
**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): **February 14, 2020**

OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36751
(Commission
File Number)

04-3522315
(I.R.S. Employer
Identification Number)

**5 Great Valley Parkway, Suite 160
Malvern, Pennsylvania 19355
(484) 328-4701**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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, \$0.01 par value per share	OCGN	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

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

Attached as Exhibit 99.1 and furnished for purposes of Regulation FD is a presentation that Ocugen, Inc. (“Ocugen”) will post on its website on February 14, 2020, and may use from time to time in presentations or discussions with investors, analysts and other parties.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished solely to satisfy the requirements of Regulation FD and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

Item 9.01 Financial Statements and Exhibits

The following exhibit is being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Ocugen, Inc. Presentation

SIGNATURE

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

Date: February 14, 2020

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chief Executive Officer and Chairman



Developing
Transformative Therapies
to Treat the Whole Eye

NASDAQ: OCGN

Corporate Deck



Forward Looking Statement

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our business strategy, future results of operations and financial position, prospective products, product approvals, research and development costs, timing and likelihood of success, estimated market size or growth, and plans and objectives of management for future operations, are forward-looking statements. When used in this presentation, the words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements involve known and unknown risks, uncertainties and other factors, including those risks set forth in the Company’s filings with the Securities and Exchange Commission, which are available at www.sec.gov, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements are based on our management’s beliefs and assumptions and on information available to management as of the date of this presentation. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

This presentation includes estimates by us of statistical data relating to market size and growth and other estimated data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. This presentation also includes statistical and other industry and market data that was obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.



Company Highlights

OCGN
(NASDAQ)

Strong
Global IP

Diversified
Portfolio

THREE WAVES OF TECHNOLOGICAL INNOVATION



SMALL MOLECULE PHASE 3 RARE DISEASE ASSET
OCU300 for ocular Graft Versus Host Disease (oGVHD)



MODIFIER GENE THERAPY PLATFORM
OCU400 for Inherited Retinal Diseases
OCU410 for Dry AMD



NOVEL BIOLOGIC THERAPIES FOR RETINAL DISEASES
OCU200 for DME, Diabetic Retinopathy, Wet AMD

Strategic Gene Therapy
Manufacturing Partnershi



CanSinoBIO

Experienced Leadership Team

- Diverse experience in large pharma, signature biotech, and small companies
- Development, Manufacturing and Commercialization expertise provides know-how to take pipeline from preclinical to market



Shankar Musunuri, PhD, MBA

Chairman, CEO and Co-Founder



Sanjay Subramanian, MBA

Chief Financial Officer



Daniel Jorgensen, MD, MPH, MBA

Chief Medical Officer



Kelly Beck, MBA

Vice President, Investor Relations & Administration



Rasappa Arumugham, PhD

Chief Scientific Officer















Vijay Tammara, PhD

Senior Vice President, Regulatory & Quality



Three Waves of Technological Innovation

	Indication		Prevalence (US)	Preclinical	Phase 1	Phase 2	Phase 3
OCULAR SURFACE DISEASE (small molecule)							
OCU300	oGVHD		63,000				
MODIFIER GENE THERAPY PLATFORM							
OCU400 <small>NR2E3-AAV</small>	NR2E3 Mutation-Associated Retinal Degeneration		500-600				
	CEP290 Mutation-Associated Retinal Degeneration		2,500-3,000				
	Rhodopsin Mutation-Associated Retinal Degeneration		10,400-12,700				
OCU410 <small>RORA-AAV</small>	Dry AMD		9-10M				
RETINAL DISEASES (novel biologics)							
OCU200 <small>Tumstatin-Transferrin</small>	Diabetic Macular Edema		745,000				
	Diabetic Retinopathy		7.7M				
	Wet AMD		1.1M				

OCU300: oGVHD

***Near-term Commercialization Opportunity
Potential to be First FDA Approved Treatment***

OCU300 for oGVHD: Unmet Need for Patients with Rare Ocular Disease

Ocular Graft vs Host Disease (oGVHD)

- Autoimmune disease that occurs in allogeneic bone marrow transplant (BMT) patients
 - Donor derived leukocytes attack recipient ocular tissue
- Patients encounter dry, tearless eyes, vision issues, severe pain, discomfort, and potential ocular scarring
- May lead to significant vision loss and irreparable ocular surface damage

Ocugen is the **first and only company to receive orphan drug designation** from FDA for treatment of oGVHD

~60% of allogeneic bone marrow transplant patients will develop oGVHD

~63,000 patients in the US



~3-6 months from transplant is when patients will develop oGVHD

Top 30 BMT centers treat majority of patients with oGVHD



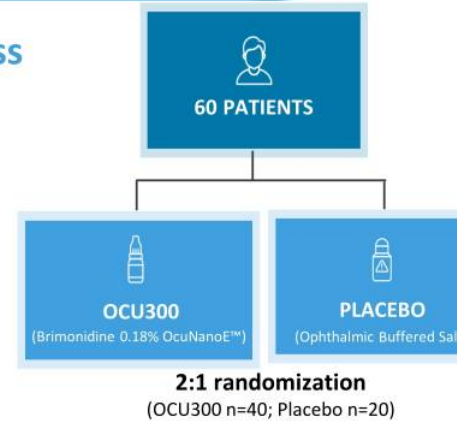
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Source: Prevalence of Hematopoietic Cell Transplant Survivors in the United States, Majhail N et al Oct 2014
Source: <https://bethematch.org/tcdirectory/search/advanced/#-/-/false/-/TotalTransplants->

Phase 3 Study With Topline Results Expected 2H2020

Indication: Treatment of ocular discomfort and ocular redness in patients with oGVHD

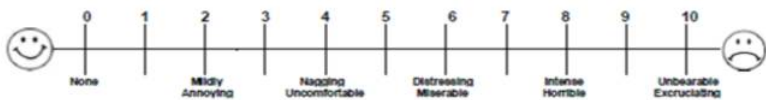
- 84-day, Randomized, Double-Masked, Placebo-Controlled Study
- Key inclusion criteria: diagnosis of 'definite' oGVHD using the International Chronic Ocular GVHD Consensus Group revised diagnostic criteria (Ogawa, 2013)
- Patients referred to specialty BMT centers; 10+ centers are active in this study



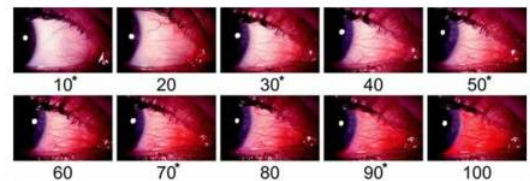
Co-primary endpoints include:

- **Symptom:** Ocular discomfort based on Visual Analog Scale (VAS)

On a scale from 0-10, what was the intensity of your Ocular Discomfort, at its worst, over the past 24 hours?



- **Sign:** Ocular redness based on Validated Bulbar Redness (VBR) Score



Active Ingredient Proven Safe and Effective

Safety

Existing Molecule (Brimonidine)

- 505(b)(2) regulatory pathway allows use of safety data already available for brimonidine
- Brimonidine approved for chronic treatment in glaucoma

Efficacy

Early stage clinical studies led to Phase 3 design

OcuNanoE™ drug delivery system improves overall efficacy

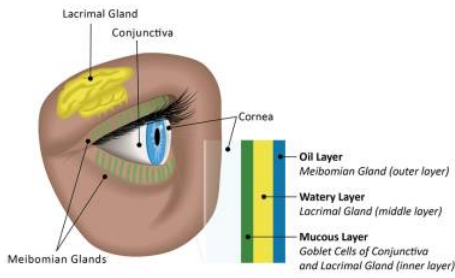
OCU300 is preservative-free (no BAK)

- BAK (benzalkonium chloride) is damaging to the cornea

Generic substitution prohibited

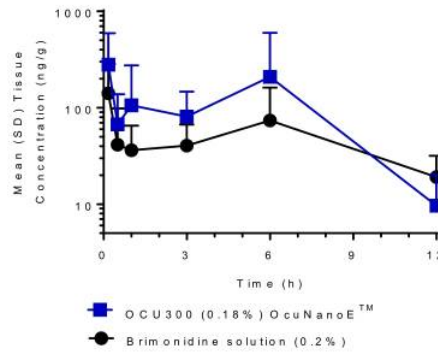
- Generic brimonidine (0.2%) not approved for oGVHD
- Concentration/formulation different from OCU300
- Contains BAK preservative
- OCU300 completing controlled studies in oGVHD patients
- AB criteria not applicable

OcuNanoE™ Drug Delivery System Improves Overall Efficacy

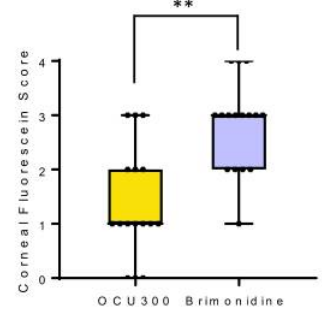


Drug distribution to lacrimal gland from traditional eye drops is low relative to other target tissues

Brimonidine Level in Lacrimal Gland (Preclinical)



Mouse DED Model (Preclinical)



- OCU300 = Brimonidine (0.18%) OcuNanoE™
- Brimonidine = Commercial 0.2% solution
- Figure shows median, interquartile range & min/fluorescein score
- **p<0.01

OcuNanoE™ increases brimonidine in lacrimal gland and improves overall efficacy of OCU300

OCU300 has Compelling Value Proposition

Patients



Physicians



Market Access



Market Potential



- Spend **3 months** in hospital after receiving **bone marrow transplant**
- Most **exhibit symptoms** while still **under hematologist/oncologist care**

- **Hematologists/Oncologists** are **first prescribers**, then referred to **specialized ophthalmologists**
- Hematologists looking for **approved therapy**; no knowledge of off-label options

- **No** approved therapy
- Seek to establish **ICD-10** diagnostic code
- Analysis supports **premium pricing**
- Opportunities to **partner** for **commercialization**

- Potential to be **first approved product** in US market
- First and only company to receive **Orphan Drug Designation** for oGVHD
- Advances in hematopoietic transplantation leading to **increase in number of transplant survivors**

~63,000 Patients

Targeted BMT Centers

Premium Pricing

Orphan Drug



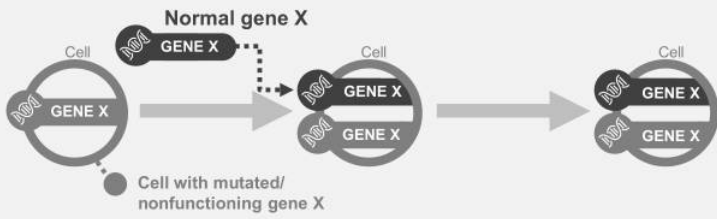
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**Breakthrough Modifier Gene Therapy Platform
Addressing Multiple Diseases with One Product**

Potential to Treat Many Diseases with One Product

Gene Augmentation: Transfer functional version of a non-functional gene into the target cells.

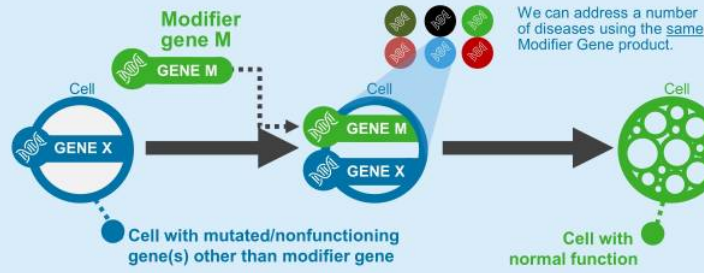


Traditional Gene Therapy



- ✓ Traditional approach that targets one individual gene mutation at a time
- ✓ Regulatory pathway focused on specific product for one disease
- ✓ Longer time to recoup development costs

Modifier Gene Therapy: Introduce a functional gene to modify the expression of many genes, gene-networks and reset homeostasis.



OCU400

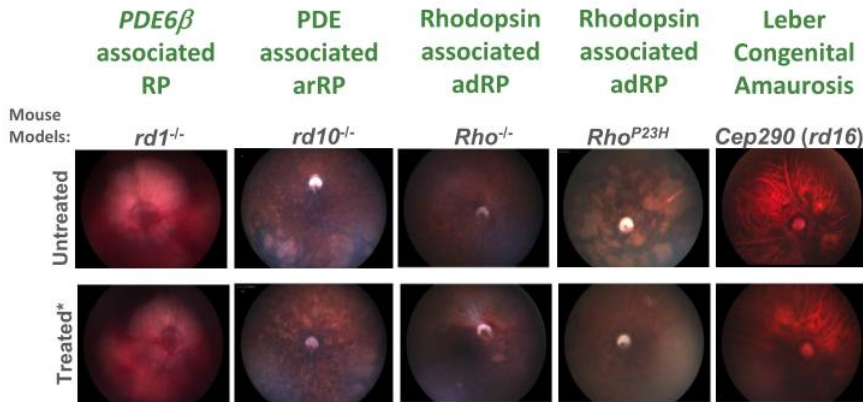


- NR2E3 Mutation-Associated Retinal Disease
- CEP290 Mutation-Associated Retinal Disease
- Rhodopsin Mutation-Associated Retinal Disease

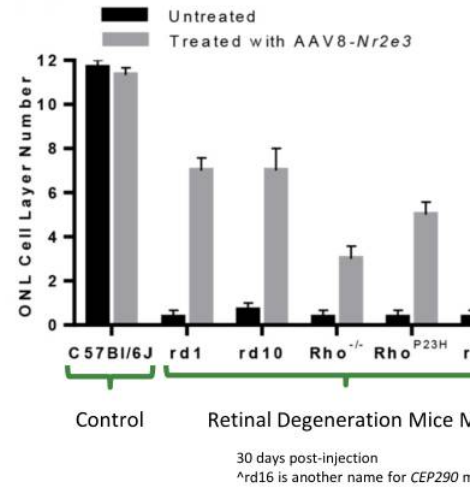
- ✓ Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina
- ✓ Smoother regulatory pathway due to ability to target multiple diseases with one product
- ✓ Ability to recoup development costs over multiple therapeutic indications

OCU400 (NR2E3-AAV) Rescues Vision Loss in Multiple Inherited Retinal Diseases (IRDs)

Human Disease:



*Treated fundus photos: subretinal single injection



One Product Rescues Multiple IRDs after onset



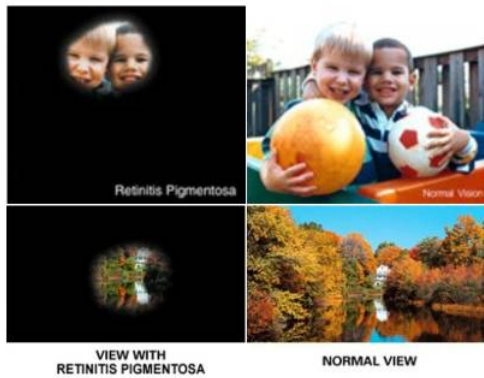
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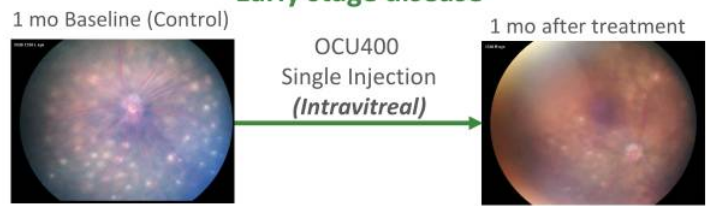
OCU400: Orphan Drug Designation

NR2E3 Mutation-Associated Retinal Degeneration

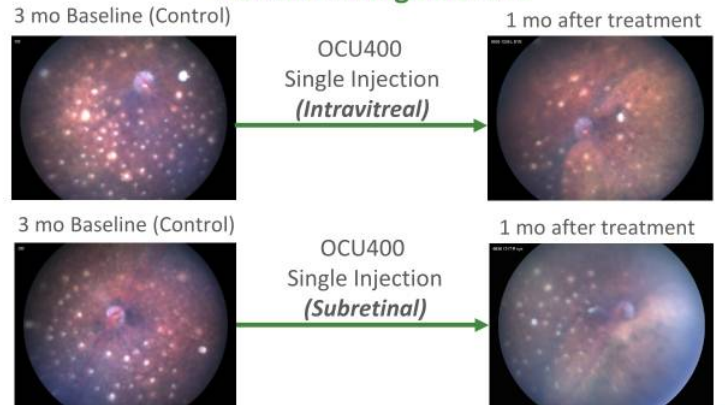


Our First Potentially Transformative Gene Therapy Candidate Bringing Hope to Patients with No Current Treatment Options

Early stage disease



Advanced stage disease



Gene Therapy Manufacturing: Plagued by Backlog and Timing Delays

Cell & gene therapy manufacturing demand continues to increase

- 1,060 clinical trials globally; 80 cell and gene therapy trials in Phase 3
- Large pharma acquiring companies to support internal programs
 - eg: Roche acquired Spark; Pfizer acquired Bamboo; Celgene acquired Juno
- Others being acquired by major CMOs to establish their presence in the gene therapy
 - eg: Thermo Fisher acquired Brammer Bio; Catalent acquired Paragon



Gene therapy companies facing manufacturing bottleneck & costs

- Long wait in the queue for CMO while large pharma can bypass (due to scope and financial power)
- Traditional CMO model not appropriate for implementing specialized process optimization steps
- High cost for the CMC development and clinical supplies; approximately:
 - \$7M - \$10M for Phase 1
 - \$8M - \$10M for late stage
 - \$10M - \$15M for scale-up development for commercialization/BLA filing

Critical to find a Strategic and Reliable Partner that also shares costs

OCU400 Gene Therapy Manufacturing: Strategic Partnership with CanSinoBIO

CanSinoBIO

- Biotech company publicly-listed on Hong Kong exchange (6185.HK) with market cap of ~\$2 Billion USD
- State-of-the-art facilities with world class team
- Provides scalable GMP cell lines (such as HEK293 suspension culture adopted) for commercial manufacturing

CanSinoBIO to perform CMC development & manufacturing of clinical supplies

- CanSinoBIO responsible for all associated costs
- Option for commercial manufacturing agreement

CanSinoBIO has rights to develop, manufacture and commercialize OCU400 for Greater China market



Partnership paves a path for Ocugen to advance OCU400 into the clinic
with significantly reduced capital and resources

OCU410 (RORA-AAV): Dry AMD

Dry Age-Related Macular Degeneration (AMD)

- Leads to irreversible blindness due to degeneration of the retina

~9-10M patients in the US



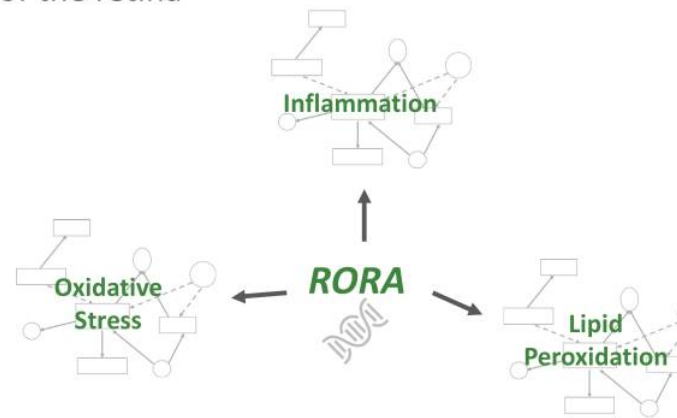
Normal Retina



Dry AMD

Contributing Factors

- Aging
- Genetics
- Environmental Factors



Currently no approved treatment for Dry AMD

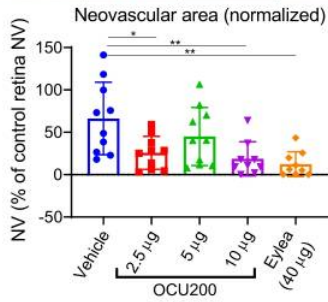
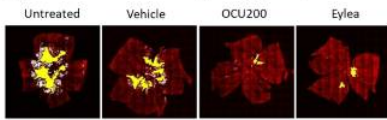
**OCU200: Diabetic Macular Edema (DME)
Diabetic Retinopathy (DR)
Wet AMD**

***Novel Biologic Offering Benefits Beyond
Anti-VEGF***

OCU200: Tumstatin-Transferrin Fusion Protein

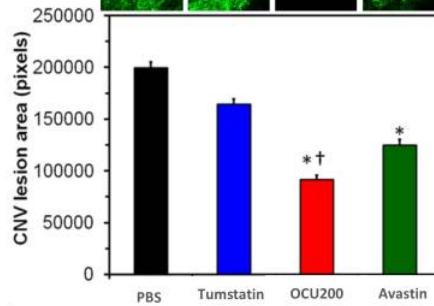
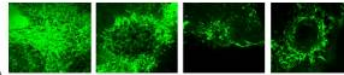
- Inhibits new blood vessel formation
- Anti-inflammatory
- Anti-oxidative

DME/DR Oxygen-Induced Retinopathy (OIR) Mouse Model



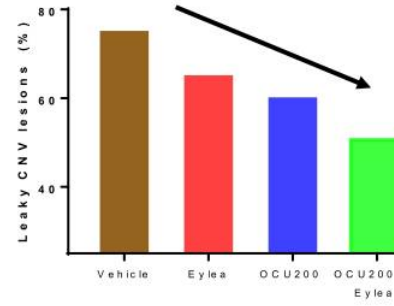
Effect of OCU200 intravitreal treatments on Neovascularization (NV). Data are presented as mean ± SD. Filled circles represent data points from individual eyes
* P < 0.05, ** P < 0.01 (n = 9-10 eyes per group)

Wet AMD In-Vivo Laser-Induced Rat CNV Model



* indicates p<0.05 when compared to PBS and/or tumstatin treatment
† indicates p<0.05 when compared to Avastin; CNV lesions measured on day 14 after treatment

Wet AMD In-Vivo Laser-Induced Mouse CNV Model



Data expressed as percentage of CNV lesions on Day 10 after treatment. Laser induction & treatment start on Day 0

OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies



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Summary of Near-Term Milestones

OCU300 ocular GVHD <i>(Phase 3 small molecule)</i>	OCU400 (NR2E3-AAV) Retinal Degenerative Diseases <i>(gene therapy)</i>	OCU200 DME, DR, Wet AMD <i>(novel biologic)</i>
<ul style="list-style-type: none"> ✓ Dec 2019: 50% Enrollment Achieved • 1H2020: Expected Completion of Enrollment • 2H2020: Topline Results Expected 	<ul style="list-style-type: none"> ✓ Feb 2019: Pre-IND Meeting ✓ Feb 2019: ODD for NR2E3 Mutation-Associated Retinal Diseases ✓ Aug 2019: ODD for CEP290 Mutation-Associated Retinal Diseases ✓ Sept 2019: CanSinoBIO Co-Development & Manufacturing Partnership • 2019-2020: Continue IND-Enabling Studies • 2021: Target Phase 1/2a Clinical Trial 	<ul style="list-style-type: none"> • 2019-2020: Continue IND-Enabling Studies • 2021: Target Phase 1/2a Clinical Trial

Note: Check mark (✓) denotes completed milestone. All other milestones are anticipated future milestones.



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A Bold Vision to Treat the Whole Eye

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