# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

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# FORM 8–K

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**CURRENT REPORT**
**Pursuant to Section 13 OR 15 (d)**
**of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **October 20, 2020**

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# OCUGEN, INC.

(Exact Name of Registrant as Specified in its Charter)

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| **Delaware** | **001-36751** | **04-3522315** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (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<br>(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 2.02 Results of Operations and Financial Condition**

The corporate presentation of Ocugen, Inc. ("Ocugen"), which Ocugen will post on its website on October 20, 2020 and is attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Corporate Presentation"), contains on slide 21 certain preliminary estimates of Ocugen's cash and cash equivalents and principal amount of indebtedness outstanding each as of September 30, 2020 (the "Preliminary Estimates").

The Preliminary Estimates should not be viewed as a substitute for interim financial statements prepared in accordance with U.S. GAAP. The Preliminary Estimates are based on preliminary unaudited information and management estimates for the quarter ended September 30, 2020, are not a comprehensive statement of our financial results, and are subject to completion of our financial closing procedures. As a result, these Preliminary Estimates may differ from the actual results that will be reflected in our financial statements when they are completed and publicly disclosed. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of and for the quarter ended September 30, 2020. Our independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these Preliminary Estimates.

The information disclosed under this Item 2.02 (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, and shall not be deemed to be incorporated by reference in any Company filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 7.01 Regulation FD Disclosure**

The Corporate Presentation is hereby furnished for purposes of Regulation FD. Ocugen will post the Corporate Presentation on its website on October 20, 2020 and may use the Corporate Presentation from time to time in presentations or discussions with investors, analysts and other parties.

As of October 15, 2020, there were 162,026,473 shares of Ocugen's common stock outstanding.

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 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 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: October 20, 2020

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chief Executive Officer and Chairman

ocugen

# Our Mission is to Develop **Gene Therapies** to Cure Blindness Diseases

NASDAQ: OCGN

Corporate Deck: Oct 2020

# 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 statem When used in this presentation, the words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "projec "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying wo

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 Excl 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 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 state 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 tha obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally in 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 belie 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 secur 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 sec shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

# Ocugen Overview

## Developing transformative therapies with the potential to cure blindness diseases

**OCUGEN'S BREAKTHROUGH MODIFIER GENE THERAPY PLATFORM**

- Modifier Gene Therapy Platform – potential for one product to treat many diseases & multi-factor approach
- Technology developed at Dr. Neena Haider's Lab, Harvard Medical School (POC study results published in Nature
- **OCU400 (AAV-*NR2E3*):** 4 FDA Orphan Drug Designations with the potential to treat broad Retinitis Pigmentosa (I which has over 150 gene mutations, in lieu of developing separate therapies for each mutation under traditional therapy – initiation of Phase 1/2a within a year
- **OCU410 (AAV-*RORA*):** Potential to treat dry age-related macular degeneration (Dry AMD) through multi-factor treatment approach – initiation of Phase 1/2 in 2022
- Strategic manufacturing partnership with CanSinoBio (~$7B market cap) – sets clear path for critical manufacturi

**NOVEL BIOLOGIC**

- **OCU200:** Targeting major retinal diseases: Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Wet A Related Macular Degeneration (Wet AMD) – initiation of Phase 1/2 in 2022
- Novel mechanism of action (MOA) – integrin targeting
- Potential to initially treat non-responders to anti-VEGF/corticosteroids therapies totaling approximately 50% of t patient population of DME, DR and Wet AMD (estimated total current global market size over $10B)

## Multiple near and mid-term milestones

- Plan to initiate four Phase 1/2 trials within 1-2 years, with data readouts beginning in 2022

# Experienced Leadership Team

## Leadership Team

**Shankar Musunuri, PhD, MBA**
*Chairman, CEO and Co-Founder*

**Rasappa Arumugham, PhD**
*Chief Scientific Officer*

**Vijay Tammara, PhD**
SVP, Regulatory & Quality

**Sanjay Subramanian, MBA**
*Chief Financial Officer*

**Jessica Crespo, CPA**
*Corporate Controller*

**Arun Upadhyay, PhD**
*Head of Discovery*

## Retina Scientific Advisory Board

**Mohamed Genead, MD**
*Acting CMO and Chair of SAB*

**David Boyer, MD**

**Carl D. Regillo, MD, FACS**

**Mark Pennesi, MD, PhD**

**Geeta Lalwani, MD**

# Pipeline Overview

| | Program | Indication | | Prevalence (US) | Discovery | Preclinical | IND-Enabling | Phase |
|---|---|---|---|---|---|---|---|---|
| Modifier Gene Therapy Platform | OCU400 AAV-hNR2E3 | *NR2E3* Mutation - Associated Retinal Degeneration * | Orphan US | 500 - 600 | | | | |
| | | *RHO* Mutation - Associated Retinal Degeneration * | Orphan US | 10,400 - 12,700 | | | | |
| | | *CEP290* Mutation - Associated Retinal Degeneration * | Orphan US | 2,500 - 3,000 | | | | |
| | | *PDE6B* Mutation - Associated Retinal Degeneration * | Orphan US | 1800 - 2800 | | | | |
| | OCU410 AAV-hRORA | Dry Age Related Macular Degeneration (Dry AMD) * | | 9M - 10M | | | | |
| Novel Biologic | OCU200 Transferrin-Tumstatin | Diabetic Macular Edema | | 0.75M | | | | |
| | | Diabetic Retinopathy | | 7.7M | | | | |
| | | Wet Age Related Macular Degeneration (Wet AMD) | | 1.1M | | | | |

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* No approved therapies exist

https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment

https://www.aao.org/eye-health/diseases/amd-treatment

# Ocugen's Modifier Gene Therapy Platform

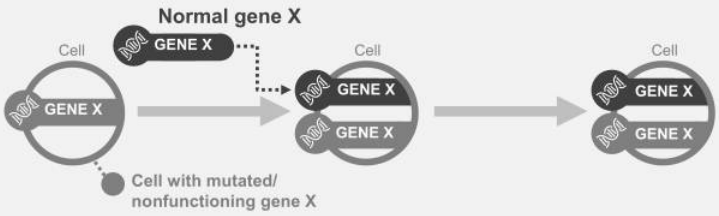
## Breakthrough Technology Designed to

### Address Multiple Diseases with One Product

### Approach Complex Diseases Through Multiple Factors

# Traditional Approach vs. Ocugen's Novel Platform

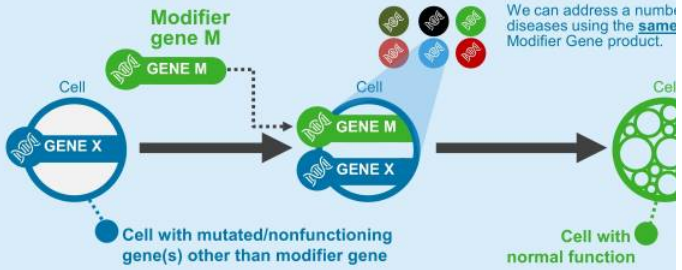
**Gene Augmentation:** Transfer functional version of a non-functional gene into the target cells.





- ✓ 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 expression of many genes, gene-networks and regulate basic biological processes in retina





- ✓ 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 product
- ✓ Ability to recoup development costs over multiple therapeutic indications

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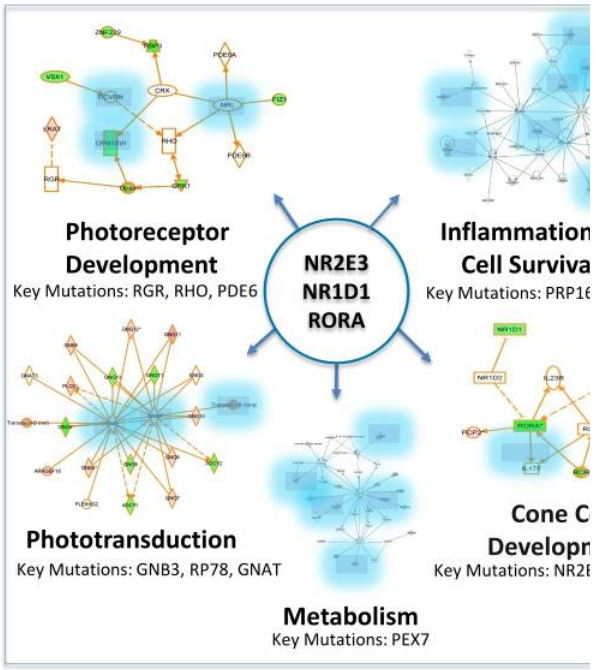
# Why Target Nuclear Hormone Receptor Genes (NHRs)?

- Modulators of retinal development & function
- Act as “master genes” in the retina
- Molecular reset of key transcription factors and associated gene networks – retinal homeostasis
- Gene modifier concept including impact on clinical phenotypes is well known in other disease areas, CF and SMA *



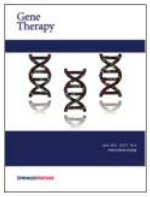



* References: https://pubmed.ncbi.nlm.nih.gov/28556246/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409218/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339951/
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183526

# Nature Gene Therapy Publication

## Preclinical POC Data for *Nr2e3* Published in *Nature Gene Therapy*

- **Efficacy results shown in 5 unique mouse models of RP**
- **Technology developed at Harvard Medical School, Dr. Neena Haider's Lab**
- **Study demonstrates potency of modifier gene therapy to elicit broad-spectrum therapeutic benef early and advanced stages of RP**
- **Results show evidence of vision rescue in Early & Advanced Stages of disease**

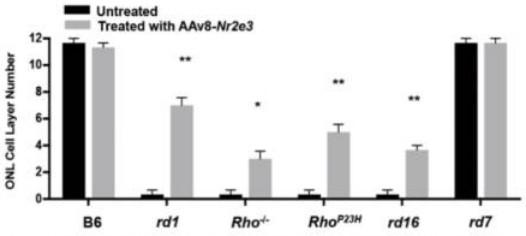



- Important milestone for development of therapy; demonstrated proof of principle
- Protection elicited in multiple animal models of degeneration caused by different mutations
- Potential to represent first broad-spectrum therapy and to provide rescue even after disease ons


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

# OCU400 – Rescue in Early & Advanced Stage of Disease

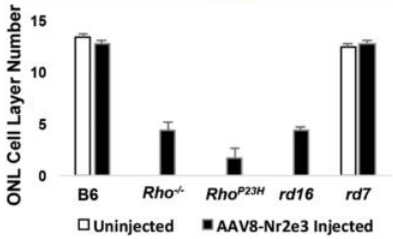
## Early Stage Rescue




- P0 single subretinal injection, evaluation 3-4 months post injection
- *rd1* evaluated one-month post injection

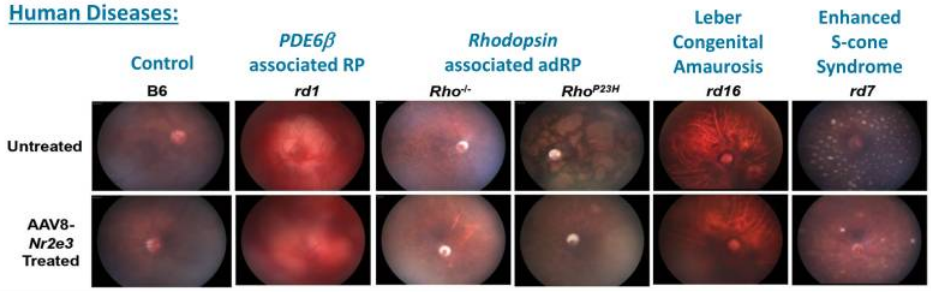
**ONL: Outer Nuclear Layer**

## Advanced Stage Rescue




- P21 subretinal injection, evaluation 2–3 months post injection
- Restored ONL photoreceptors morphology in rd7
- ONL cell layer change in *rd7* model doesn't progress until 4-5 mos. of ag

**Human Diseases:**



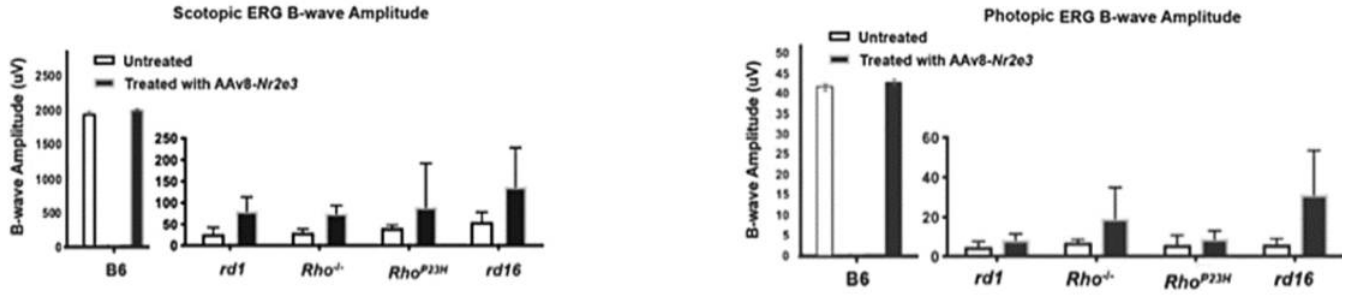

➢ **Fundus images and ONL count show how single product recuses vision in multiple mutations**



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

# OCU400 – Demonstrates Improved Vision Signals in Retina

## Electroretinogram (ERG) Response Reveals Rescue under Both Scotopic (dim-lit) as well as Photopic (well-lit) Conditions




**ERG response**: P0 single subretinal injection, evaluation 3-4 months post injection

**Human vision is enabled by three primary modes:**

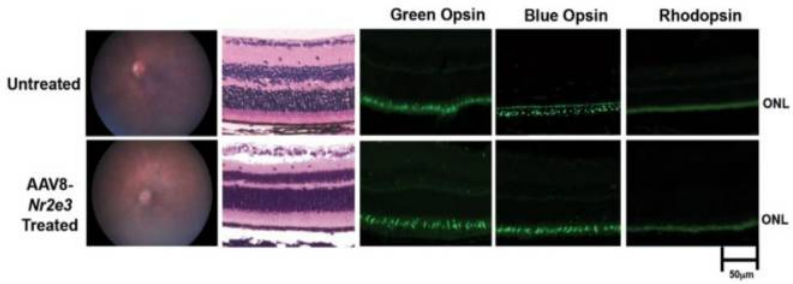
- **Photopic vision:** Vision under well-lit conditions, which provides for color perception and functions primarily due to cone cell the eye
- **Mesopic vision:** A combination of photopic vision and scotopic vision in low lighting, which functions due to a combination of and cone cells in the eye
- **Scotopic vision:** Monochromatic vision in very low light, which functions primarily due to rod cells in the eye

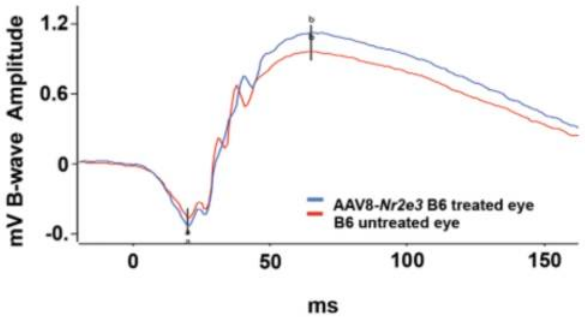


nature research https://www.nature.com/articles/s41434-020-0134-z

# OCU400 – Demonstrated Safety in Mouse Model

## Study Results Confirm Overexpression of *Nr2e3* by subretinal AAV8-*Nr2e3* Injection Is Not Detrimental to Retina – No Off-Target Effects

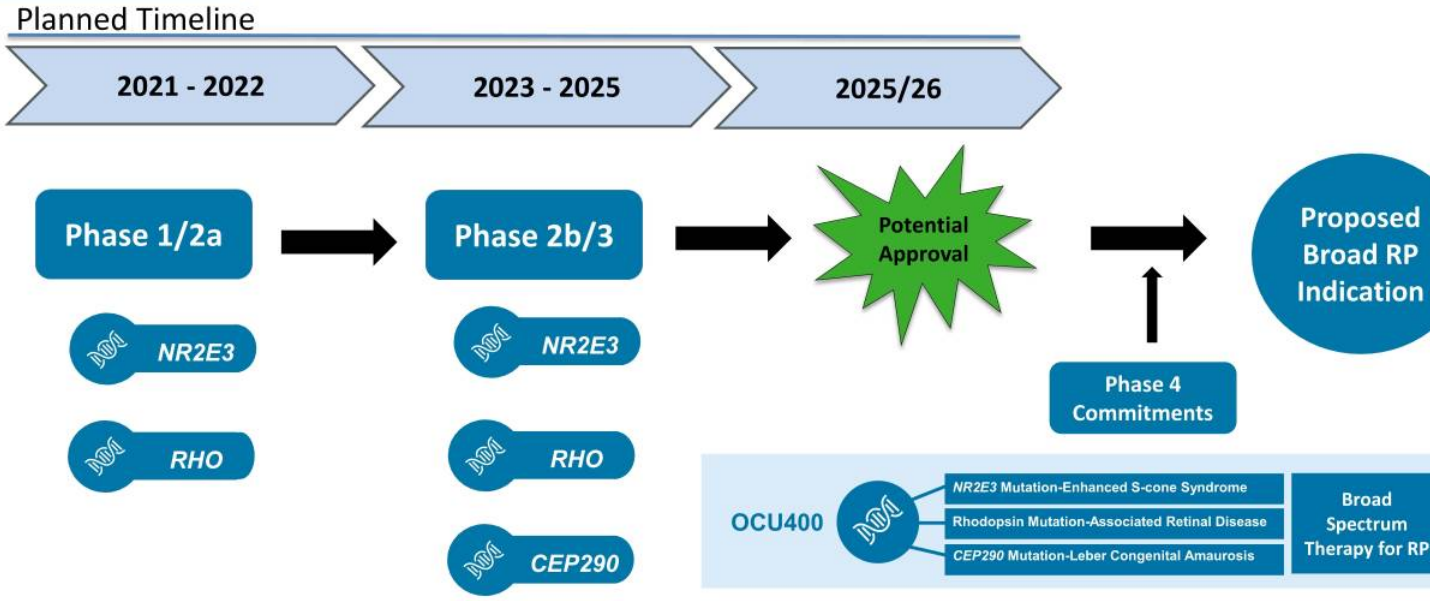





nature research https://www.nature.com/articles/s41434-020-0134-z

# OCU400 – Clinical and Regulatory Strategy



# OCU400 – Competitive Overview

| Features | OCU400 | Traditional Gene Therapy | Cell Therapy |
|---|---|---|---|
| | ocugen | Roche, HORAMA, Biogen, MEIRAGTx, agtc, NOVARTIS, Allergan, SANOFI | astellas, jCyte, ReNeuron |
| One product for many IRDs (including broad RP indication) | ✓ | ✗ | Limited ✓ |
| Technology established in the ocular disease space | ✓ | ✓ | ✗ |
| POC data in RP models with different genetic mutations | ✓ | ✗ | ✗ |
| Expected long-term outcome | Potentially longer benefit due to promotion of homeostasis | Potentially limited due to loss of retinal cells over time | Not established |
| Target Patient Population | Large | Small (specific to mutation) | Variable |
| Developmental cost | Low (economies of scale) | High (No economies of scale) | High |

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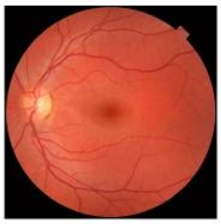
Potential Competitors pursuing treatment of RP with Traditional Gene Therapy

Potential Competitors pursuing treatment of RP with Cell Therapy

# OCU410 (AAV-*RORA*) – Dry Age-Related Macular Degeneration

## We Believe OCU410 Has the Potential to Address this Disease through its Multi-Factor Approach



Normal Retina

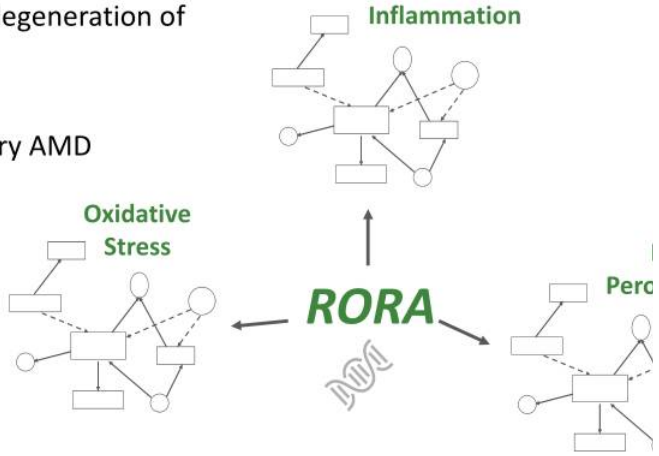
### Dry AMD

- Leads to irreversible blindness due to degeneration of the retina
- ~9-10M patients in the U.S.
- Currently no approved treatment for Dry AMD

Dry AMD

### Contributing Factors

- Aging
- Genetics
- Environmental Factors






**References:** https://www.brightfocus.org/macular/article/age-related-macular-facts-figures
https://www.uniprot.org/uniprot/P35398#function
https://pubmed.ncbi.nlm.nih.gov/21998696/
https://pubmed.ncbi.nlm.nih.gov/19786043/

# Gene Therapy Manufacturing

## Partnership Helps Advance OCU400 into the Clinic with Significantly Reduced Capital and Resource

ocugen ⟷ CanSinoBIO

### Ocugen Partnership with CanSino Biologics Inc. (CanSinoBIO)

**CanSinoBIO to perform CMC development & manufacturing of clinical supplies for OCU400**

- Publicly-listed (6185.HK) with market cap of ~$7B
- State-of-the-art facilities with world class team
- Provides scalable GMP cell lines (such as HEK293 suspension culture adopted) for commercial manufacturing
- Responsible for all associated costs (typical costs until BLA filing ~$25M-$35M)
- Manufacturing at commercial scale (200L) for Phase 1/2 for product consistency

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

- Ocugen to receive mid to high single-digit royalties on Greater China sales
- CanSinoBio to receive low to mid single-digit royalties on all other global sales




**Source:** Manufacturing Cures: Infrastructure Challenges Facing Cell And Gene Therapy Developers
In Vivo June 2019 invivo.pharmaintelligence.informa.com
Bloomberg: How a Chinese Firm Jumped to the Front of the Virus Vaccine Race

# OCU200:

## Diabetic Macular Edema (DME)
## Diabetic Retinopathy (DR)
## Wet Age-Related Macular Degeneration (Wet AM

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

# OCU200 – Potential to Treat DME, DR & Wet AMD

**OCU200 Provides Hope to All patients with DME, DR or Wet AMD**

**DME** → **~0.7M patients in the US***
**DR** → **~7.7M patients in the US***
**Wet AMD** → **~1.1M patients in the US***

**~50% of Patients DO NOT Respo to Anti-VEGF/Corticosteroids Therapies**

- **OCU200 is a Transferrin-Tumstatin Fusion Protein**
  - Tumstatin: Multiple MOAs for treatment and prevention of macular degeneration and neovasculariza
  - Transferrin: Targets the site of action and improves uptake (better target engagement)
- Integrin Targeting provides hope to these patients who are non-responders to current therapies
- Distinct MOA through targeting Integrin pathways can potentially also help reduce number of injections for patients who do respond to Anti-VEGF & corticosteroids therapies
- Significant global market potential

ocugen 

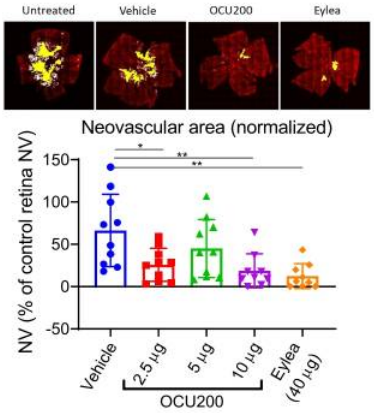
(*) https://www.gene.com/stories/retinal-diseases-fact-sheet
https://www.brightfocus.org/macular/article/age-related-macular-facts-figures

# OCU200 –Transferrin-Tumstatin Fusion Protein

## OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies

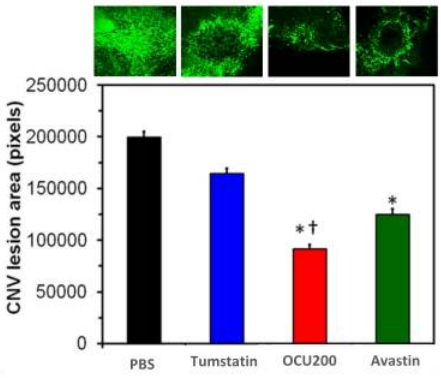
- Inhibits new blood vessel formation
- Anti-inflammatory
- Anti-oxidative

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



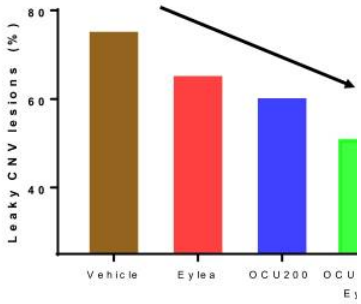

Effect of OCU200 intravitreal treatments on Neovascularization (NV). Data are presented as mean± SD. Filled circles represent data points from individual eyes
* P < 0.05, ** P < 0.01 (n = 9-10 eyes per group)

**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**




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

# OCU200 – Distinct Mechanism of Action

**We believe OCU200 has the potential to become a disease modifying therapeutic for broader patient population**

| Features | OCU200 | Anti-VEGF | Anti-Integrin |
|---|---|---|---|
| | ocugen | Genentech[1] NOVARTIS[1] REGENERON[1] KODIAK | ASCLEPIX Allegro |
| Reduces VEGF level/Fluid | ✓ | ✓ | ✓ |
| Selectively works on active endothelial cells (Neovascular) | ✓ | ✗ | ✓ |
| Activates native anti-angiogenic response | ✓ | ✗ | ✓ |
| Enhanced effective delivery through Transferrin | ✓ | ✗ | ✗ |
| Pro-apoptotic and anti-oxidative | ✓ | ✗ | ✓ |
| Dosing Frequency | Expected once in 3 months | 1-3 months | 1-3 months |

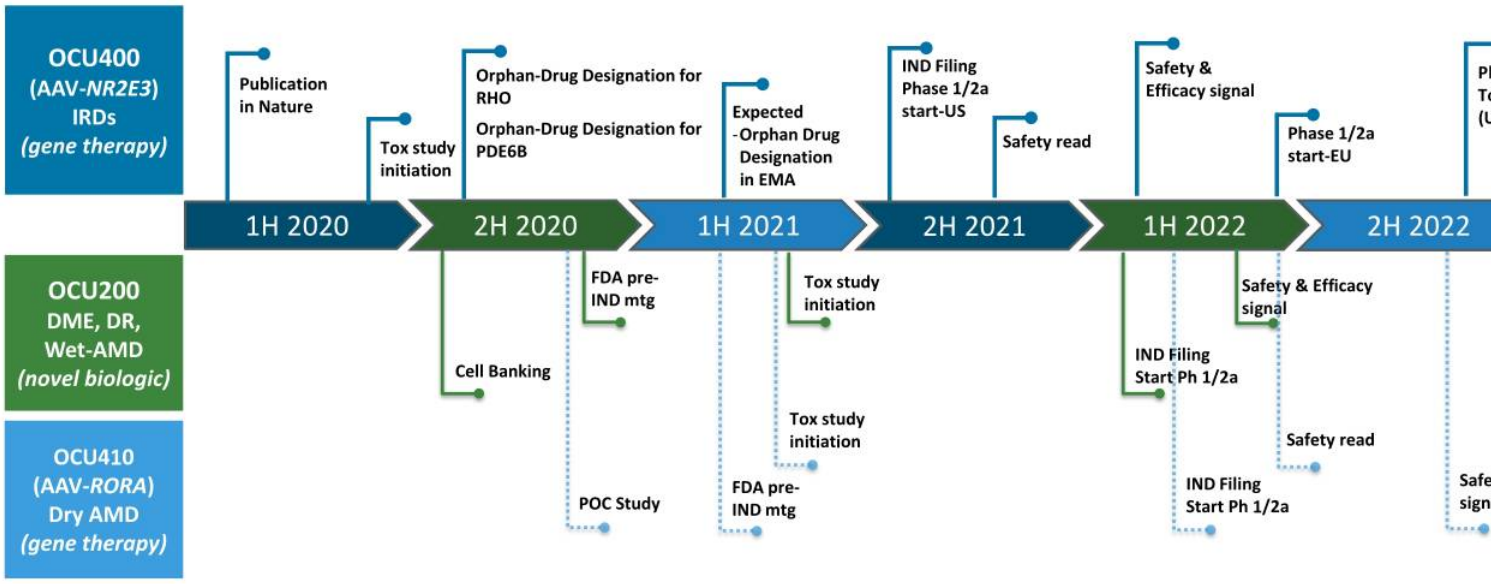


Potential Competitors pursuing treatment using Anti-VEGF approach

Potential Competitors pursuing treatment using Anti-Integrin approach

(1) Approved

# Near & Mid-Term Milestones: Planned Timeline



# Capital Structure Summary

| Capital Structure Summary | |
|---|---|
| Cash & Cash Equivalents (9/30/20) | $19.1M |
| Debt Principal O/S (9/30/20)<br>• EB5 Loan : 1.5M<br>• PPP Loan : 0.4M<br>• Apr '20 Notes: 1.3M | $3.2M |
| Common Stock O/S (10/15/20) | 162.0M |
| Warrants O/S (9/30/20) | 0.9M |
| Options O/S (9/30/20) | 4.3M |

# Investment Highlights

- Modifier Gene Therapy Platform has the potential for one product to treat many diseases
- Strategic manufacturing partnership with CanSinoBio sets clear path for critical manufacturing
- OCU200 novel biologic has the potential to treat anti-VEGF/corticosteroids non responders totaling approximately 50% of the patient population
- Multiple near and mid-term milestones with plan to initiate four Phase 1/2 trials within 1-2 years

# A Bold Vision to Cure Blindness Diseases with Gene Therapies

**For more information, contact:**
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