
**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): **January 5, 2021**

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 January 5, 2021 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: January 5, 2021

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

and

Develop a **Vaccine** to fight
COVID-19

NASDAQ: OCGN

Corporate Deck: January 2021



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 has been 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.



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Ocugen Overview

Developing transformative therapies for blindness diseases and a vaccine for COVID-19

OCUGEN'S BREAKTHROUGH MODIFIER GENE THERAPY PLATFORM

- Potential for one product to treat many diseases & multi-factor approach (POC study results published in Nature)
- **OCU400 (AAV-NR2E3)**: 4 FDA Orphan Drug Designations with the potential to treat broad Retinitis Pigmentosa (RP) 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 manufacturing

NOVEL BIOLOGIC

- **OCU200**: Targeting major retinal diseases: Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Wet Age Related Macular Degeneration (Wet AMD) (estimated global market size over \$10B) – initiation of Phase 1/2 in 2022
- Novel MoA: Potential to initially treat non-responders to anti-VEGF/ therapies (~50% of patients)

COVID-19 VACCINE

- **COVAXIN™**: Whole-virion inactivated COVID-19 vaccine candidate (with adjuvant). Co-develop with Bharat Biotech for the US market (currently received EUA in India). Standard vaccine storage condition (2-8°C)
- Promising safety and immunogenicity demonstrated by the Phase 1 and Phase 2 trials in India. Currently in Phase 3 trials in India involving about 26,000 volunteers
- Potential coverage against multiple protein antigens of the virus and potentially applicable to broader population



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Ophthalmology and Vaccine-Focused Expertise

Leadership Team



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



Mohamed Genead, MD
Acting CMO and Chair of SAB



Sanjay Subramanian, MBA
CFO and Head of Corporate Development



Vijay Tammara, PhD
SVP, Regulatory & Quality



Arun Upadhyay, PhD
Head of Research & Development



Jessica Crespo, CPA
Corporate Controller



Scientific Advisory Boards

Retina Scientific Advisory Board



Mohamed Genead, MD
Chair



David Boyer, MD



Carl D. Regillo, MD, FACS



Mark Pennesi, MD, PhD



Geeta Lalwani, MD



Vaccine Scientific Advisory Board



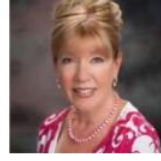
Satish Chandran PhD



David Fajgenbaum, MD, MBA,
MSc, FCPP



Bruce Forrest, MD, MBA, MB, BS



Catharine Pachuck, PhD



Harvey Rubin, MD, PhD



Susan Weiss, PhD



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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 | | | | |
| Vaccine | COVAXIN™ Whole-Virion Inactivated Vaccine | COVID-19 | | | <ul style="list-style-type: none"> • EUA in India • Phase-3 in progress in India • US EUA pathway in development | | | |



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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>





COVAXIN™

**Whole-Virion Inactivated COVID-19 Vaccine
Being Co-Developed for the US Market**

COVID-19 Vaccine in Development for US Market

COVAXIN™ has received Emergency Use Authorization (EUA) in India

- Evaluated in about 1,000 subjects in Phase 1 & 2 clinical trials in India. Phase 3 trial underway in India involving about 26,000 volunteers
- Promising safety and immunogenicity demonstrated by the Phase 1 and Phase 2 data
 - The adjuvanted inactivated virus vaccine candidate elicited strong IgG responses against spike (S1) protein, receptor-binding domain (RBD), and the nucleocapsid (N) protein of SARS-CoV-2 along with strong cellular responses
- Highly purified and inactivated vaccine, manufactured in a vero cell manufacturing platform with an excellent safety track record
- Vaccine scientific advisory board (SAB) established with esteemed thought leaders from industry and academia
- Evaluating clinical and regulatory path for EUA in US



Ocugen's Modifier Gene Therapy Platform

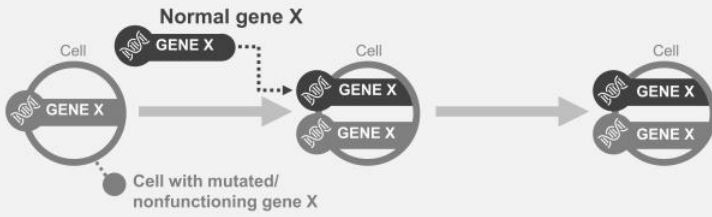
Breakthrough Technology Designed to

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.

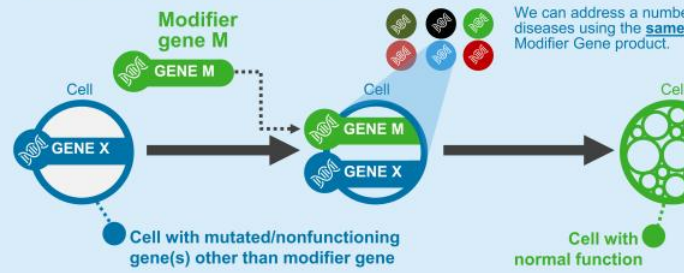


Traditional Gene Therapy

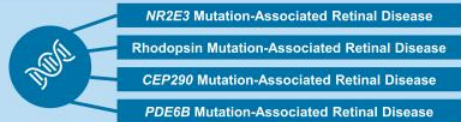


- ✓ Traditional approach that targets one individual gene mutation at a time
- ✓ Regulatory pathway focused on specific product for one disease
- ✓ Longer time to recoup development costs

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



OCU400

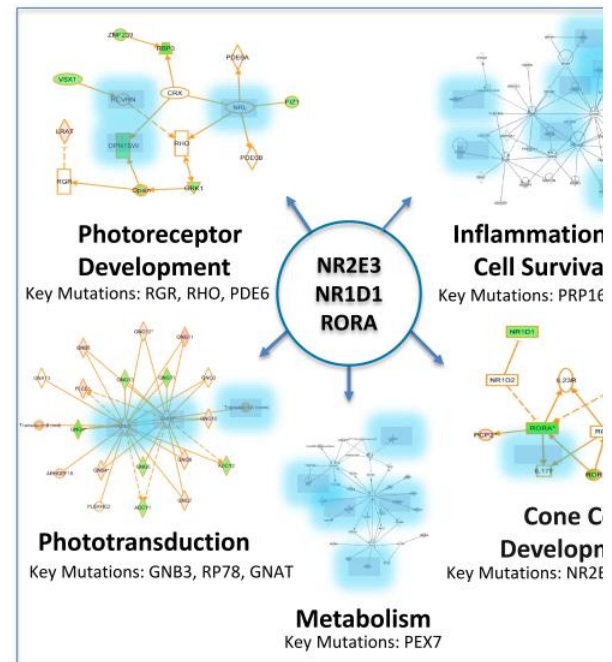


Broad Spectrum Therapy

- ✓ 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

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 *



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* 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 benefit 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 onset



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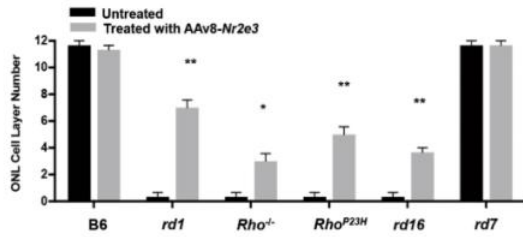


<https://www.nature.com/articles/s41434-020-0134-z>



OCU400 – Rescue in Early & Advanced Stage of Disease

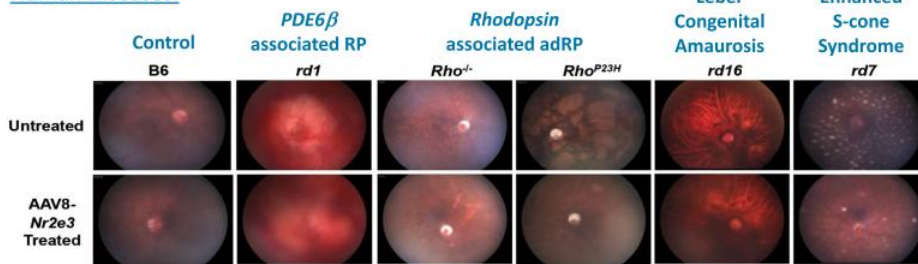
Early Stage Rescue



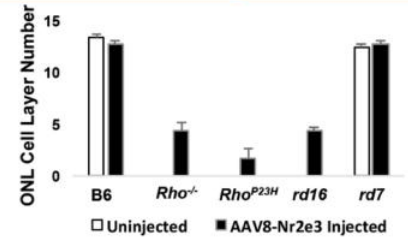
- P0 single subretinal injection, evaluation 3-4 months post injection
- *rd1* evaluated one-month post injection

ONL: Outer Nuclear Layer

Human Diseases:



Advanced Stage Rescue

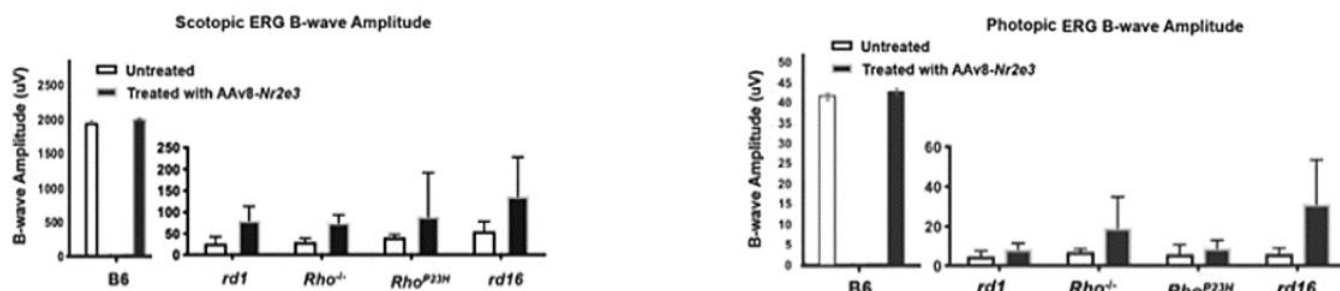


- P21 subretinal injection, evaluation 2-3 months post injection
- Restored ONL photoreceptors morphology in *rd7*
- ONL cell layer change in *rd7* model doesn't progress until 4-5 mos. of age

➤ Fundus images and ONL count show how single product rescues vision in multiple mutations

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

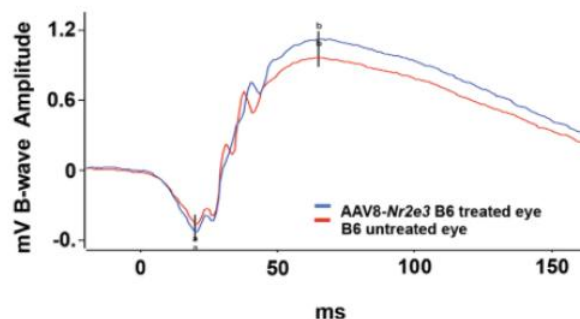
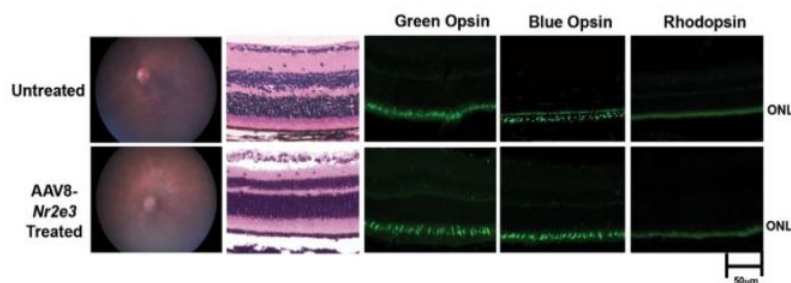
Human vision is enabled by three primary modes:

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



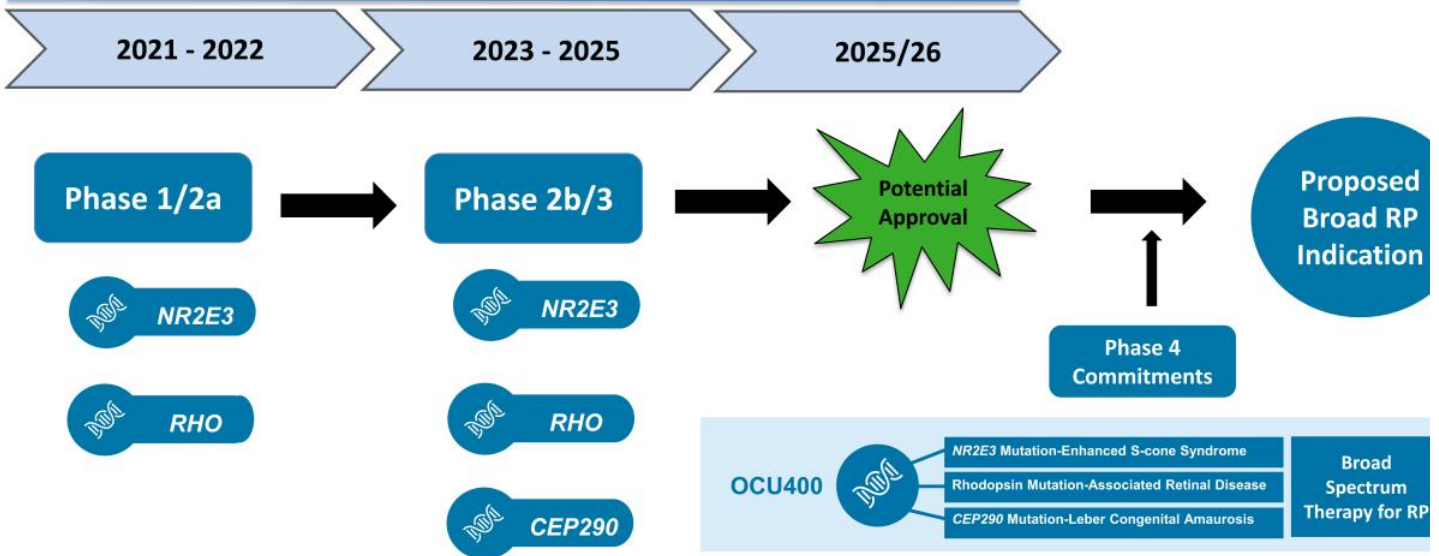
OCU400 – Demonstrated Safety in Mouse Model

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






OCU400 – Clinical and Regulatory Strategy

Planned Timeline



OCU400 – Competitive Overview

| Features | OCU400 | Traditional Gene Therapy | Cell Therapy |
|---|---|--|---|
| |  |  |  |
| 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

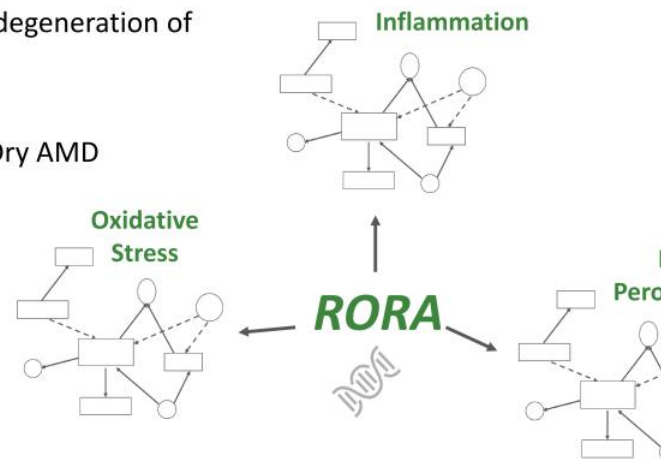
- Leads to irreversible blindness due to degeneration of the retina
- ~9-10M patients in the U.S.
- Currently no approved treatment for Dry AMD



Dry AMD

Contributing Factors

- Aging
- Genetics
- Environmental Factors



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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/>



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



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



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Source: Manufacturing Cures: Infrastructure Challenges Facing Cell And Gene Therapy Developers
In Vivo June 2019 invo.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 AMD)

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 Respond to Anti-VEGF/Corticosteroids Therapies

➤ OCU200 is a Transferrin-Tumstatin Fusion Protein

- Tumstatin: Multiple MOAs for treatment and prevention of macular degeneration and neovascularization
 - 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



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

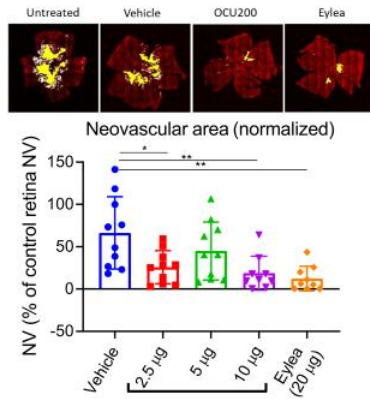


OCU200 –Transferrin-Tumstatin Fusion Protein

OCU200 Demonstrated Superior Efficacy Compared to Existing Anti-VEGF Therapies

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

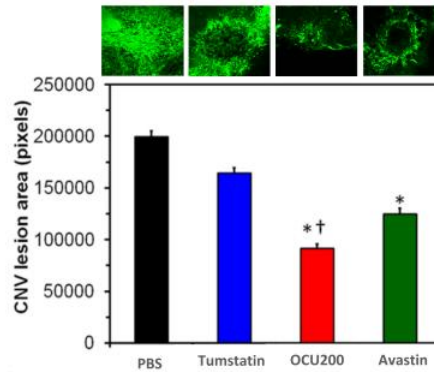
DME/DR Oxygen-Induced Retinopathy (OIR) Mouse Model



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)

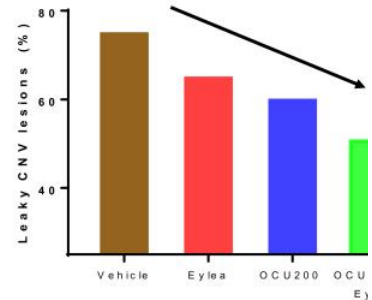
Wet AMD In-Vivo Laser-Induced Rat CNV Model



* 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 & treatment 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 |
|---|---|--|---|
| |  |    KODIAK |   |
| 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 |



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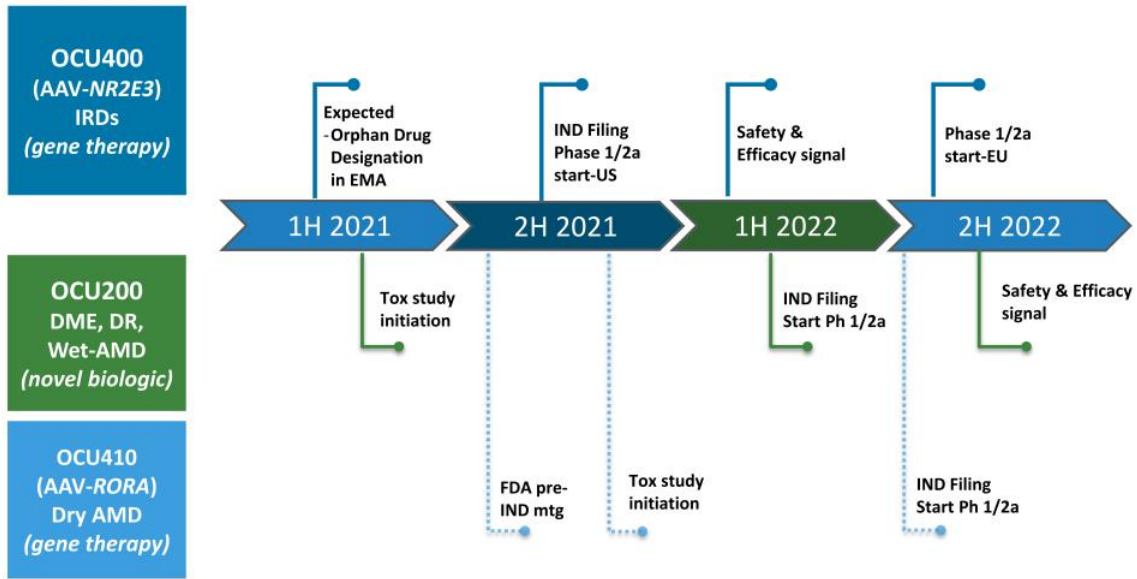


Potential Competitors pursuing treatment using Anti-VEGF approach

Potential Competitors pursuing treatment using Anti-Integrin approach

(1) Approved

Near & Mid-Term Milestones: Planned Timeline



Investment Highlights

- Modifier Gene Therapy Platform has the potential for one product to treat many diseases
- OCU200 novel biologic has the potential to treat anti-VEGF /corticosteroids non-responders (~50% of the patients)
- Multiple near and mid-term milestones with plan to initiate four Phase 1/2 trials within 1-2 years
- COVAXIN™ - Vaccine candidate for the US market



**A Bold Vision to Cure
Blindness Diseases
and
Offer a Differentiated
Vaccine for COVID-19 in
the US**

For more information, contact:

IR@ocugen.com



