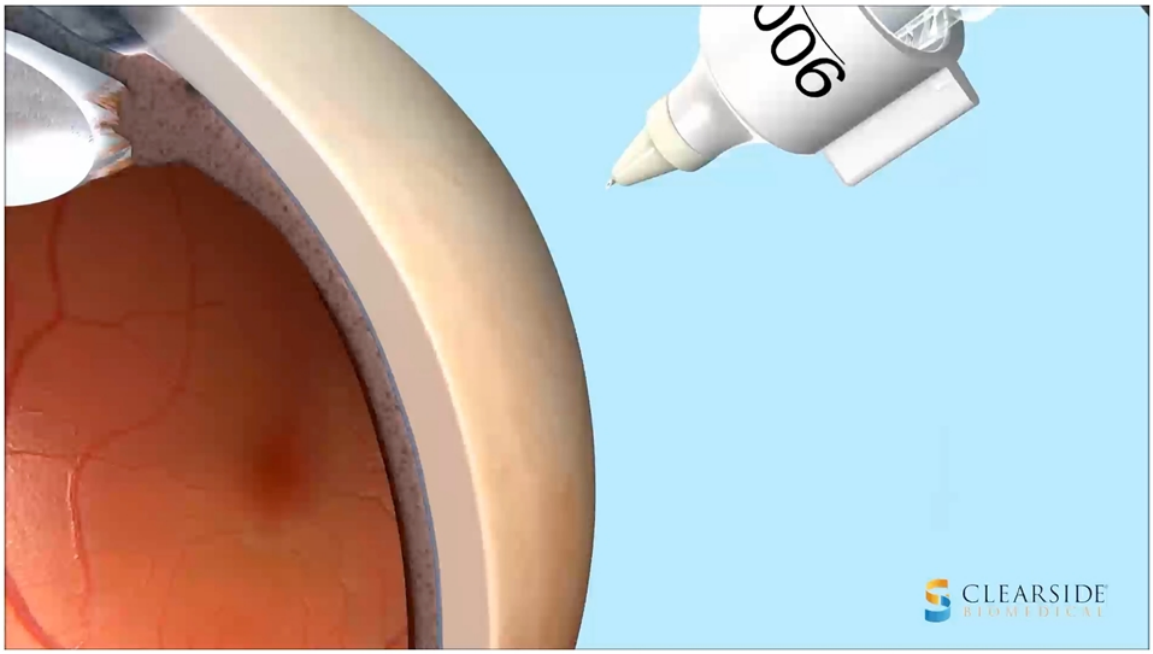
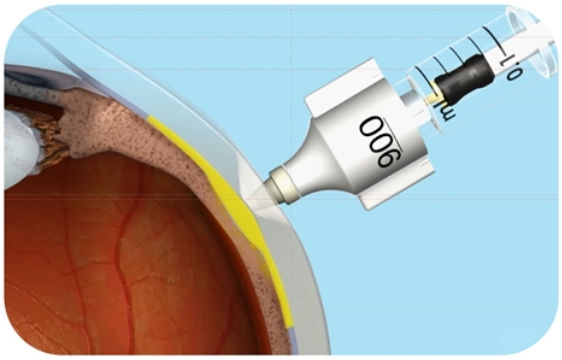
Exclusive and Proprietary Access to the Back of the Eye



Differences in Procedures to Reach the Back of the Eye

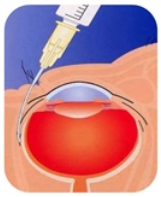
Suprachoroidal Space (SCS) Injection



- Fluid flows instantaneously and posteriorly
- Consistent suprachoroidal injection procedure
- Fluid with drug is absorbed into the choroid, retina, and retinal pigment epithelium (RPE)

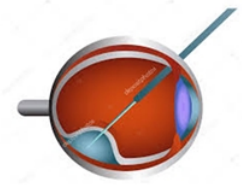
Intravitreal Injection

Broad diffusion to all areas of the eye including the anterior chamber and lens



Periocular Injection

Highly variable drug diffusion across the sclera into the eye



Subretinal Injection

Invasive surgery with variable results

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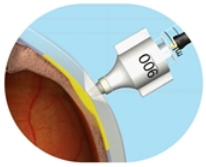
Novel Treatment Opportunities Via the Suprachoroidal Space (SCS)

TARGETED

The back of the eye is the location of many irreversible and debilitating visual impairments[1]

EXPANDABLE

The suprachoroidal space can extend in a volume-dependent manner, diffusing fluid into the back of the eye, then naturally return to its original thickness



BIOAVAILABLE

Fluid spreads circumferentially and posteriorly when injected within the suprachoroidal space, bathing the choroid and adjacent areas with drug[2]

COMPARTMENTALIZED

Drug is compartmentalized in the suprachoroidal space, which helps keep it away from non-diseased tissues[2]

References: 1. Rai UDJ, Young SA, Thrimawithana TR, et al. The suprachoroidal pathway: a new drug delivery route to the back of the eye. Drug Discov Today. 2015;20(4):491-495. 3. Moisseiev E, Loewenstein A, Yiu G. The suprachoroidal space: from potential space to a space with potential. Clin Ophthalmol. 2016;10:173-178. 2. Chiang B, Jung JH, Prausnitz MR. The suprachoroidal space as a route of administration to the posterior segment of the eye. Adv Drug Deliv Rev. 2018;126:58-66.

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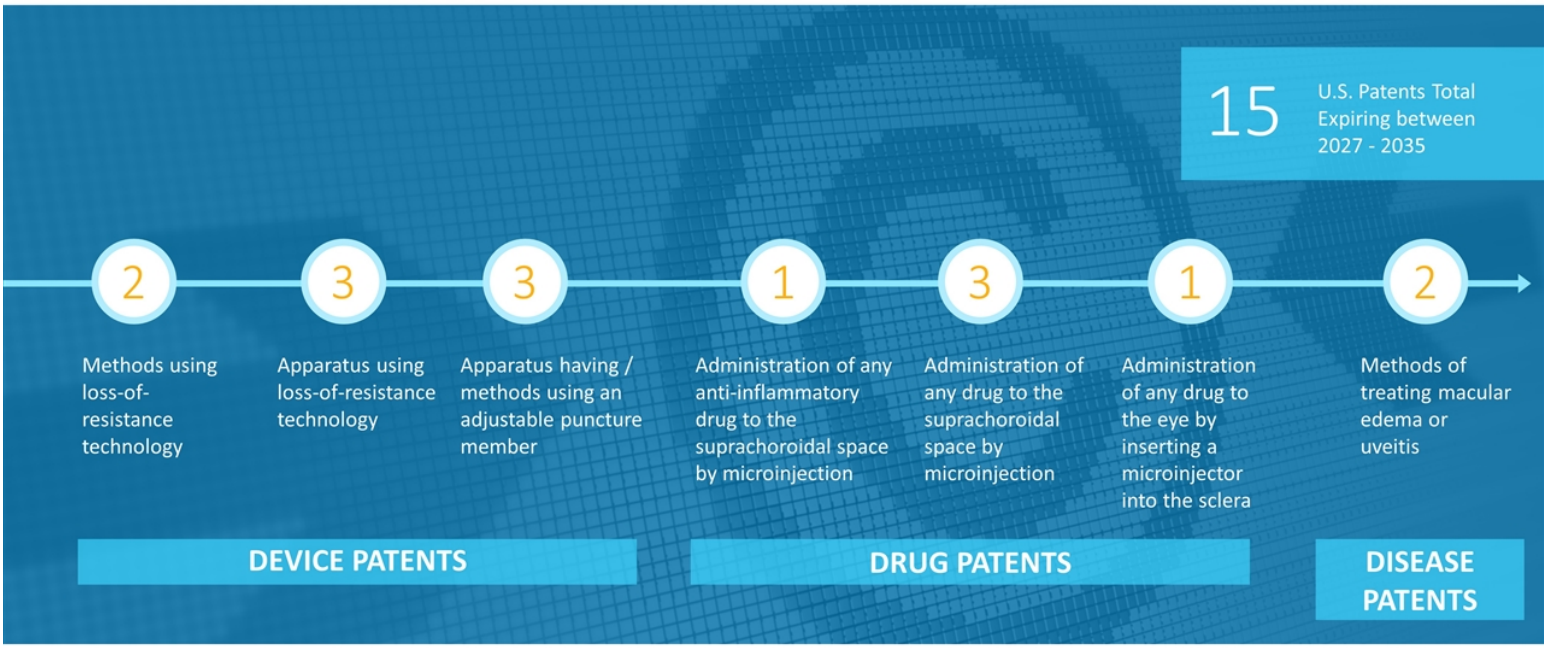
Strong Intellectual Property Coverage of SCS Platform



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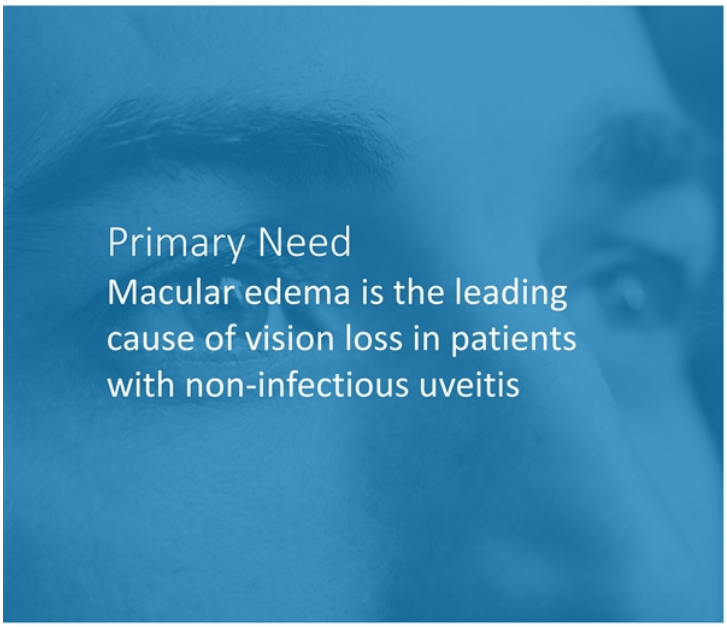
Pipeline of SCS Treatments with Broad Applicability

INDICATION	STUDY DRUG	CURRENT STATUS
Uveitis (macular edema associated with uveitis)	XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection	PRECLINICAL · PHASE 1 · PHASE 2 · PHASE 3 · NDA
DME (diabetic macular edema)	XIPERE™	PRECLINICAL · PHASE 1 · PHASE 2 · PHASE 3 · NDA
Wet AMD	Undisclosed	PRECLINICAL · PHASE 1 · PHASE 2 · PHASE 3 · NDA
DME	Undisclosed	PRECLINICAL · PHASE 1 · PHASE 2 · PHASE 3 · NDA
Inherited Retinal Diseases	Gene Therapy	PRECLINICAL · PHASE 1 · PHASE 2 · PHASE 3 · NDA

Macular Edema Associated with Uveitis

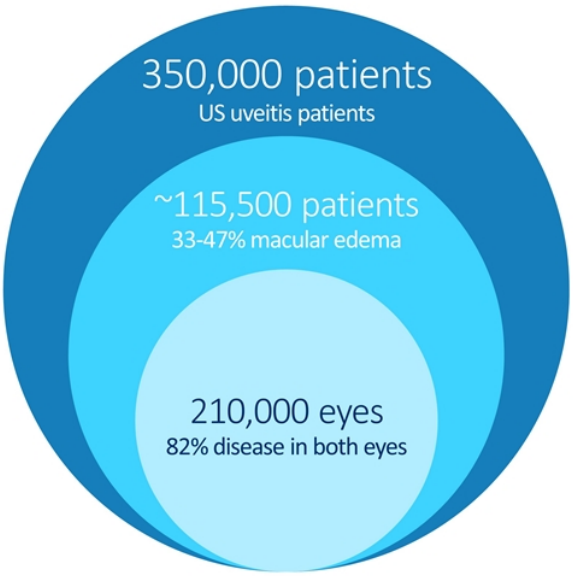


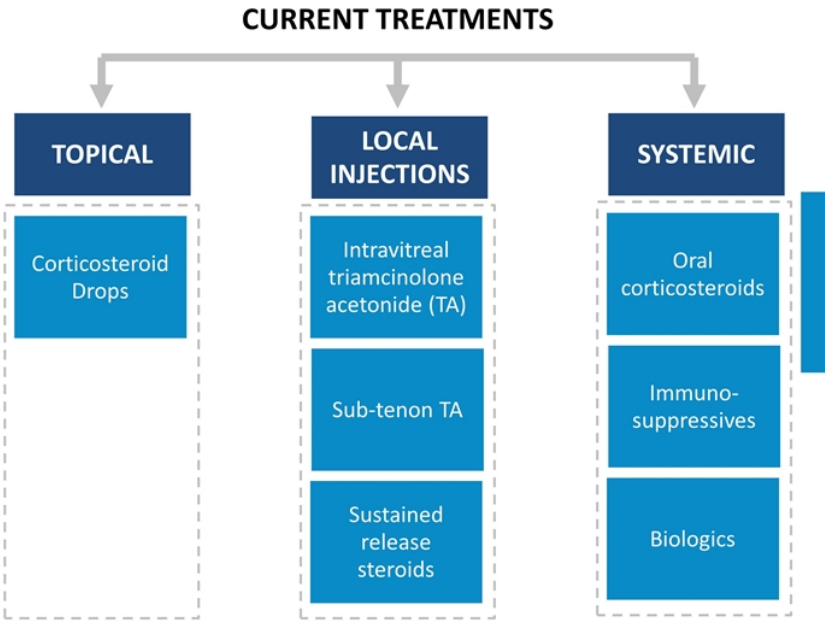
The Opportunity

1. No approved treatment for macular edema associated with uveitis
2. All anatomic locations of uveitis included in Clearside clinical trials
3. ~50% of patients continue to have macular edema, even after a course of treatment for non-infectious uveitis

Source: Durrani, 2004

Market Size and Current Treatment Paradigm for Uveitis





Sources: 1) Target Ophthalmologist ATU, May 2018; 2) Lardenoye, C. et al. Ophthalmology 113.8 (2006): 1446-1449.

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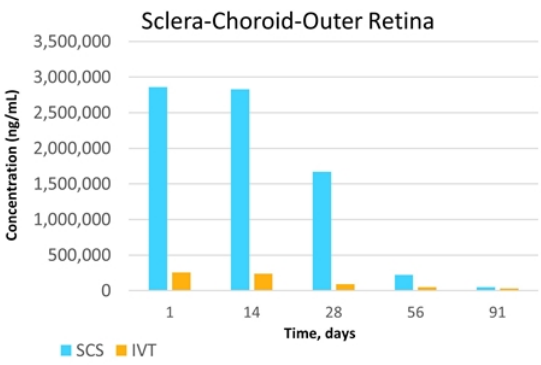
Novel Approach to Targeting Uveitic Macular Edema

XIPERE™
(triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

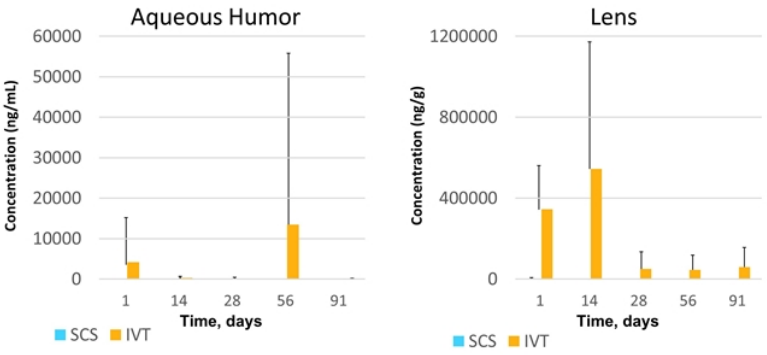
- Pivotal Phase 3 PEACHTREE trial met its primary endpoint
- NDA submitted in Q4 2018 with October 19, 2019 PDUFA date
- If approved, XIPERE would be the first therapy for this indication
- If approved, commercial launch for XIPERE anticipated in Q1 2020

XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection is an investigational product under FDA review.

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

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

Based on non-clinical studies

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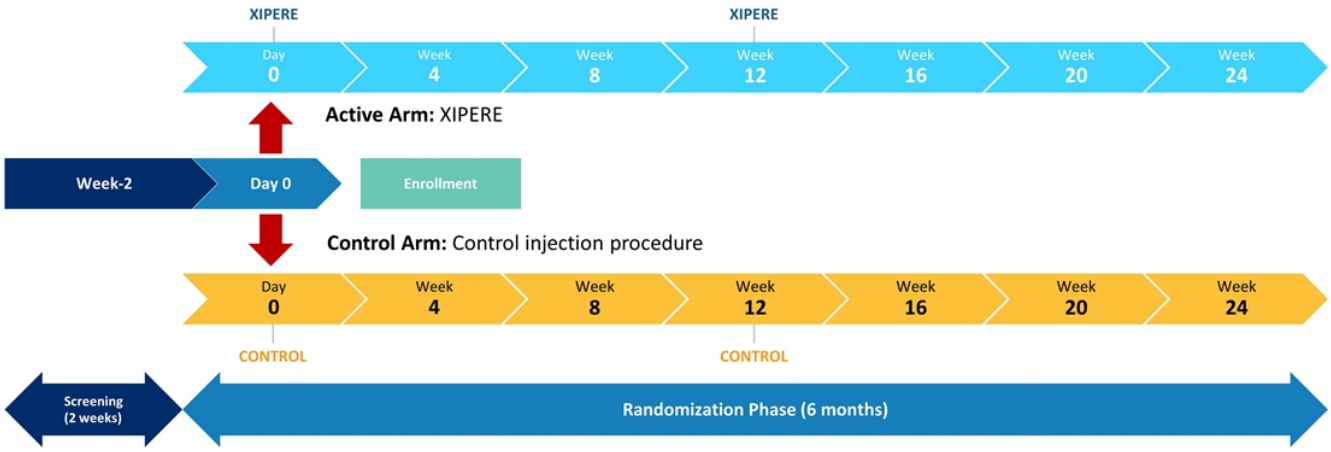
PEACHTREE: Pivotal Phase 3 Clinical Trial for Macular Edema Associated with Non-Infectious Uveitis (NIU)



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

3:2 randomization of XIPERE vs. sham injection; 160 subjects total

Primary endpoint at 6 months; proportion of patients gaining three lines of vision compared to sham

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

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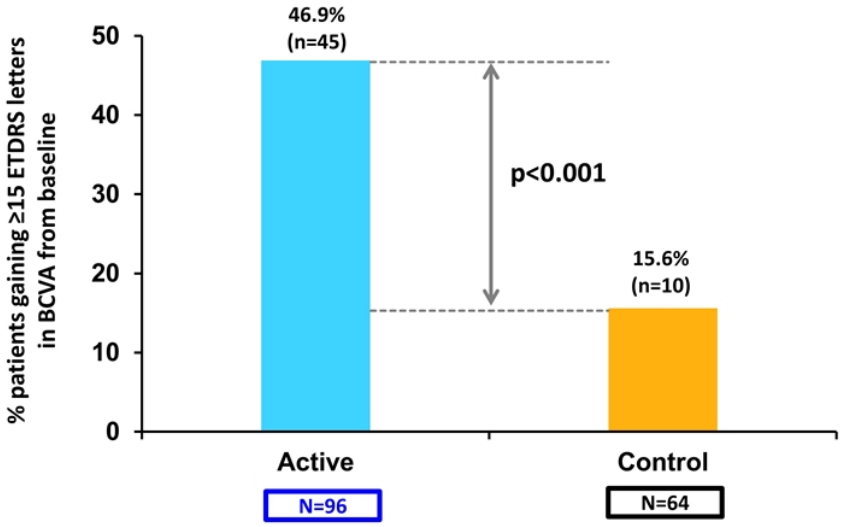
PEACHTREE Met Its Primary Endpoint

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



XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

ETDRS = Early Treatment Diabetic Retinopathy Study | BCVA = Best Corrected Visual Acuity

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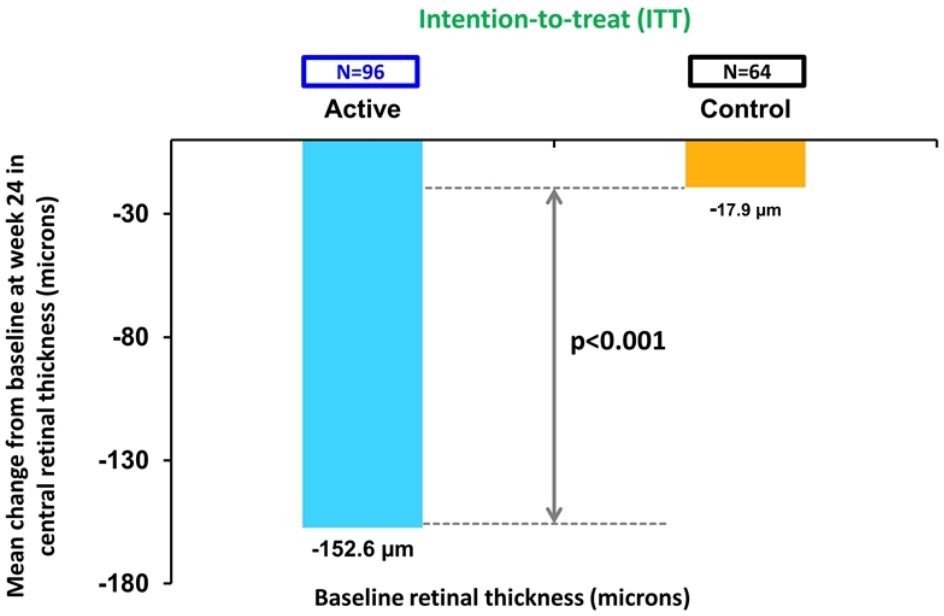
PEACHTREE Met Its Secondary Endpoint

Mean Change from Baseline in CST at Week 24 in Microns



480.9 µm: active arm; 525.4 µm: control arm

Source: Phase 3 PEACHTREE data. | CST = Central Subfield Thickness

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

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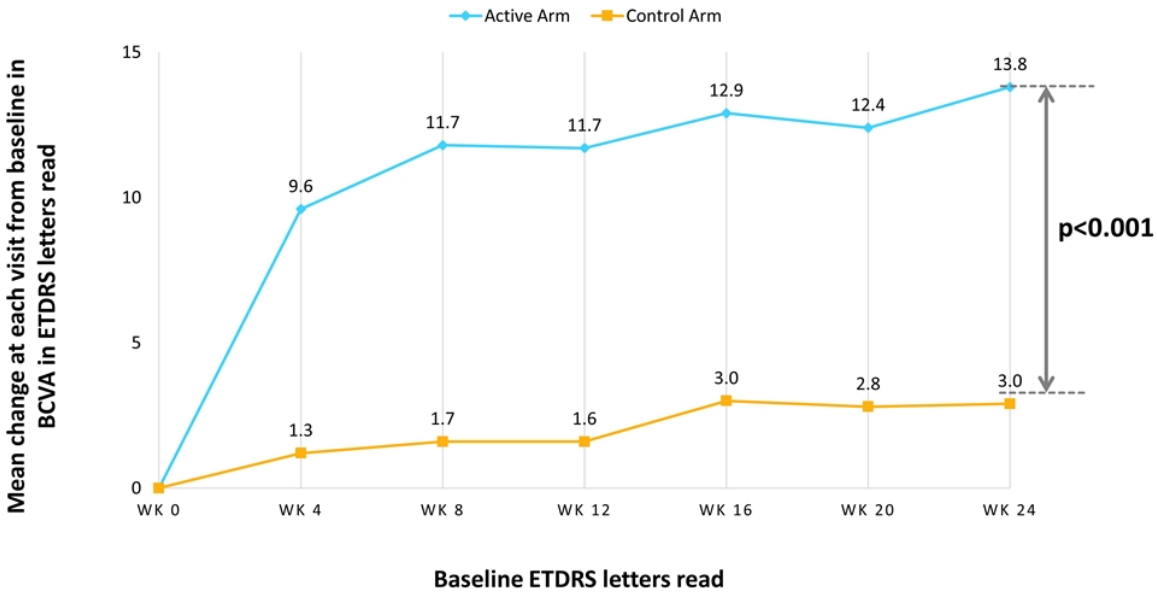
Vision Gained Rapidly and Sustained Through Week 24

Mean Change in BCVA in ETDRS Letters by Visit



Baseline ETDRS letters read

54.7: active arm; 53.5: control arm

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

Source: Phase 3 PEACHTREE data

BCVA = Best Corrected Visual Acuity | ETDRS = Early Treatment Diabetic Retinopathy Study

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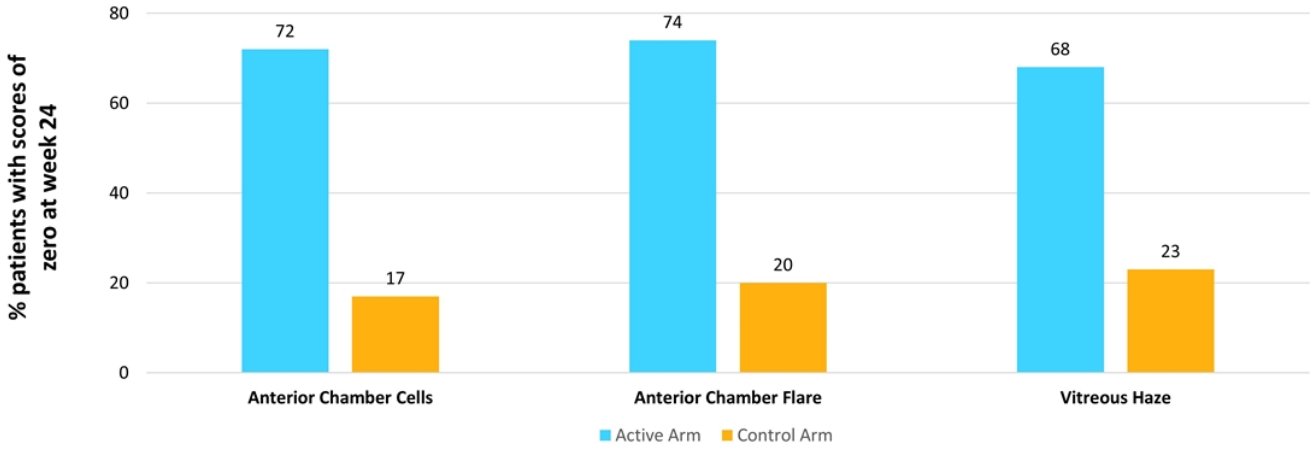
Resolved Inflammation in ~70% of Patients in PEACHTREE



- Resolution of each of these three signs of inflammation on the SUN* scales is clinically and statistically significant
- In subjects with scores of 2 or greater in vitreous haze, 40.9% experienced resolution in the active arm, compared to 0% of subjects in the control arm

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

*SUN = Standardization of Uveitis Nomenclature

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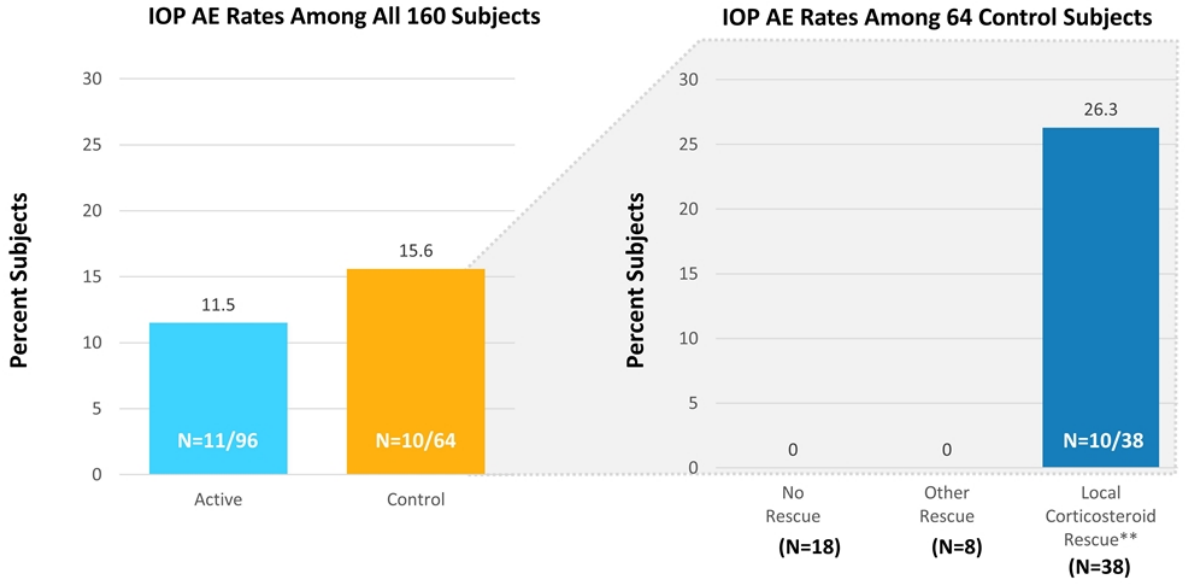
Favorable Intraocular Pressure (IOP) Profile Compared to Patients Rescued with Local Corticosteroids



IOP lowering medications were initiated in 7.3% and 9.4% subjects in the XIPERE and control arms respectively

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

AE = adverse event
"Elevated IOP" includes (a) increased IOP, (b) ocular hypertension, and (c) glaucoma

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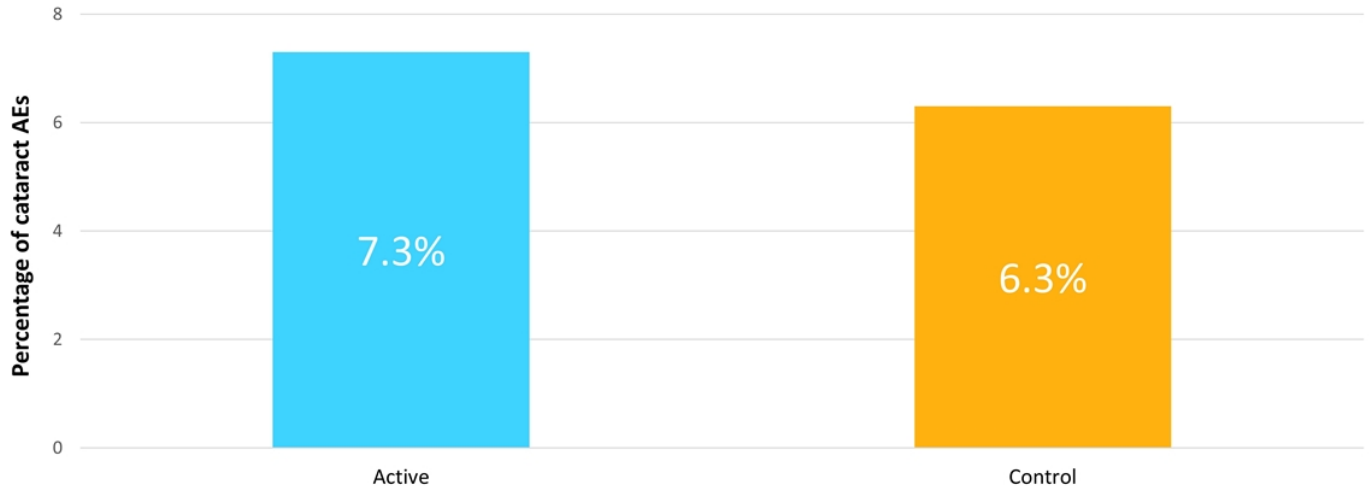
Percentage of Cataract Adverse Events (AEs) Were Balanced Between Arms



XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

Mar-2018 | NIU program | P3, PEACHTREE, trial | Topline data

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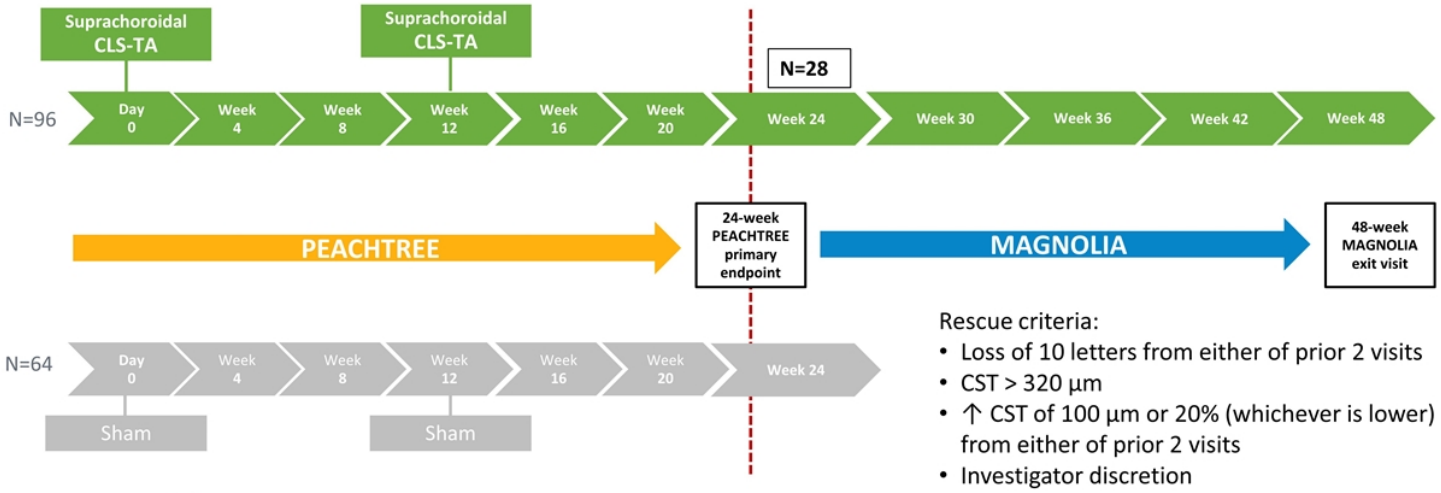
MAGNOLIA: Prospective, Non-interventional, Masked, Observational 24 week Extension Trial

- To be eligible for MAGNOLIA, subjects must have completed PEACHTREE and NOT have received rescue medication
- Primary Endpoint: Time to rescue therapy relative to Day 0 of PEACHTREE



Rescue criteria:

- Loss of 10 letters from either of prior 2 visits
- CST > 320 µm
- ↑ CST of 100 µm or 20% (whichever is lower) from either of prior 2 visits
- Investigator discretion

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

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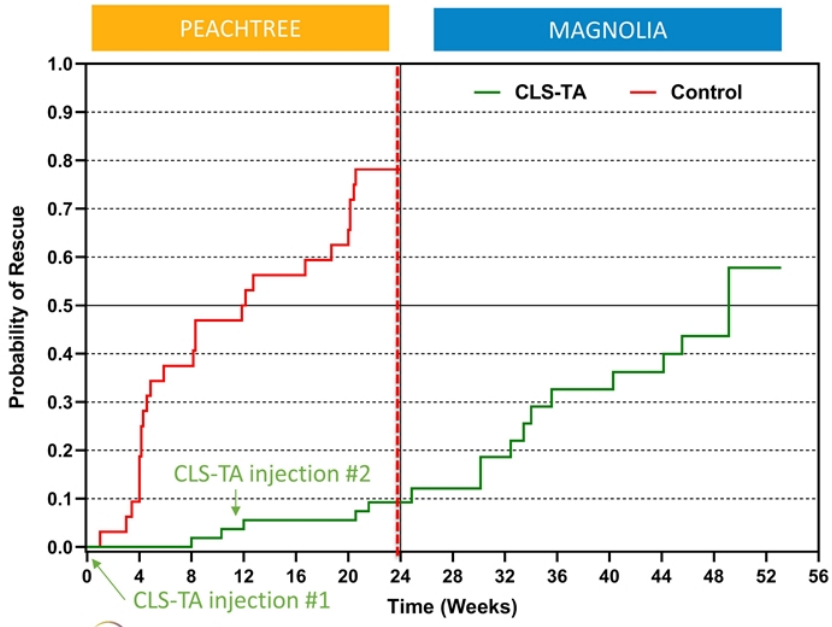
Magnolia Extension Study Demonstrates Positive Efficacy and Durability Results



Efficacy

- 50% of patients did not receive additional medication through week 48
- Results were durable for 36 weeks after last injection of XIPERE
- Suprachoroidally injected XIPERE significantly improved vision (~12 letters) and macular edema (~170 microns)

Safety

- There were no Serious AEs related to study medication
- Elevations in IOP were consistent with those seen in the PEACHTREE trial and were low

XIPERE® (triamcinolone acetonide suprachoroidal injectable suspension) 40 mg/mL

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XIPERE Launch Preparations

PHYSICIANS

- Education materials
- Injection training
- Patient access support

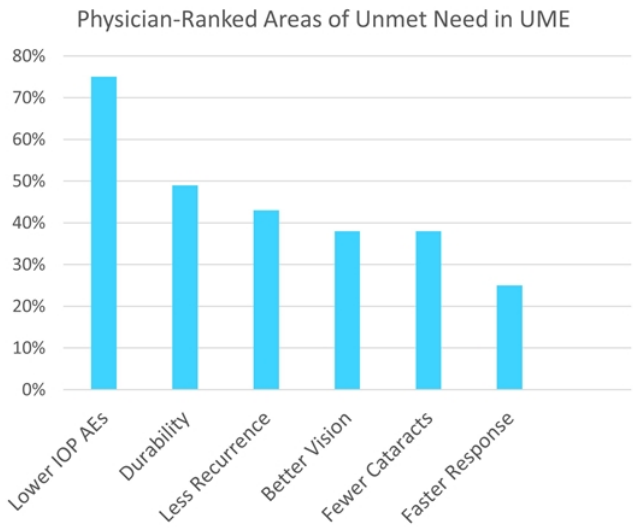
PATIENTS

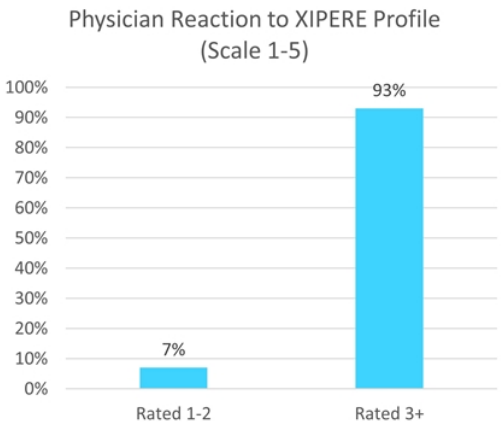
- Education materials
- Reimbursement support services

PAYERS

- Proactive education on uveitic macular edema as an unmet need

Physicians Recognize the Unmet Need and Over 90% Had a Favorable Reaction to the XIPERE Profile





Source: Target Ophthalmologist ATU, May 2018

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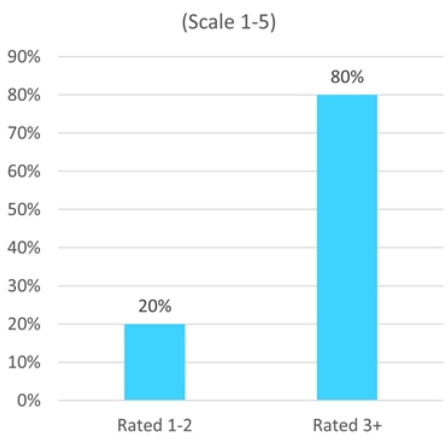
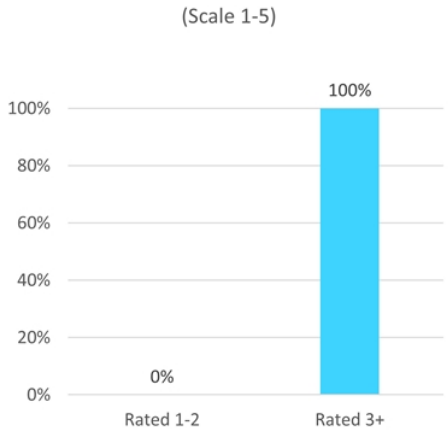
Payers Believe XIPERE Helps Fill the Unmet Need in Uveitic Macular Edema

Payers View of UME as Unmet Need



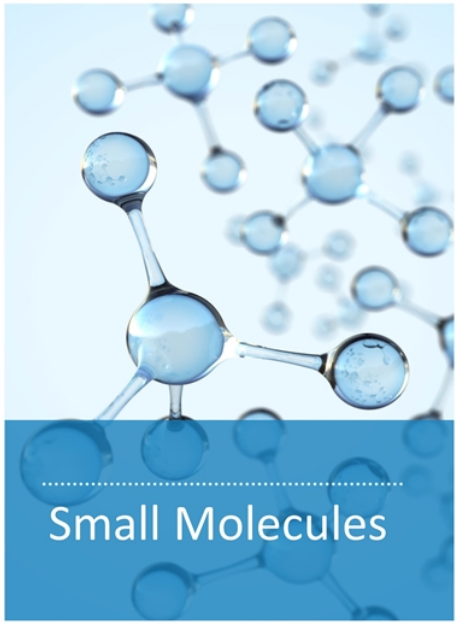
Payer Reaction to XIPERE Profile



Sources: Target Ophthalmologist ATU, May 2018. | Payer Research, Precision for Medicine, Aug 2018. | N=10 Medical Directors, encompassing 114M covered lives

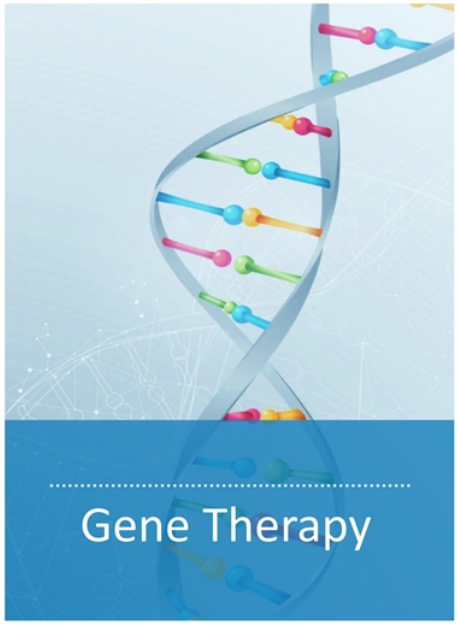
CLEARSIDE BIOMEDICAL

Broad Applicability of SCS Injection Platform



Small Molecules

Biologics



Gene Therapy

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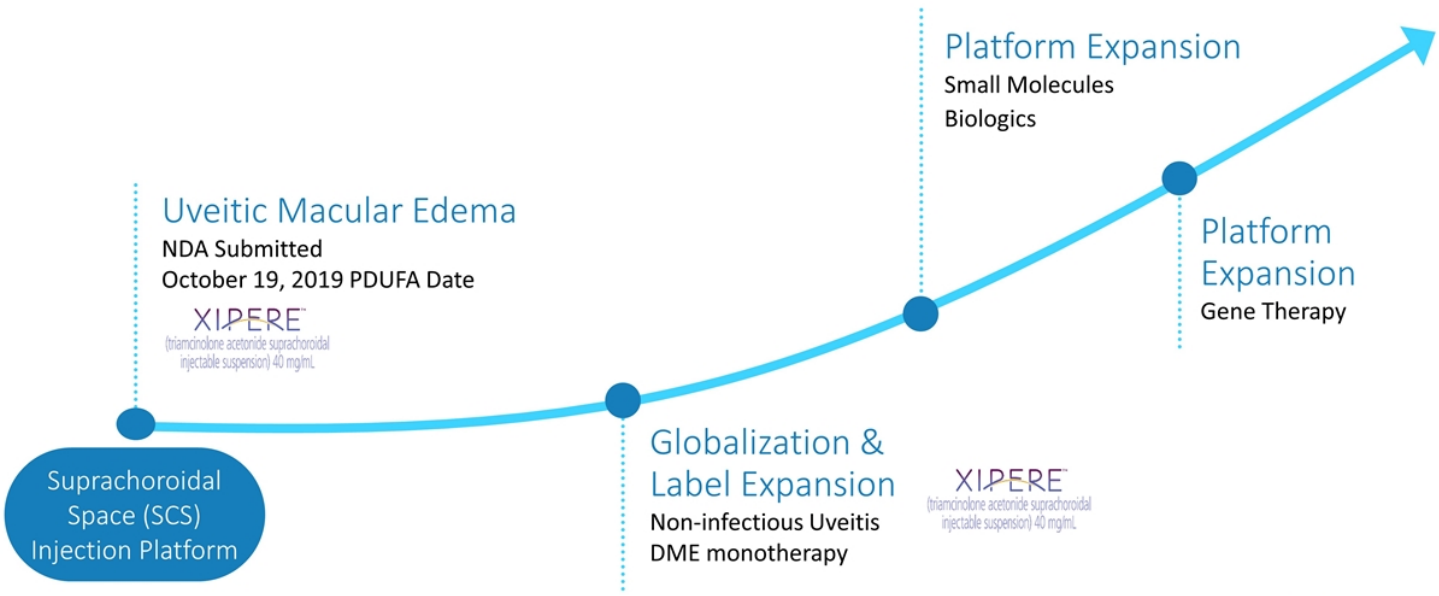
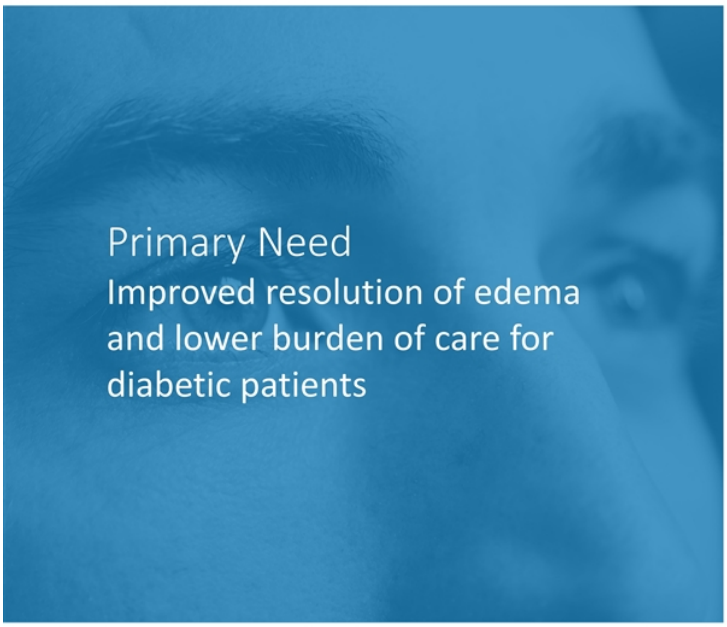
Clearside Opportunities to Leverage SCS Injection Platform



XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection is an investigational product under FDA review.

Potential Label Expansion: Diabetic Macular Edema (DME)

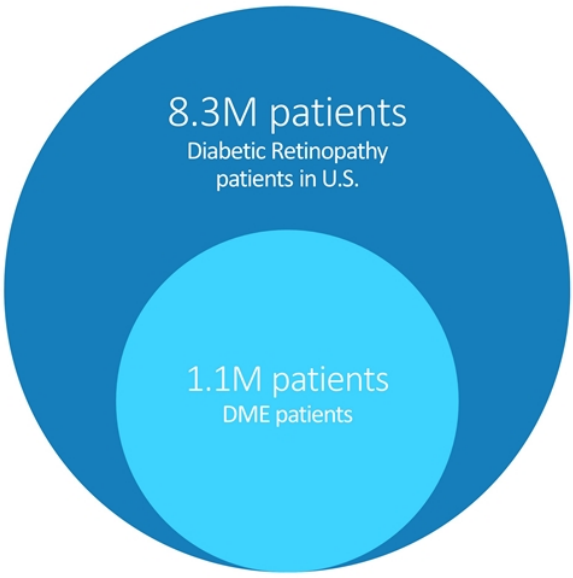


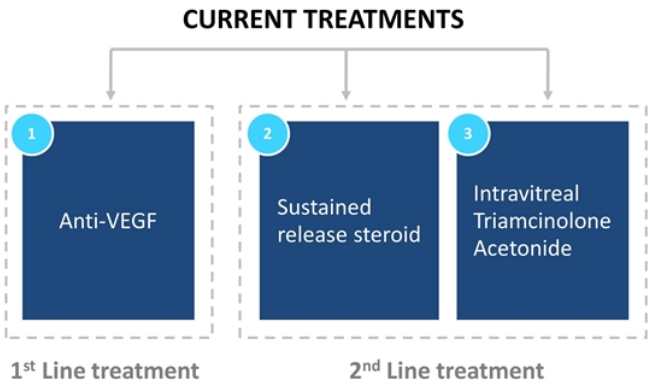
The Opportunity

1. Real world data demonstrates patients missing out on visual gains
2. Patients have variable response to anti-VEGF treatment
3. High burden for DME patients leading to poor compliance

Sources: Protocol I – Bressler | Vestrum | Ciulla AAO 2018 https://doi.org/10.1016/j.oret.2018.06.004

Market Size and Current Treatment Paradigm for DME





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Treatment Burden and Patient Compliance Create Need For Options

Real world data demonstrates patients missing out on visual gains

- DME subjects receive 3-7 anti-VEGF injections and gain ~5 letters in vision
- Phase 3 trials demonstrate that compliant subjects have the potential to gain ~10 to 12 letters*

XIPERE has the potential to maintain visual gains on a quarterly dosing regimen

- Current anti-VEGFs require retreatment every 4 to 8 weeks
- Subjects gained approximately 10 letters and were maintained for 12 weeks with XIPERE + intravitreal Eylea in TYBEE

Future plans to advance clinical development of XIPERE for DME

- Target monotherapy in a therapeutic rotation with anti-VEGF
- Consult with FDA on potential path to approval

*Lucentis PI, 2018; Eylea PI, 2018 | Holekamp AJO July 2018 | Ciulla AAO 2018 https://doi.org/10.1016/j.oret.2018.06.004

Potential Platform Expansion: Small Molecules and Biologics

The Opportunity

1. Current intravitreal treatments have diffuse distribution
2. Protection of off-target tissues
3. Migration of small molecules into the anterior chamber
4. Limited duration of action

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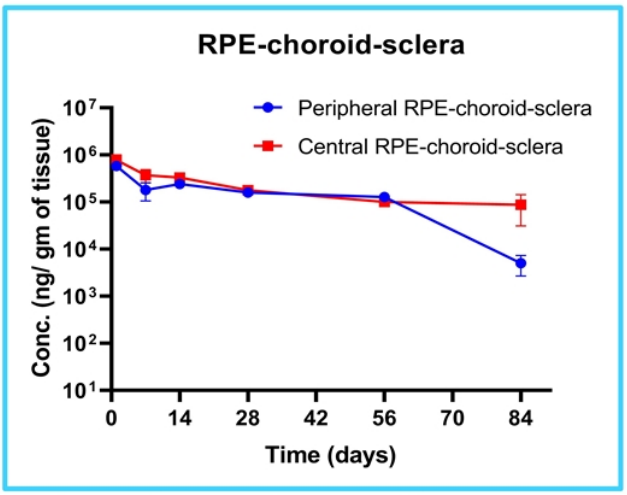
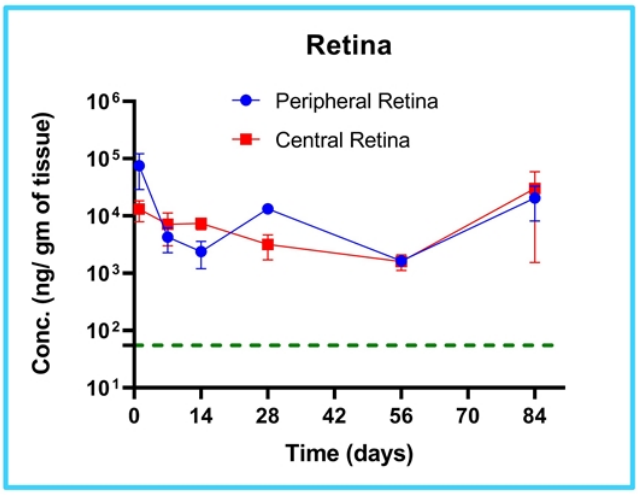
Potential Platform Expansion: Small Molecules
SCS Platform May Offer Unique Distribution and Better Duration





Concentration presented as mean ± SEM

High drug levels achieved in retina and choroid-RPE-sclera

Based on non-clinical data

Potential Platform Expansion: Ocular Gene Therapy

Opportunity

1. Avoid risks of vitrectomy (surgery)
2. Avoid risks of retinotomy, subretinal injection, and macular detachment
3. Potential for broader retinal coverage
4. Enhance patient access
    - Convert gene therapy into an office-based procedure

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Experienced Leadership Team

George Lasezkay
Pharm.D., J.D. | Interim CEO and Director

30 years experience
Allergan, Acucela, Novagali, Amakem, RetroSense

Thomas Ciulla
M.D., MBA | Chief Medical Officer

27 years experience
Spark Therapeutics, Ophthotech, Indiana University School of Medicine

Charles Deignan
Chief Financial Officer

27 years experience
AtheroGenics, AAIPharma, Schering-Plough

Brion Raymond
Chief Commercial Officer

17 years experience
Genentech, Carl Zeiss, Meditec, Xoma

Leslie Zacks
General Counsel & Chief Compliance Officer

24 years experience
Arbor, Shionogi

Clearside Team Ophthalmic Experience

Alcon · Allergan · CIBA VISION · Genentech · MERCK · NOVARTIS · Spark THERAPEUTICS

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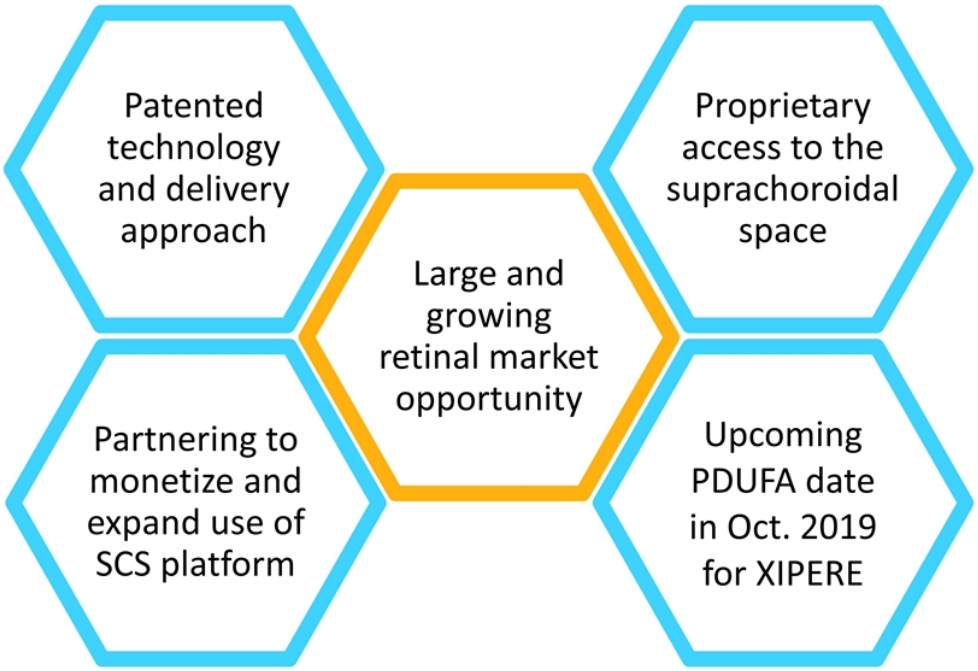
Financial Summary

($000's except share count)	March 31, 2019
Cash, cash equivalents and short-term investments	$34,938
Total assets	37,534
Long-term debt (including current portion)	10,036
Total liabilities	21,443
Total stockholders' equity	16,091
Common shares outstanding (as of May 6, 2019)	37,595,551

Clearside Biomedical: Five Key Investment Themes



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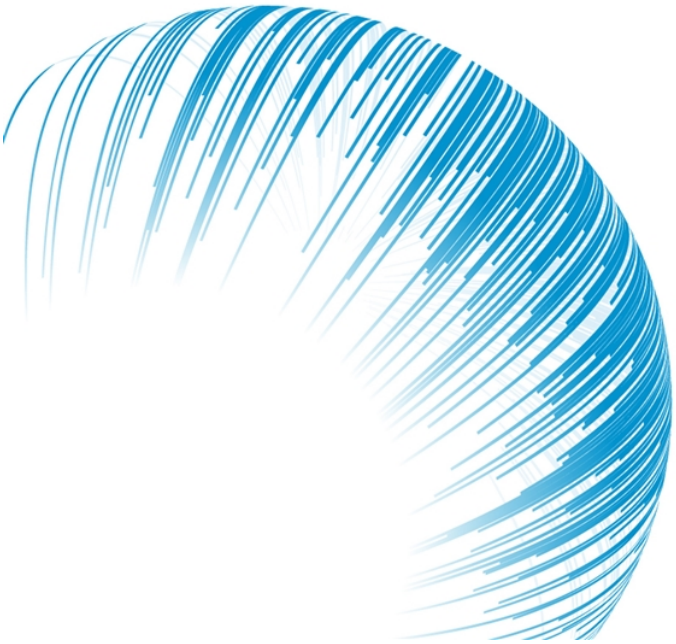

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