
**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 3, 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

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 June 3, 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 the 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

<u>Exhibit No.</u>	<u>Document</u>
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: June 3, 2020

OCUGEN, INC.

By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chief Executive Officer and Chairman



Our Mission is to develop
Gene Therapies to Cure
Blindness Diseases

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 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 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

CUTTING-EDGE TECHNOLOGY PLATFORM



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



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

Strategic Gene Therap
Manufacturing Partners



CanSinoBIO



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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



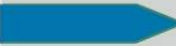
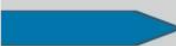




<p>Shankar Musunuri, PhD, MBA Chairman, CEO and Co-Founder</p>			
<p>Sanjay Subramanian, MBA Chief Financial Officer</p>			
<p>Daniel Jorgensen, MD, MPH, MBA Chief Medical Officer</p>			
<p>Rasappa Arumugham, PhD Chief Scientific Officer</p>			
<p>Vijay Tammara, PhD Senior Vice President, Regulatory & Quality</p>			
<p>Kelly Beck, MBA Vice President, Investor Relations & Administration</p>			



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Pipeline Overview

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

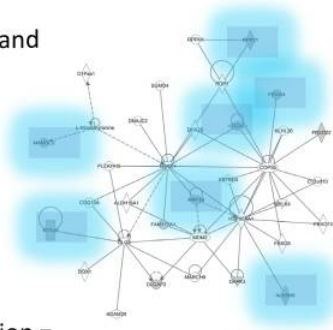




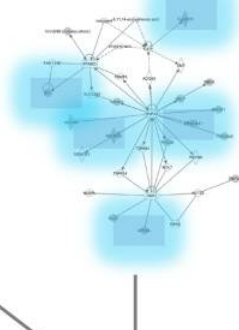
**Breakthrough Modifier Gene Therapy Platform
Addressing Multiple Diseases with One Product**

Nuclear Hormone Receptor Genes (NHRs) are Important Modulators of Retinal Development & Function

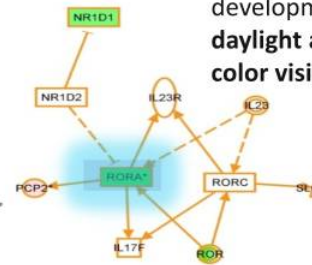
Inflammation and Cell Survival



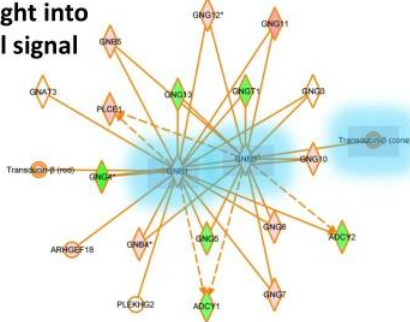
Metabolism = energy



Cone cell development
daylight ; color vision

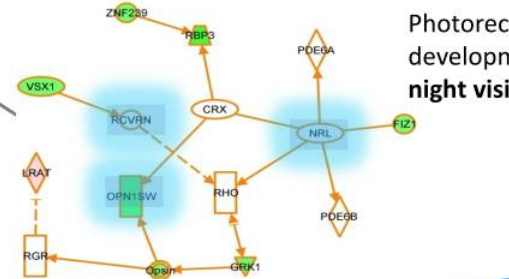


Phototransduction = translates light into an electrical signal



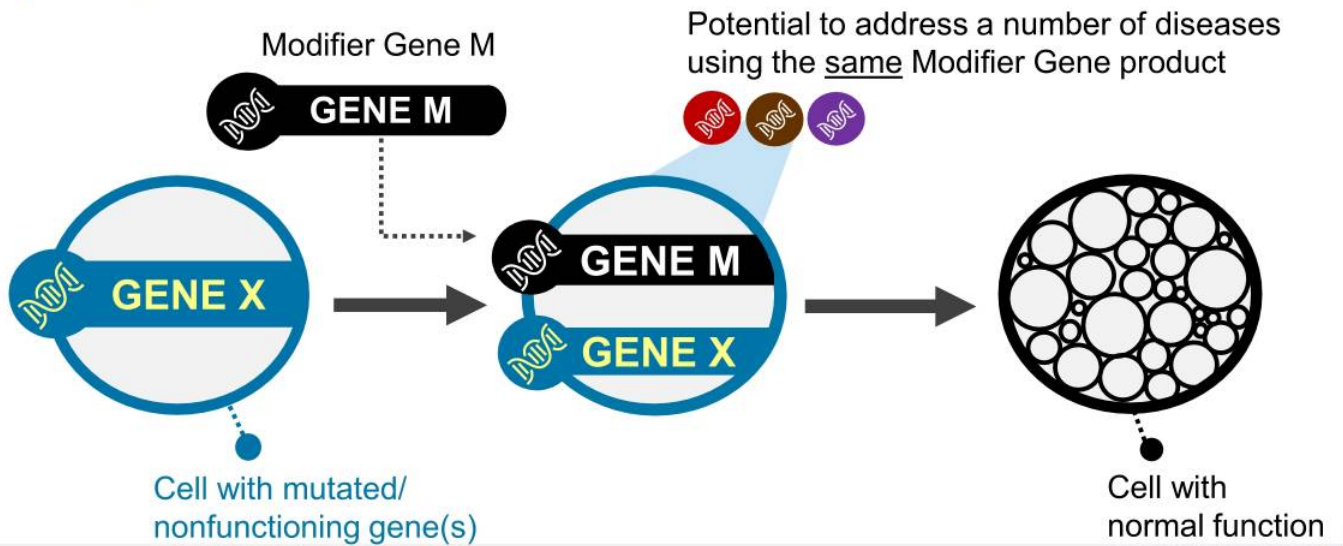
NR2E3
NR1D1
RORA

Photoreceptor development
night vision



Potential to Treat Many Diseases with One Product

Modifier Gene Therapy: Introduce a functional gene to modify the expression of many genes and gene-networks, and regulate basic biological processes in retina



Preclinical Data Published in *Nature Gene Therapy*

Efficacy results in 5 unique mouse models of retinitis pigmentosa (RP)

Underwent administration of AAV-NR2E3 by subretinal injection

Study demonstrates potency of novel modifier gene therapy to elicit broad-spectrum therapeutic benefits in early and intermediate stages of RP

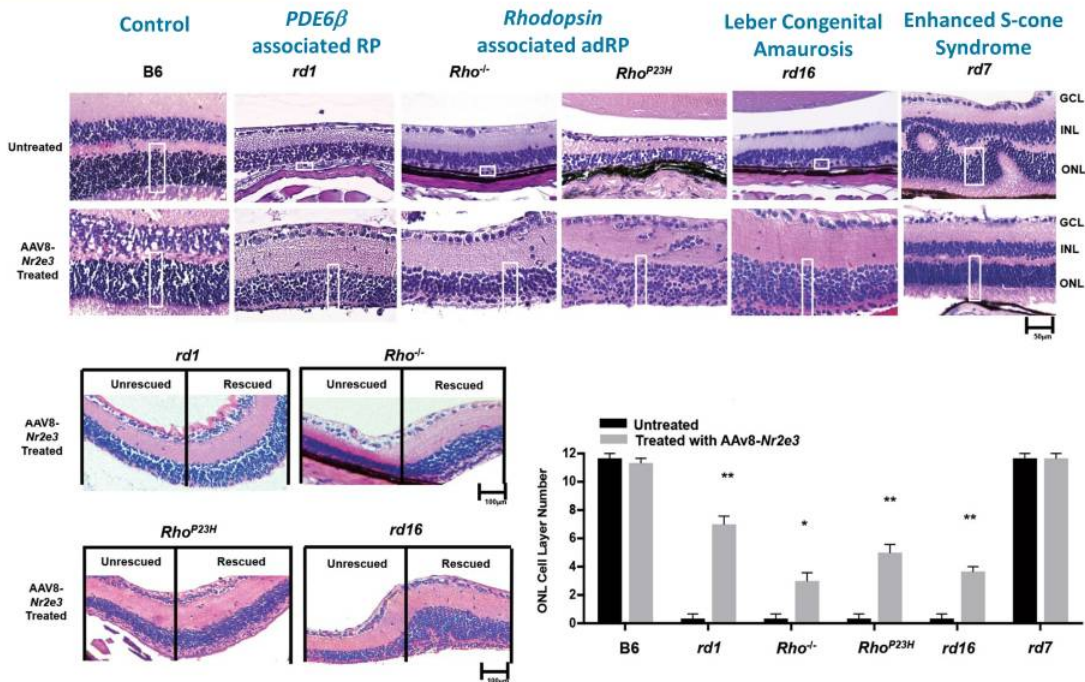
- Important milestone for development of therapy; demonstrated proof of principle
- Protection elicited in multiple animal models of degeneration caused by different mutations
- Potential to represent first broad-spectrum therapy and to provide rescue even after disease on



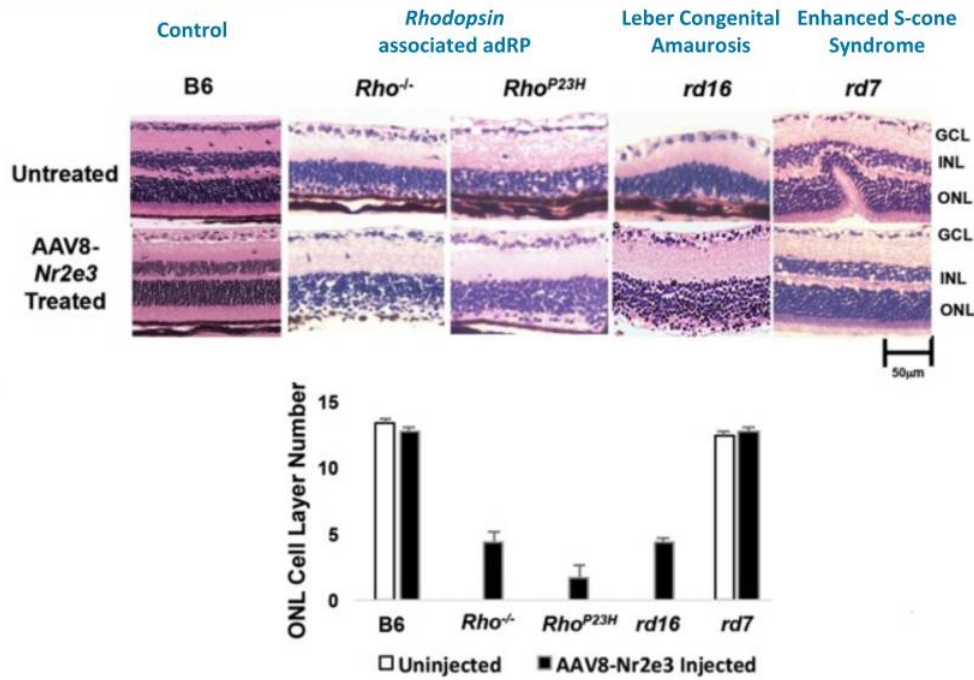
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natureresearch <https://www.nature.com/articles/s41434-020-0134-z>

OCU400 Preserves Photoreceptors in Early Stage of Disease



OCU400 Preserves Photoreceptors in Advanced Stage of Disease

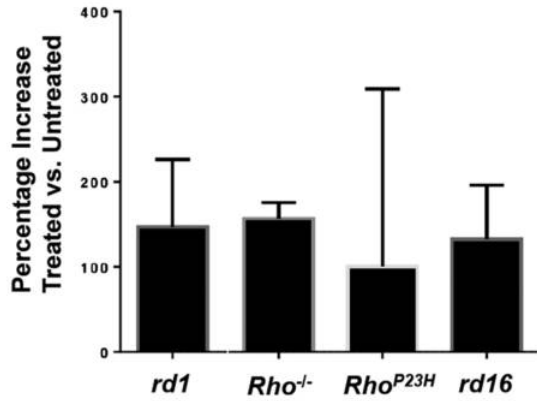


Retina histology

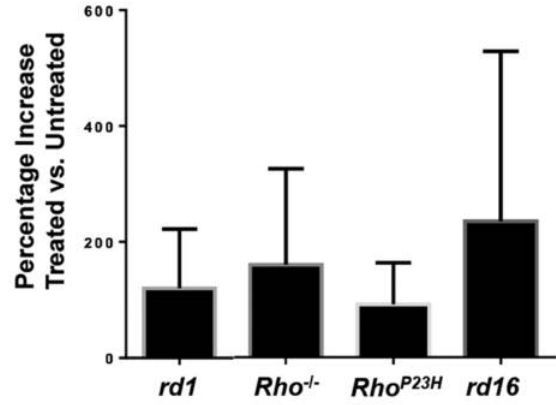
- Animals injected at P21 and evaluated 2–3 months post-injection
- Restored ONL photoreceptor morphology in $rd7$
- ONL cell layer change in $rd7$ model doesn't progress until 4-5 mos. of age

OCU400 Demonstrates Improved Vision Signals in Retina

Scotopic ERG B-wave Percentage Increase



Photopic ERG B-wave Percentage Increase



- ERG response: P0 single subretinal injection, evaluation 3-4 months post injection
- rd1 evaluated 1- month post injection

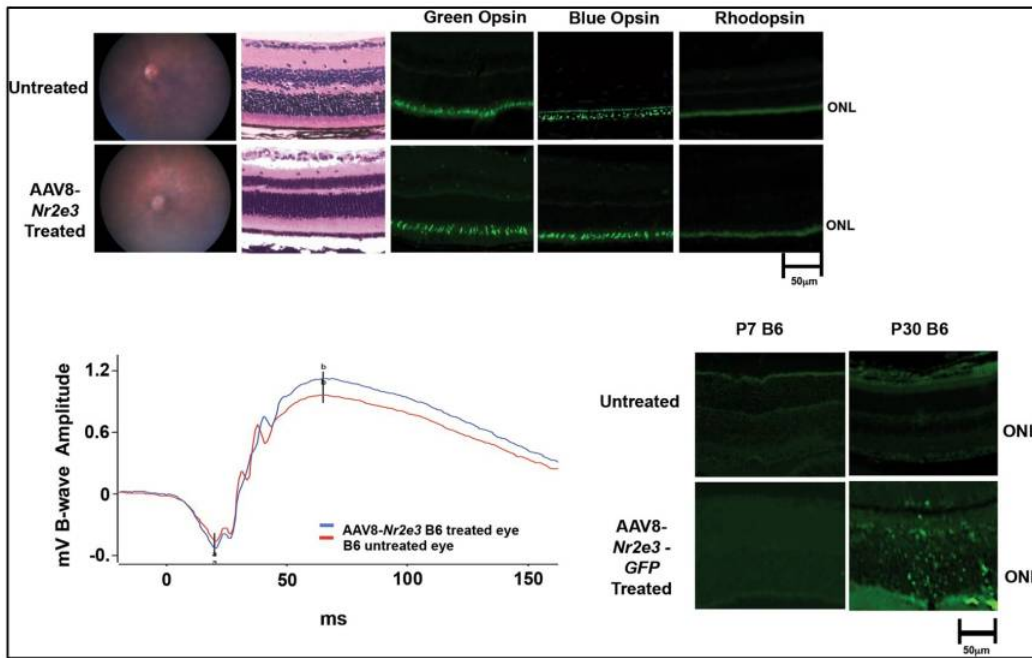


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nature research

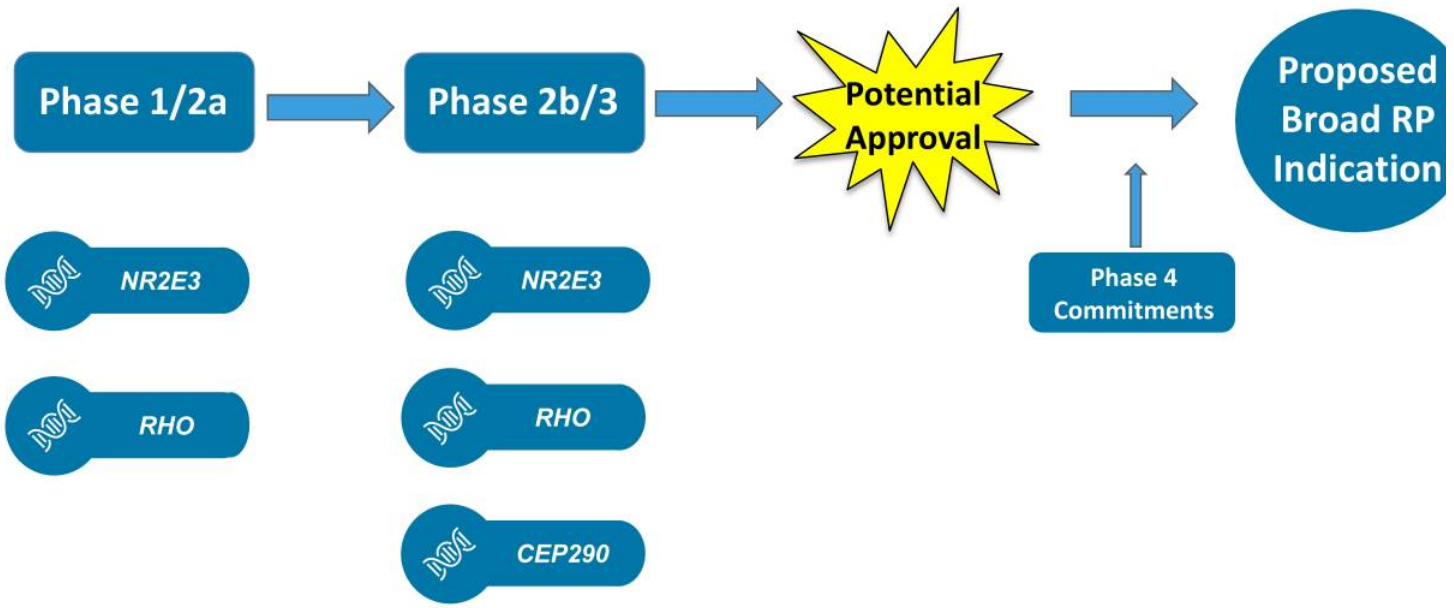
<https://www.nature.com/articles/s41434-020-0134-z>

OCU400 Demonstrated Safety in Mouse Model



Study results confi
overexpression o
Nr2e3 by subretin
AAV8-*Nr2e3* injecti
is not detrimental
retina

OCU400 Regulatory Strategy



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 ~\$7 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 (AAV-RORA): Dry AMD

Dry Age-Related Macular Degeneration (AMD)

- Leads to irreversible blindness due to degeneration of the retina

~9-10M patients in the US



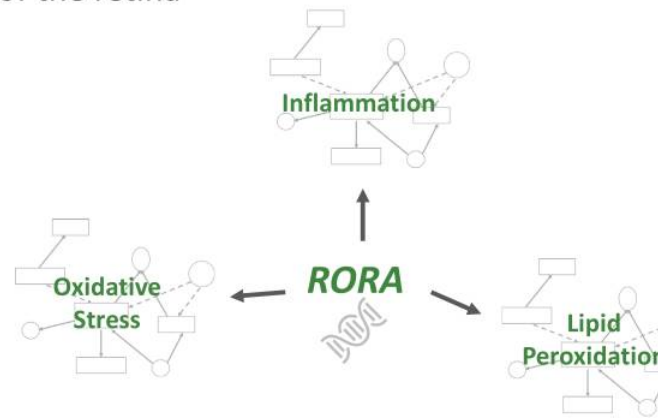
Normal Retina



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***

DME, DR & Wet AMD are Leading Causes of Blindness

Diabetic Macular Edema (DME)

Diabetic Retinopathy (DR)

Wet AMD

- Most common causes of vision loss in patients with diabetes and aging population
- Anti-VEGF & corticosteroids therapies not effective in approximately 50% of patients
- Leakage and fluid accumulation continues in sub-retinal space even after many months of treatment

~745,000 DME patients in the US



~7.7M DR patients in the US



~1.1M Wet AMD patients in the US



Targeting Integrin Pathways Offer New Opportunities



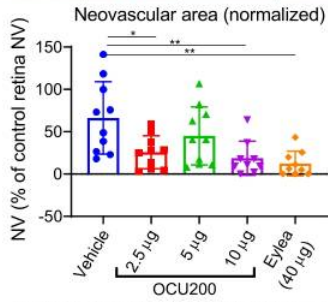
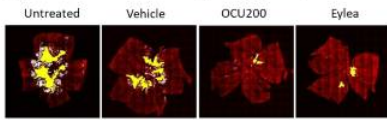
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OCU200: Tumstatin-Transferrin Fusion Protein

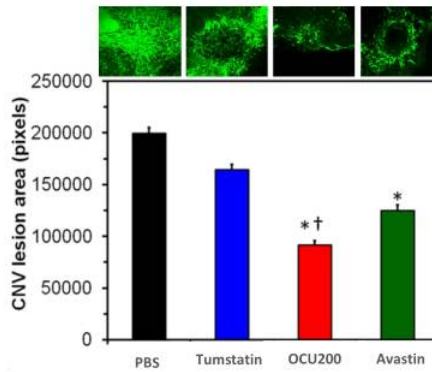
- Inhibits new blood vessel formation
- Anti-inflammatory
- Anti-oxidative

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



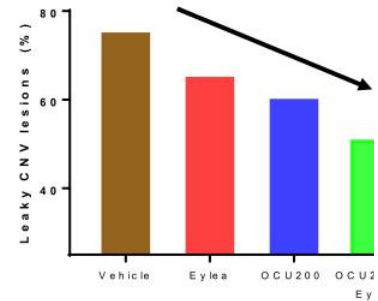
Effect of OCU200 intravitreal treatments on Neovascularization (NV). Data are presented as mean ± SD. Filled circles represent data points from individual eyes
* P < 0.05, ** P < 0.01 (n = 9-10 eyes per group)

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 Mo



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

OCU400 (AAV-NR2E3) Retinal Degenerative Diseases <i>(gene therapy)</i>	OCU410 (AAV-RORA) Dry AMD <i>(gene therapy)</i>	OCU200 DME, DR, Wet AMD <i>(novel biologic)</i>
<ul style="list-style-type: none">✓ Mar 2020: Preclinical Data Published in Nature Gene Therapy• 2020: Continue IND-Enabling Studies✓ Initiated Tox Studies• 2021: Target Phase 1/2a Clinical Trial	<ul style="list-style-type: none">• 2020-2021: Continue IND-Enabling Studies• 2022: Target Phase 1/2a Clinical Trial	<ul style="list-style-type: none">• 2020-2021: Continue IND-Enabling Studies• 2022: 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 Cure Blindness Diseases with Gene Therapies

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