

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): April 8, 2020

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, 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 8.01 Other Events.

On April 8, 2020, Clearside Biomedical, Inc. (the “Company”) will be posting an updated corporate presentation on its website. A copy of the presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference.

Among other things, the updated presentation includes a slide related to the Company’s entry into the License Agreement (the “Agreement”) with Arctic Vision (Hong Kong) Limited (“Arctic Vision”), as previously disclosed on the Company’s Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on March 13, 2020.

Pursuant to the Agreement, the Company has granted an exclusive license to Arctic Vision to develop, distribute, promote, market and commercialize XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), subject to specified exceptions, in China, Hong Kong, Macau, Taiwan and South Korea (the “Territory”). Arctic Vision has agreed to use commercially reasonable efforts to pursue development and commercialization of XIPERE for indications associated with uveitis in the Territory. In addition, upon receipt of the Company’s consent, Arctic Vision will have the right, but not the obligation, to develop and commercialize XIPERE for additional indications in the Territory.

The slide related to the Agreement in the updated presentation includes a description of the following terms of the Agreement:

- the Company has received a \$4.0 million upfront payment from Arctic Vision;
- the Company is eligible to receive up to an additional \$31.5 million in aggregate milestone payments for pre-specified approval, development and sales milestone events; and
- the Company will also be entitled to receive tiered royalties of ten to twelve percent of net sales based on achieving certain annual net sales thresholds in the Territory, which, subject to customary reductions, will be payable on a product-by-product and country-by-country basis, commencing at launch in such country and lasting until the latest of (i) the date that all valid claims within the licensed patent rights covering XIPERE have expired, (ii) the date of the loss of marketing or regulatory exclusivity of XIPERE in a given country, or (iii) ten years from the first commercial sale of XIPERE in a given country.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation

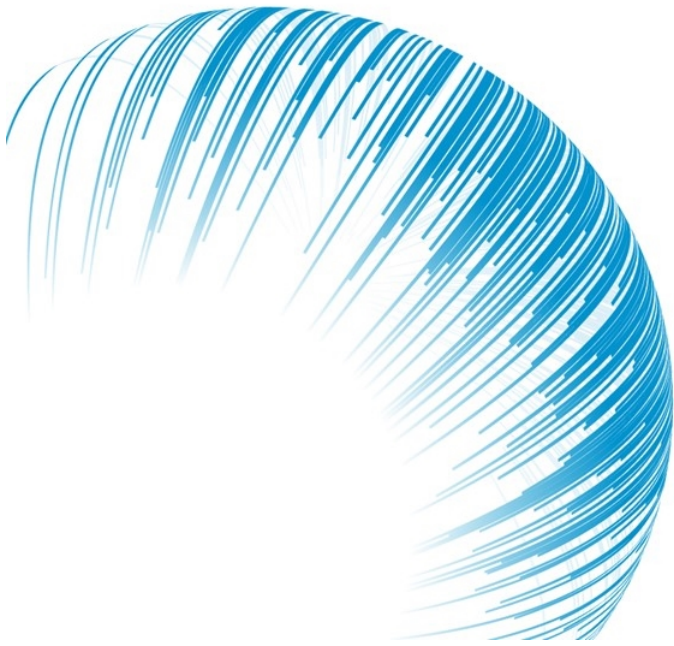
SIGNATURES

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 A. Deignan
Chief Financial Officer

Date: April 8, 2020



Corporate Presentation | April 2020



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, Clearside’s Quarterly Report on Form 10-Q, filed with the SEC on November 8, 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.

Dedicated to Developing Treatments that Restore and Preserve Vision for People with Serious Eye Diseases

Versatile Therapeutic Platform

SCS Microinjector™ with proprietary drug formulations target the Suprachoroidal Space



Proprietary Access to the Suprachoroidal Space (SCS®)

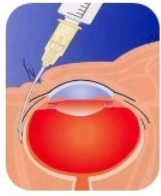
Utilization Across Small Molecules and Gene Therapy

Ability to Target Multiple Ocular Diseases

Internal Research & Development Pipeline

External Collaborations for Pipeline Expansion

Evolution of Injection Procedures to Reach the Back of the Eye



Periocular Injection

Highly variable drug diffusion across the sclera into the eye



Intravitreal Injection

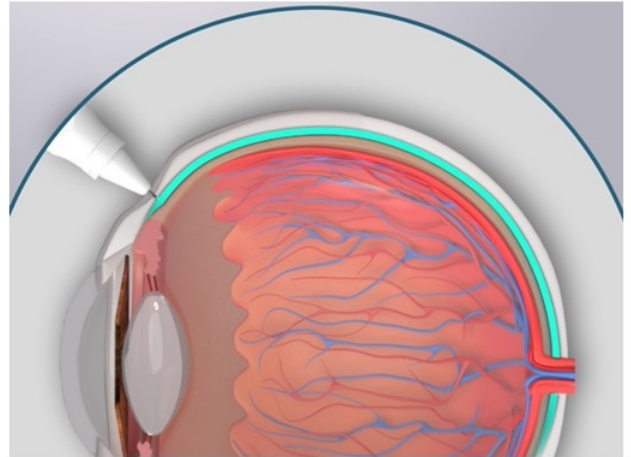
Broad diffusion to all areas of the eye including the anterior chamber and lens



Subretinal Injection

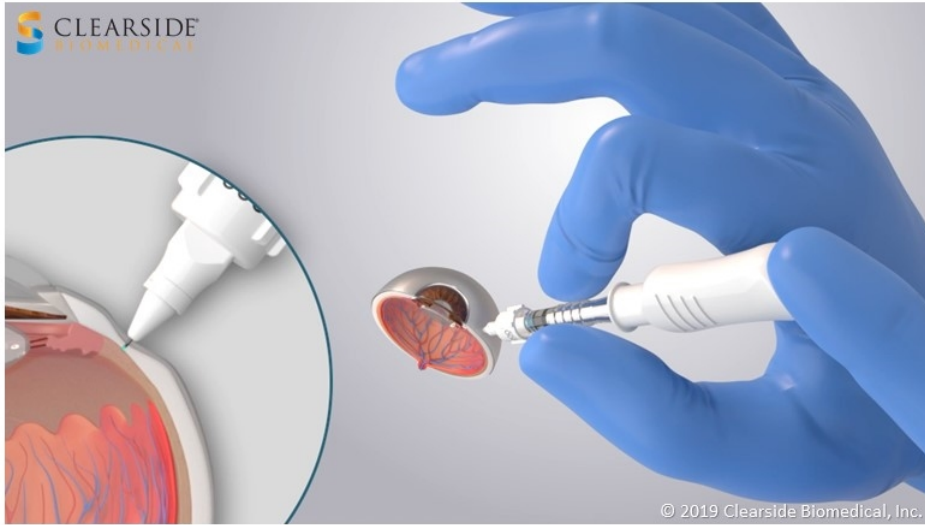
Invasive surgery with variable results

Suprachoroidal Space Injection



Novel SCS Microinjector™ allows for precise delivery into the suprachoroidal space

Exclusive Access to the Back of the Eye Using Clearside's Proprietary SCS Microinjector™



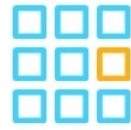
Core Advantages of Treating Via the Suprachoroidal Space



TARGETED

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

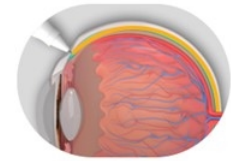
for efficacy



COMPARTMENTALIZED

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

for safety



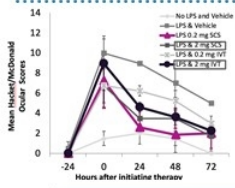
BIOAVAILABLE PROLONGED PK

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

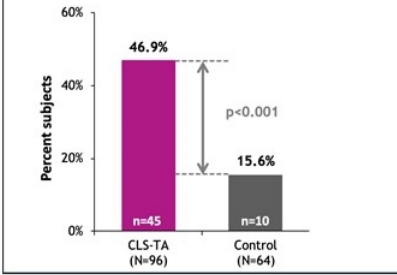
for durability

Preclinical Data Leads to Clinical Results

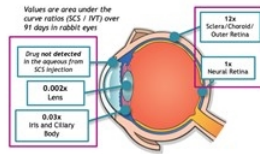
TARGETED for efficacy



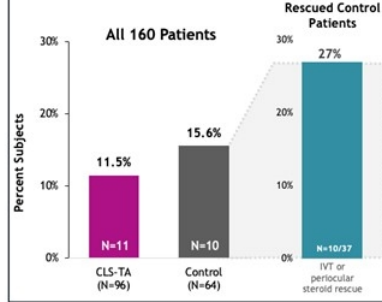
PEACHTREE Met its Primary Endpoint: Efficacy Data
Subjects gaining ≥ 15 BCVA letters from baseline, %



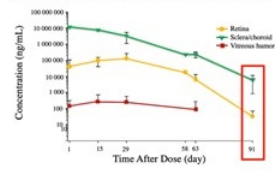
COMPARTMENTALIZED for safety



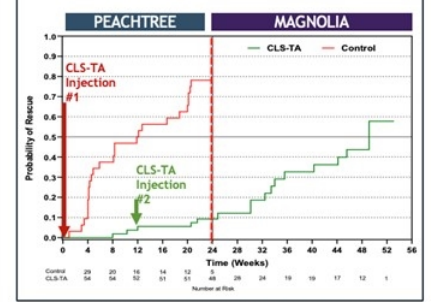
PEACHTREE IOP AE Rates: Safety Data



BIOAVAILABLE PROLONGED PK for durability



MAGNOLIA: Durability Data



Pipeline of SCS Treatments with Broad Applicability

STUDY DRUG	INDICATION	PRECLINICAL	IND-Enabling	PHASE 1/2	PHASE 3	NDA
CLS-AX (axitinib injectable suspension)	Wet AMD					
Gene Therapy	Inherited Retinal Disease					

PARTNER PROGRAMS using SCS Microinjector™

PARTNER	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
BAUSCH HEALTH	Macular edema associated with uveitis (XIPERE™)					
ARCTIC VISION	Macular edema associated with uveitis (XIPERE™)					
REGENXBIO	Wet AMD					
REGENXBIO	Diabetic Retinopathy					
AURA BIOSCIENCES	Ocular Oncology / Choroidal Melanoma					

Internal Pipeline Opportunities

Axitinib for Suprachoroidal Injection (CLS-AX): A Potential Solution for Treatment Burden

Primary Need

Durable maintenance of vision
and reduced treatment burden
in wet AMD patients

The Opportunity

- Reduce patient burden from monthly injections to every six months or longer
- Pan-VEGF inhibition potentially more efficacious than current approaches
- Improve long-term, real-world visual outcomes for patients
- Provide physicians with ability to titrate dose based on patient need
- Protect the anterior chamber from toxic exposure to TKIs

CLS-AX via SCS May Address Unmet Needs in Neovascular AMD

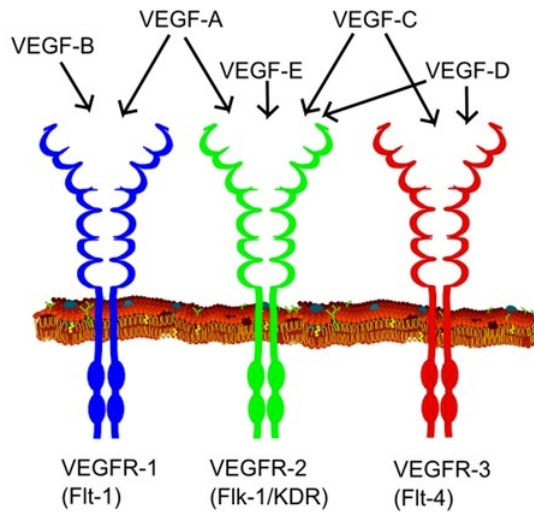


Sources: 1. Heier JS et al. Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. *Ophthalmology*. 2012;119:2537-2548. | 2. Brown DM et al. Ranibizumab versus verteporfin photodynamic therapy for neovascular age-related macular degeneration: two-year results of the ANCHOR study. *Ophthalmology*. 2009;116:57-65.e5. | 3. Rosenfeld PJ et al. Ranibizumab for neovascular age-related macular degeneration. *N Engl J Med*. 2006;355:1419-1431. | 4. Ciulla TA et al. Visual Acuity Outcomes and Anti-Vascular Endothelial Growth Factor Therapy Intensity in Neovascular Age-Related Macular Degeneration Patients: A Real-World Analysis of 49,485 Eyes. *Ophthalmol Retina*. 2019 May 25. pii: S2468-6530(19)30280-5. | 5. Rao P, Lum F, Wood K, et al. Real-world vision in age-related macular degeneration patients treated with single anti-VEGF drug type for 1 year in the IRIS Registry. *Ophthalmology*. 2018;125:522e528. | 6. Busbee BG et al. Twelve-month efficacy and safety of 0.5 mg or 2.0 mg ranibizumab in patients with subfoveal neovascular age-related macular degeneration. *Ophthalmology*. 2013;120:1046-1056. | 7. Schmidt-Erfurth U et al. Intravitreal aflibercept injection for neovascular age-related macular degeneration: ninety-six-week results of the VIEW studies. *Ophthalmology*. 2014;121:193-201.

AMD Vascular Endothelial Growth Factor Treatment Approaches

Current AMD Therapies Predominantly Focus on Binding VEGF-A

- Anti-VEGF-A increases expression of VEGF-C¹ VEGF-D²
- Broad VEGF receptor blockade may improve outcomes
- A Phase 2 study yielded better AMD outcomes with anti-VEGF-A,C,D vs anti-VEGF-A

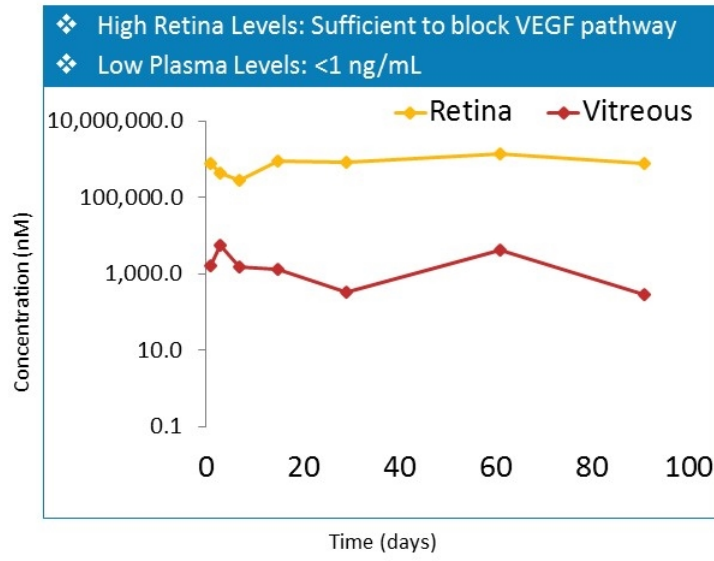


Suprachoroidal Axitinib May Improve Outcomes with Its Broad VEGF Receptor Blockade

- Inhibits VEGFR-1, VEGFR-2, VEGFR-3 receptors
- Inhibited corneal, retinal, and choroidal angiogenesis in animal models³⁻⁷
- More effective than other TKIs for experimental corneal neovascularization in animal models
- Better ocular cell biocompatibility than other TKIs⁸

Sources: 1. Cabral T et al. Bevacizumab Injection in Patients with Neovascular Age-Related Macular Degeneration Increases Angiogenic Biomarkers. *Ophthalmol Retina*. 2018 January ; 2(1): 31–37. doi:10.1016/j.oret.2017.04.004. | 2. Liu et al. The Association of Alternate VEGF Ligands with Resistance to Anti-VEGF Therapy in Metastatic Colorectal Cancer. *PLoS ONE* 8(10): e77117. | 3. Riquelme et al. Topical axitinib is a potent inhibitor of corneal neovascularization. *Clinical and Experimental Ophthalmology* 2016; 46: 1063–1074 | 4. Yuan et al. Ocular Drug Delivery Nanowafers with Enhanced Therapeutic Efficacy. *ACS Nano*. 2015 Feb 24;9(2):1749–58. | 5. Giddabasappa et al. Axitinib inhibits retinal and choroidal neovascularization in in-vitro and in-vivo models. *Exp Eye Res*. 2016; 145: 373-379. | 6. Nakano et al. Short-term treatment with VEGF receptor inhibitors induces retinopathy of prematurity-like abnormal vascular growth in neonatal Rats. *Exp Eye Res*. 2016; 143: 120-131. | 7. Kang et al. Antiangiogenic Effects of Axitinib, an Inhibitor of Vascular Endothelial Growth Factor Receptor Tyrosine Kinase, on Laser-Induced Choroidal Neovascularization in Mice. *Curr Eye Res*. 2012; 38: 119-127. | 8. Theille et al. Multikinase Inhibitors as a New Approach in Neovascular Age-Related Macular Degeneration (AMD) Treatment: In Vitro Safety Evaluations of Axitinib, Pazopanib and Sorafenib for Intraocular Use. *Klin Monatsbl Augenheilkd* 2013; 230: 247-254. | Image by Mikael Häggström, used with permission. Häggström, Mikael (2014). "Medical gallery of Mikael Häggström 2014". *WikiJournal of Medicine* 1 (2). DOI:10.15347/wjm/2014.008. ISSN 2002-4436. Public Domain.

CLS-AX: High Drug Levels Maintained in the Retina after SCS administration



Topical Axitinib More Effectively Inhibited Experimental Murine Corneal Neovascularization than Sunitinib and Sorafenib (same dose)

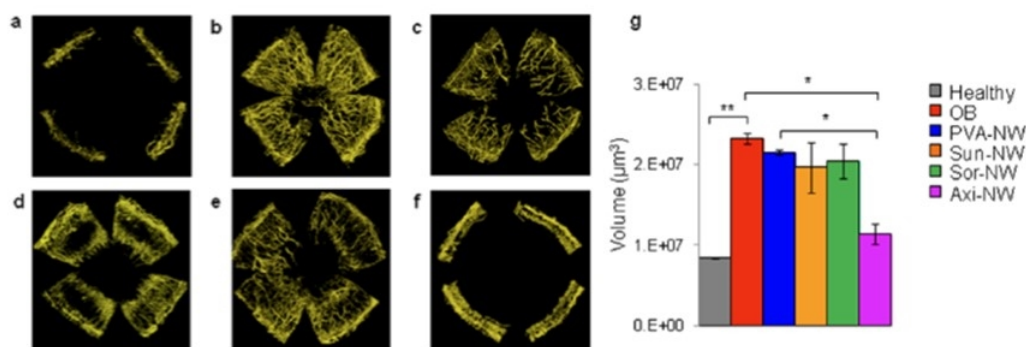
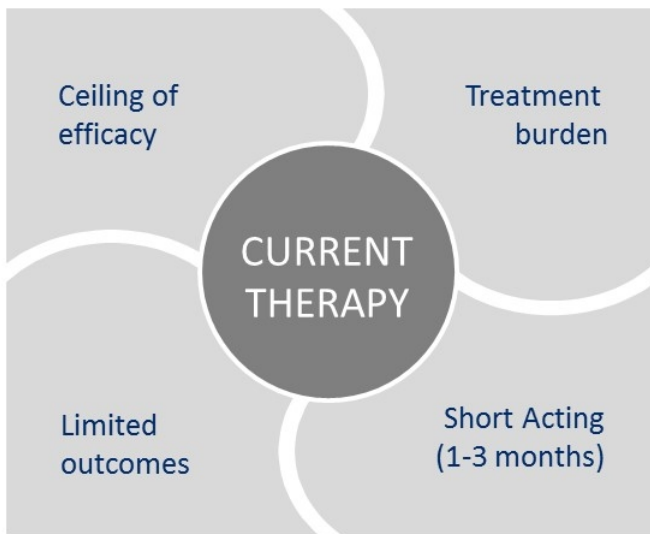


Figure 5. Selection of tyrosine kinase receptor inhibitor drugs. Screening of tyrosine kinase inhibitor drugs loaded nanowafer for their relative therapeutic efficacy in inhibiting corneal neovascularization after 10 days of treatment. Representative 3D reconstructed corneal images of fluorescence confocal microscopy: (a) healthy cornea (control); (b) untreated ocular burn (control); (c) blank PVA-NW; (d) Sora-NW; (e) Suni-NW; (f) Axi-NW. (g) Quantification of corneal neovascularization volume. $n = 3$ animals, $*P < 0.05$ vs OB control and $P < 0.05$ vs PVA-NW, $**P < 0.01$. All error bars represent standard deviation from the mean.

Potential to Disrupt the AMD Treatment Landscape

Focused VEGF Blockade



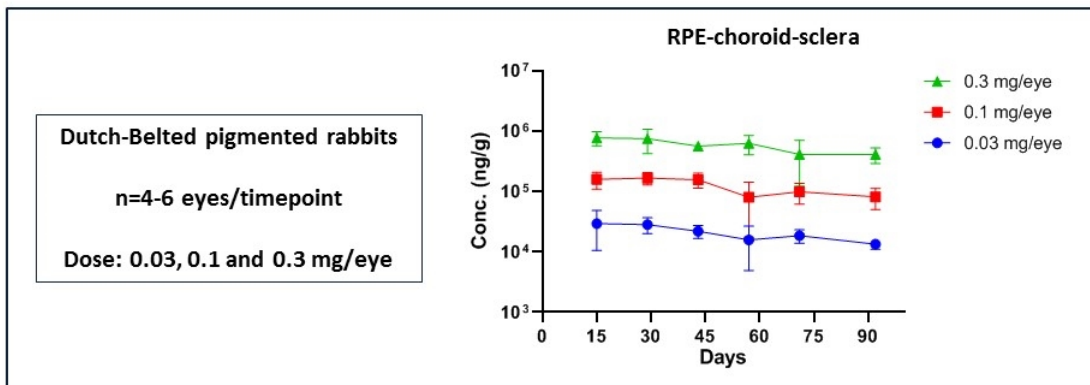
Broad VEGF Blockade



Exploratory Preclinical PK Study

Complement Inhibitor and the Suprachoroidal Space

Suprachoroidal delivery of complement inhibitor small molecule suspension resulted in **targeted, compartmentalized, and sustained ocular levels** in rabbits



- **Targeted & Compartmentalized:** High exposure for 90+ days in RPE-choroid-sclera (RCS)
- **Sustained:** Estimated half-life ($T_{1/2}$) of 66, 66, and 76 days at 0.03, 0.1, and 0.3 mg/eye level, respectively
- **Meaningful drug levels:** 3-5 orders of magnitude higher than the in-vitro (AP hemolysis assay) IC90 value (10nM)

Broad Applicability of SCS Injection Platform: Ocular Gene Therapy

Primary Need

Targeted delivery of ocular gene therapies in safe, effective, repeatable, and non-surgical manner

The Opportunity

- Avoid risks of vitrectomy (surgery)
- Avoid risks of retinotomy, subretinal injection, and macular detachment
- Deliver larger genes using non-viral vectors
- Convert gene therapy into an office-based procedure
- Potential for broader retinal coverage
- Enhance patient access

Preclinical Studies Demonstrate SCS Injections of DNA nanoparticles (DNPs) May Offer the Potential for a Safe and Efficient Delivery Method

Potential Advantages

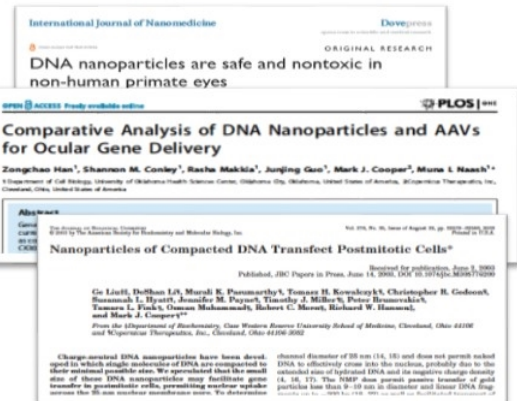
Efficacy: demonstrated in numerous ocular animal models

- Transfer large genes (up to ~20 kb)

Safety: Non-immunogenic, without viral capsid proteins or pre-existing immunity.

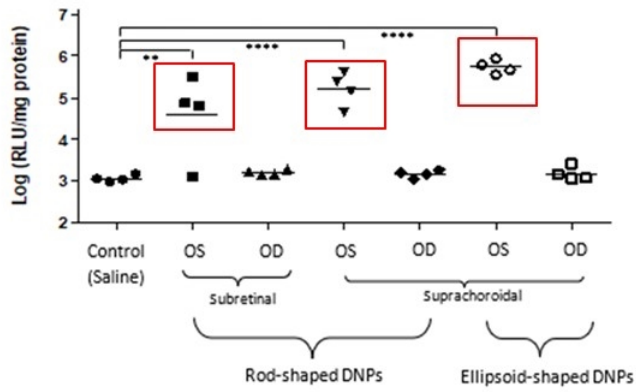
- Potential for repeat dosing facilitated by suprachoroidal injection
- Higher doses possible to enhance transfection

Well established literature on DNA nanoparticle gene therapy

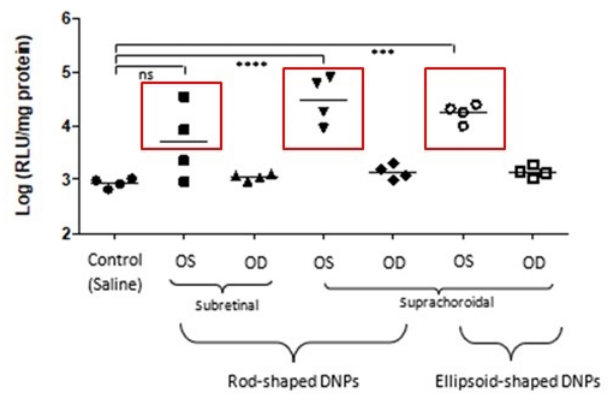


Preclinical SCS and Subretinal Injections of DNA Nanoparticles Produced Comparable Luciferase Activity

CHOROID-RPE-Sclera
Non-Viral Luciferase, Rabbit



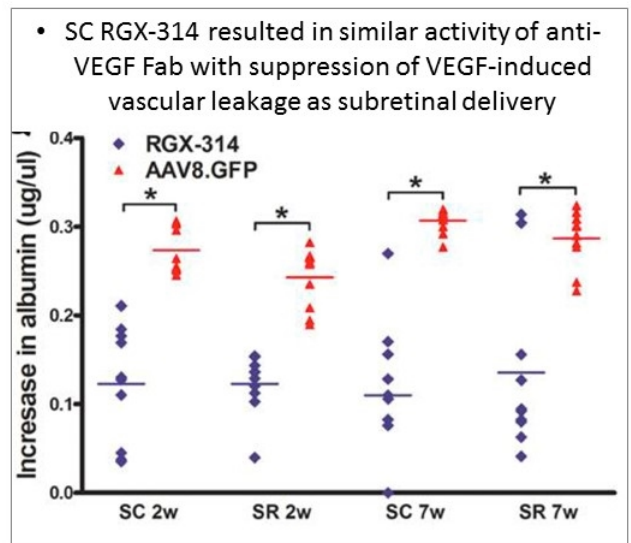
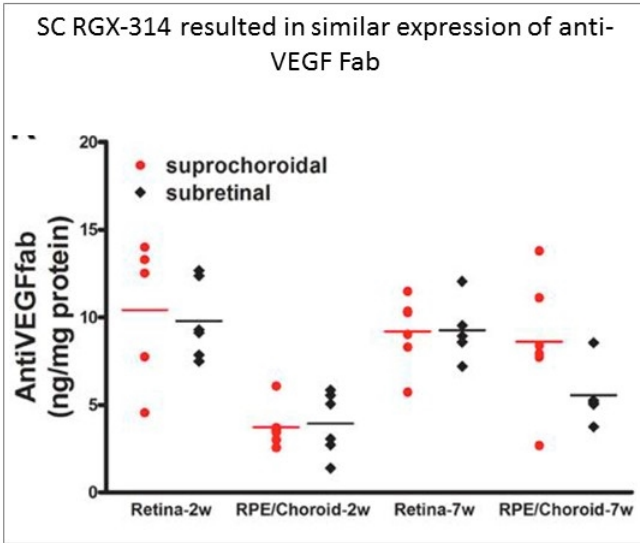
RETINA
Non-Viral Luciferase, Rabbit



DNA Nanoparticles Transfect Choroid and Retina

Published Preclinical Data on Viral Vectors in SCS

Suprachoroidal delivery of NAV AAV8-based gene therapy produced similar protein expression and suppression of vascular leakage



Corporate Collaborations

Enabling In-office Delivery of Gene Therapy for Retinal Disease

The Opportunity: Gene Therapy

- Exclusive worldwide rights to our SCS Microinjector for delivery of adeno-associated virus (AAV)-based therapeutics to the suprachoroidal space to treat wet AMD, diabetic retinopathy and other conditions for which anti-VEGF treatment is the standard of care
- Delivery of gene therapy through the SCS may provide a targeted, in-office, non-surgical treatment approach option
- Encouraging preclinical results delivering RGX-314 into the SCS

The Terms:

- \$2 million upfront / exercise of option
- Up to \$34M in development milestones across multiple indications
- Up to \$102M in sales milestones
- Mid single digit royalties on net sales of products using SCS Microinjector



REGENXBIO Initiating Two Phase 2 Trials Using SCS Microinjector™

- RGX-314 for Treatment of Wet Age-Related Macular Degeneration (AMD)
 - REGENXBIO plans to initiate Phase 2 trial of suprachoroidal delivery of RGX-314 using SCS Microinjector™ for treatment of wet AMD in **first half of 2020**.
 - Trial will build upon data from Phase 1/2a trial of RGX-314 and is expected to evaluate patients in two dose cohorts of RGX-314 versus a control arm. Interim data is expected from Cohort 1 by **end of 2020**.
- RGX-314 for Treatment of Diabetic Retinopathy (DR)
 - REGENXBIO expects to submit IND in **first half of 2020** and plans to initiate Phase 2 trial of suprachoroidal delivery of RGX-314 using SCS Microinjector for treatment of DR in **second half of 2020**.
 - Trial is expected to evaluate patients in up to three dose cohorts of RGX-314 versus control arm. Enrollment of Cohort 1 is expected to be complete by **end of 2020**, with interim data expected **in 2021**.



Optimizing Ocular Oncology Drug Delivery with SCS Microinjector™

The Opportunity: Ocular Oncology

- Non-surgical alternative to intravitreal delivery of Aura's oncology drug candidates via our SCS Microinjector
- Choroidal melanoma is the most common, primary intraocular tumor in adults
- Expect Aura to initiate clinical testing using our SCS Microinjector in the **second half of 2020**

The Terms:

- Potential future financial upside for Clearside from pre-specified development and sales milestones
- Royalties on net sales of products using SCS Microinjector

aura

Novel Approach to Targeting Uveitic Macular Edema Using SCS Microinjector™

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

BAUSCH Health

- Macular edema is the leading cause of vision loss in patients with non-infectious uveitis
- Pivotal Phase 3 PEACHTREE trial met its primary endpoint
- MAGNOLIA Phase 3 extension study demonstrated durability
- If approved, XIPERE would be the first therapy for this indication
- Expect to resubmit NDA with three months additional stability data by the end of August 2020

Maximizing Commercial Potential of XIPERE™

The Opportunity: XIPERE Commercialization & Development

- Exclusive license for XIPERE commercialization and development in the U.S. and Canada
- Right to develop and commercialize XIPERE for additional ophthalmic indications including diabetic macular edema and retinal vein occlusion
- Right to develop and commercialize a specified set of corticosteroids and non-steroidal anti-inflammatory drugs in ophthalmology using our proprietary SCS Microinjector

The Terms:

- Received \$5 million upfront payment
- Up to \$15M in FDA approval and pre-launch milestones
- Up to \$56M in milestone payments
- Tiered royalties at increasing percentages from the high-teens to 20% on annual net sales

BAUSCH Health

Maximizing Commercial Potential of XIPERE™

The Opportunity: XIPERE Commercialization & Development in Greater China and South Korea

- Exclusive license to develop and commercialize XIPERE for indications associated with uveitis in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea
- Right to develop and commercialize XIPERE for additional ophthalmic indications in Greater China and South Korea, with consent from Clearside

The Terms:

- Received \$4 million upfront payment
- Up to \$31.5M in approval, development and sales milestones
- Tiered royalties of 10% to 12% based on annual net sales starting at product launch and going until the later of ten years after launch or loss of patent protection or marketing exclusivity in the territory

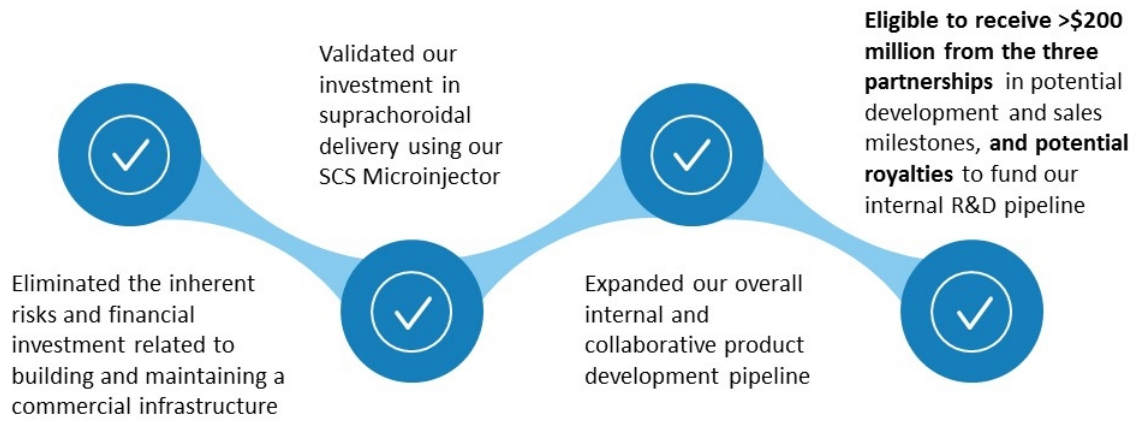


Three Partnering Deals to Drive Growth

BAUSCH+Health

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REGENXBIO



Strong Intellectual Property Coverage of SCS Platform

19 U.S. Patents Total
Expiring between
2027 - 2037

2

Methods using loss-of-resistance technology

4

Apparatus using loss-of-resistance technology

4

Apparatus having / methods using an adjustable puncture member

1

Ocular injection apparatus packaging

1

Administration of any anti-inflammatory drug to the suprachoroidal space by microinjection

3

Administration of any drug to the suprachoroidal space by microinjection

1

Administration of any drug to the eye by inserting a microinjector into the sclera

3

Methods of treating posterior ocular disorders including macular edema or uveitis

DEVICE PATENTS

DRUG PATENTS

DISEASE PATENTS

Experienced Leadership Team



GEORGE LASEZKAY
Pharm.D., J.D. | 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



RAFAEL ANDINO
VP, Engineering & Manufacturing
26 years experience
CR Bard, CIBA Vision, Dupont, GE, IBM



RICK MCELHENY
VP, Corporate Development
18 years experience
Sanofi, MEDA, Vidara



LESLIE ZACKS
General Counsel & Chief Compliance Officer
24 years experience
Arbor, Shionogi

Clearside Team Ophthalmic Experience



Research and Development Investment Highlights

Versatile therapeutic platform with proprietary access to the suprachoroidal space

Patented technology & delivery approach

Scientific presentations and publications

1Q 20

✓ *Ophthalmology*

✓ Angiogenesis

✓ Macula Society

2Q 20: ARVO

3Q 20: ASRS & Retina Society

4Q 20: AAO

Building an internal R&D pipeline

Mid 2020: IND submission for CLS-AX

2H 20: Initiation of Phase 1/2 trial for CLS-AX

Exploratory preclinical non-viral vector delivery studies ongoing

Partnering to expand use of SCS platform

REGENXBIO: RGX-314*

1H 20: Initiate Phase 2 trial in wet AMD

1H 20: Submit IND in DR

2H 20: Initiate P2 in DR

AURA: AU-011[^]

2H 20: Initiate clinical testing in choroidal melanoma

