

**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): **November 21, 2019**

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 (see General Instruction A.2. below):

- 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 November 27, 2019 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 8.01 Other Events

As previously disclosed, on October 4, 2019, in connection with a pre-merger private placement transaction with certain accredited investors (the “Investors”) pursuant to that certain Securities Purchase Agreement dated June 13, 2019, Ocugen issued certain Series B warrants (the “Series B Warrants”) to purchase shares of Ocugen’s common stock (“Common Shares”), and such warrants were amended on November 5, 2019. As further previously disclosed, the Series B Warrants include a provision pursuant to which the number of shares issuable upon exercise of the Series B Warrants shall be increased during certain “Reset Periods” (as defined in the Series B Warrants) pursuant to a formula based on the greater of (i) 80% of the arithmetic average of the two lowest dollar volume-weighted average prices of a share of Ocugen common stock on Nasdaq during the applicable Reset Period immediately preceding the applicable Reset Date to date and (ii) \$1.00 (the “Reset Price”).

A Reset Period commenced on November 20, 2019, which, in accordance with the terms of the Series B Warrants, was the day following a ten trading-day period after the effectiveness of Ocugen’s Registration Statement on Form S-3 (333- 234127). As the dollar volume-weighted average prices of Ocugen’s common stock on Nasdaq was under \$1.00 for the first two trading days of the Reset Period, the Investors elected to advance the end of the Reset Period to November 21, 2019 and the number of shares issuable upon exercise of the Series B Warrants was increased based on a Reset Price of \$1.00. This reset resulted in an aggregate of approximately 12.6 million additional Common Shares becoming issuable upon exercise of the Series B Warrants.

As of November 25, 2019, there were 36,201,635 Common Shares issued and outstanding. If investors were to fully exercise all of the Series B and Series C warrants, Ocugen expects to have approximately 53.0 million Common Shares outstanding.

Item 9.01 Financial Statements and Exhibits

The following exhibits are 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: November 26, 2019

OCUGEN, INC.

By: /s/ Shankar Musunuri

Name: Shankar Musunuri

Title: Chief Executive Officer and Chairman



Developing **Innovative Therapies** to Address Rare and Underserved Eye Diseases

NASDAQ: OCGN

Corporate Deck



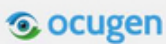
Forward Looking Statement

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 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 we 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

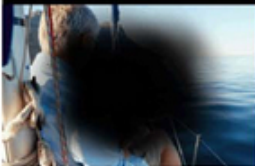
- Nasdaq-listed company as of September 30, 2019
- Robust IP portfolio with 31 issued U.S. and foreign patents and 29 U.S. and foreign patent applications
- Strategic Partnership with CanSinoBIO for OCU400 Gene Therapy Co-Development & Manufacturing



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



MODIFIER GENE THERAPY PLATFORM
OCU400 for Inherited Retinal Diseases – Orphan Drug Designations
(*NR2E3* and *CEP290* Mutation-Associated Retinal Diseases)
OCU410 for Dry AMD



NOVEL BIOLOGIC THERAPIES FOR RETINAL DISEASES
OCU200 for Wet AMD, Diabetic Macular Edema, Diabetic Retinopathy
OCU100 for Retinitis Pigmentosa

Experienced Leadership Team

- Diverse experience in large pharma, signature biotech, and small companies
- Track record of success
- Brings large and small company learnings to Ocugen



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


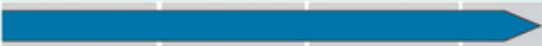
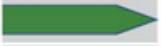









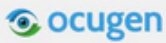
Vijay Tammara, PhD

Vice President, Regulatory & Quality



Pipeline of Diversified Assets

|  | Indication | Prevalence (US) | Preclinical | Phase 1 | Phase 2 | Phase 3 |
|--|--|-----------------|--|---------|---------|---------|
| OCULAR SURFACE DISEASE (small molecule) | | | | | | |
| OCU300 | oGVHD Orphan US | 60,000 |  | | | |
| MODIFIER GENE THERAPY PLATFORM | | | | | | |
| OCU400 <small>NR2E3-AAV</small> | NR2E3 Mutation-Associated Retinal Degeneration Orphan US | 500-600 |  | | | |
| | CEP290 Mutation-Associated Retinal Degeneration Orphan US | 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>Transferrin</small> | Wet AMD | 1.1M |  | | | |
| | Diabetic Macular Edema | 745,000 |  | | | |
| | Diabetic Retinopathy | 7.7M |  | | | |
| OCU100 <small>LEDGF-1-326</small> | Retinitis Pigmentosa Orphan US & EU | 100,000 |  | | | |



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Gene Therapy Pricing Reference:
Novartis gene therapy Zolgensma® = \$2.1M per patient
Source: [The Wall Street Journal, October 22, 2019](#)



OCU300: oGVHD

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

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

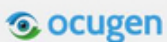
~60% of allogeneic bone marrow transplant patients will develop oGVHD

~63,000 patients in the US by 2020



~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/directory/search/advanced#/.../false//TotalTransplants>

First Phase 3 Study With Orphan Drug Designation

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

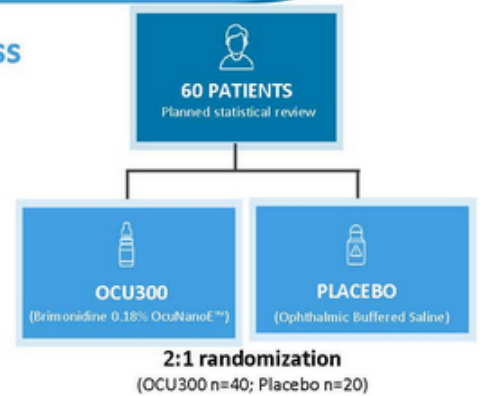
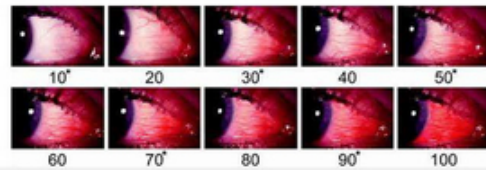
Co-primary endpoints include:

- **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



Brimonidine is already proven safe and effective

Safety

Existing Molecule

- 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

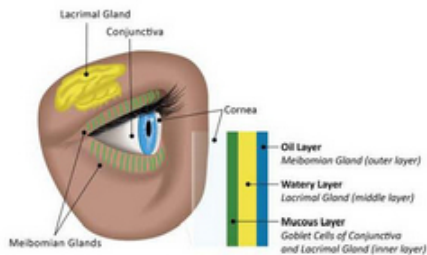
OCU300 is preservative-free (no BAK)

- BAK (benzalkonium chloride) is damaging to the cornea

Generic substitution prohibited

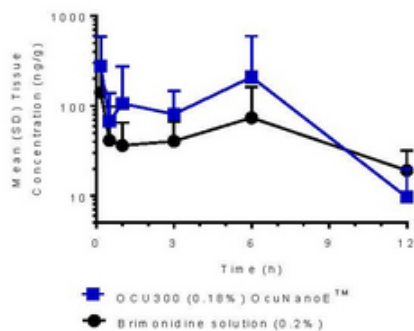
- Generic brimonidine (0.2%) not approved for oGVHD
- Concentration/formulation different from OCU300
- Contains BAK preservative
- OCU300 completing controlled studies in oGVHD patients
- AB criteria not applicable

OcuNanoE™ Drug Delivery System Improves Overall Efficacy

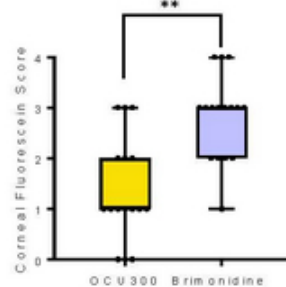


Drug distribution to lacrimal gland from traditional eye drops is low relative to other target tissues

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/max 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**

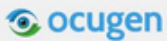
- Potential to be **first approved product** in US market
- First and only company to receive **Orphan Drug Designation** from FDA for oGVHD
- Advances in hematopoietic cell transplantation leading to **increasing number of transplant survivors**

~63,000 Patients by 2020

Targeted BMT Centers

Premium Pricing

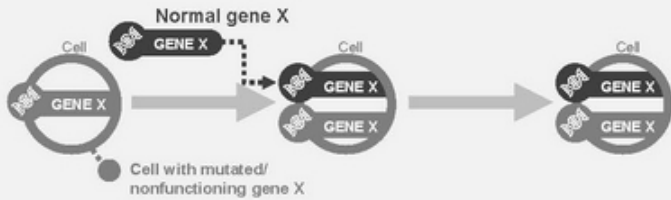
Orphan Drug



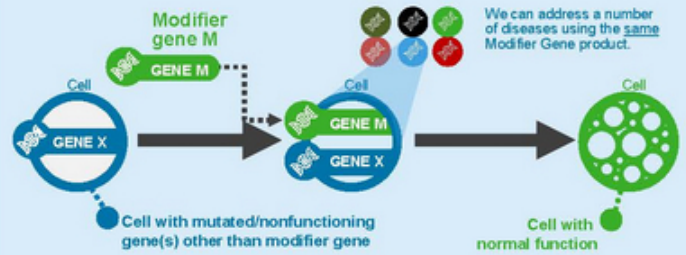
Modifier Gene Therapy Platform

Modifier Gene Therapy Has a Broader Impact

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



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



Traditional Gene Therapy



ONE Disease

- ✓ 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

OCU400

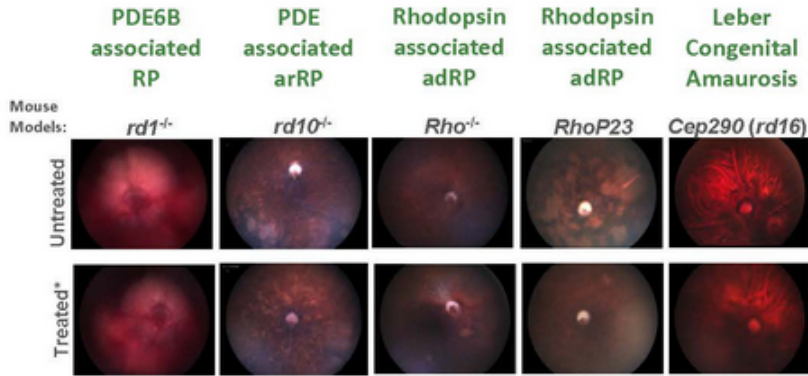


NR2E3 Mutation-Associated Retinal Disease
CEP290 Mutation-Associated Retinal Disease
Rhodopsin Mutation-Associated Retinal Disease

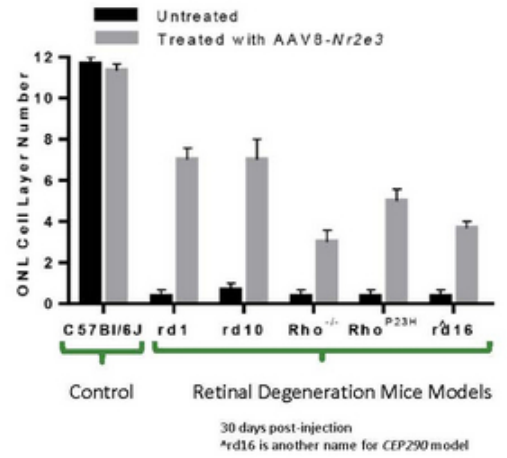
- ✓ Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina
- ✓ Smoother regulatory pathway due to ability to target multiple diseases with one product
- ✓ Ability to recoup development costs over multiple therapeutic indications

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

Human Disease:



*Treated fundus photos: subretinal single injection



One Product Rescues Multiple IRDs after onset

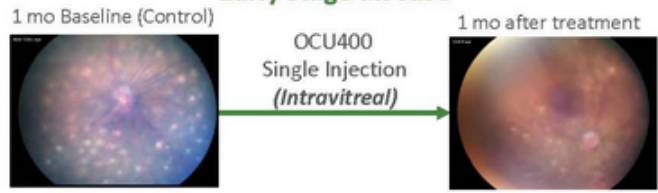
OCU400: Orphan Drug Designation

NR2E3 Mutation-Associated Retinal Degeneration

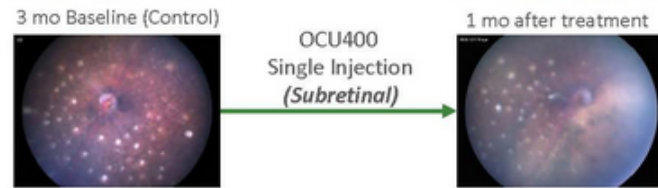
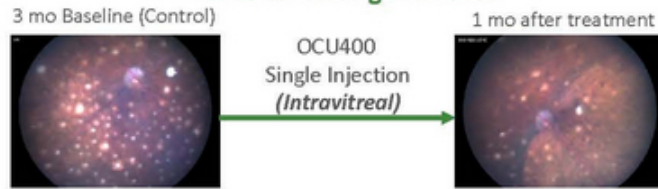


Our First Gene Therapy Product to Clinic

Early stage disease



Advanced stage disease



Gene Therapy Manufacturing: A Major Bottleneck Faced by All

Increased demand for cell & gene therapy manufacturing

- 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 ~\$1 Billion
- 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



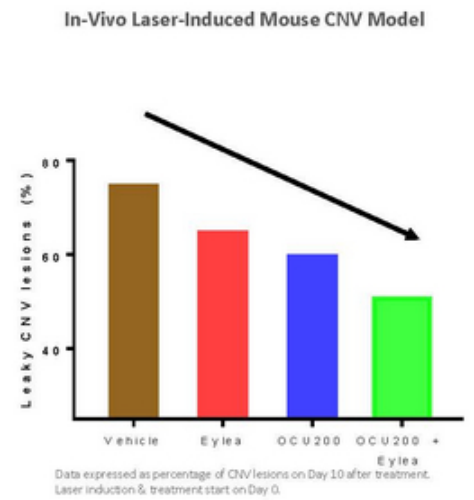
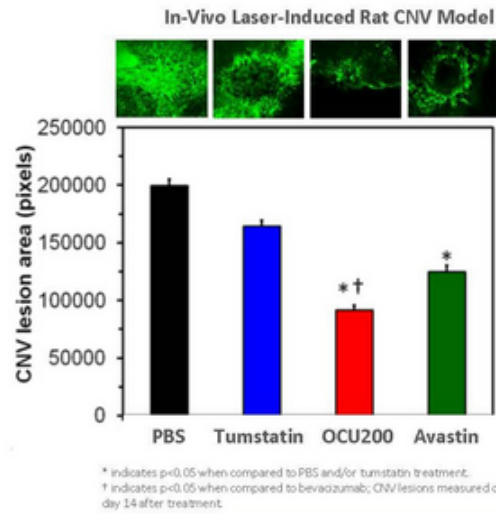
Partnership paves a path for Ocugen to advance OCU400 into the clinic
with significantly reduced capital and resources

OCU200: Wet AMD/DME/DR

**New therapies needed beyond
Anti-VEGF**

Lead Biologic OCU200: Tumstatin-Transferrin Fusion Protein Offering Benefits Beyond Anti-VEGF

- ✓ 50% of patients are non-responders to Anti-VEGF
- ✓ Selectively works on active endothelial cells
- ✓ Activates native anti-angiogenic response
- ✓ Targeting element enhances effective concentration
- ✓ Pro-apoptotic and anti-oxidative
- ✓ Inhibits new blood vessel formation
- ✓ Reduces damage to retina



OCU200 Demonstrated Superior Efficacy with Potentially Fewer Injections in Head-to-Head Studies

Summary of Near-Term Milestones

OCU300 ocular GVHD *(small molecule)*

- ✓ Dec 2018: First Patient Dosed
- 1H2020: Statistical Review
- 2H2020: Estimated Topline Results of First Study

OCU400 (NR2E3-AAV) Retinal Degenerative Diseases *(gene therapy)*

- ✓ 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

OCU200 Wet AMD, DME, DR *(novel biologic)*

- 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.

Contact

Kelly Beck

Vice President, Investor Relations & Administration

kelly.beck@ocugen.com



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21