

**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): **October 3, 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. will post on its website on October 3, 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 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: October 3, 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 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

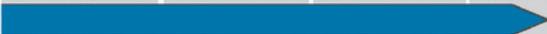


Vijay Tammara, PhD

Vice President, Regulatory & Quality



Pipeline of Diversified Assets

	Indication		Preclinical	Phase 1	Phase 2	Phase 3
OCULAR SURFACE DISEASE (small molecule)						
OCU300	oGVHD					
MODIFIER GENE THERAPY PLATFORM						
OCU400 <small>NR2E3-AAV</small>	NR2E3 Mutation-Associated Retinal Degeneration					
	CEP290 Mutation-Associated Retinal Degeneration					
	Rhodopsin Mutation-Associated Retinal Degeneration					
OCU410 <small>RORA-AAV</small>	Dry AMD					
RETINAL DISEASES (novel biologics)						
OCU200 <small>LUTM3aL1-Transferrin</small>	Wet AMD					
	Diabetic Macular Edema					
	Diabetic Retinopathy					
OCU100 <small>LEDGF 1-326</small>	Retinitis Pigmentosa					

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 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
- Significantly diminishes quality of life and restricts daily activities

~**60%** of chronic graft vs. host disease patients will develop oGVHD

~**63,000** patients in the US by 2020

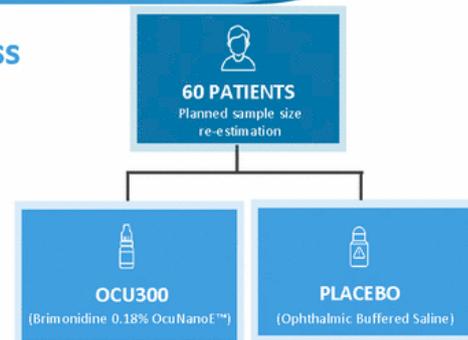


Ocugen is the **first and only company to receive orphan drug designation** from FDA for treatment of oGVHD

First Phase 3 Study With Orphan Drug Designation

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

- Randomized, Double-Masked, Placebo-Controlled, Phase 3 Study
- 84-day study
- Key inclusion criteria: diagnosis of 'definite' oGVHD using the International Chronic Ocular GVHD Consensus Group revised diagnostic criteria (Ogawa, 2013)

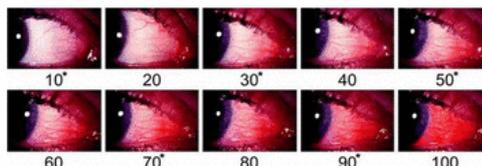


2:1 randomization
(OCU300 n=40; Placebo n=20)

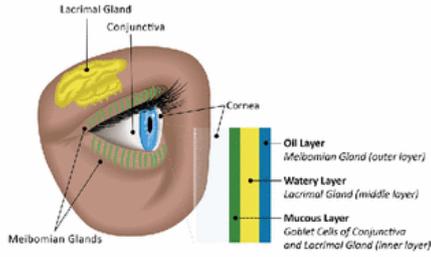
Primary endpoints include:

- **Symptom:** Ocular discomfort based on Visual Analog Scale (VAS)
- **Sign:** Ocular redness based on Validated Bulbar Redness (VBR) Score

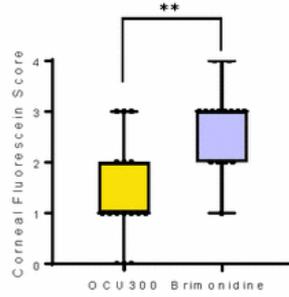
On a scale from 0-10, what was the intensity of your Ocular Discomfort, at its worst, over the past 24 hours?



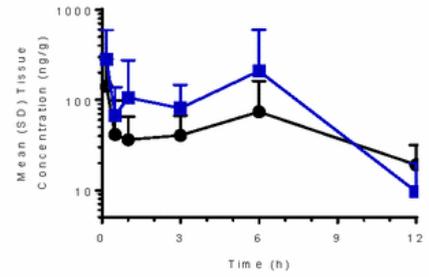
OcuNanoE™ Formulation Drug Delivery System Increases OCU300 Concentration in Lacrimal Gland



Mouse DED Model (Preclinical)



Brimonidine Level in Lacrimal Gland (Preclinical)



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

- 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



- Spend **3 months** in hospital after receiving **bone marrow transplant**
- Most **exhibit symptoms** while still **under hematologist/ oncologist care**
- On **multiple prescription therapies**; hematologist options today **limited** and **suboptimal** (artificial tears or approved dry eye products)

Physicians



- **Hematologists/Oncologists** are **first prescribers**, then referred to **specialized ophthalmologists**
- Hematologists looking for **approved therapy**; no knowledge of off-label options
- Off-label usage primarily occurs when **no approved therapy exists**; long-term risks associated with **tolerability** and **damage to ocular tissues**
- Therapies need to address **ocular discomfort (pain) and redness** – unmet need

Market Access



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

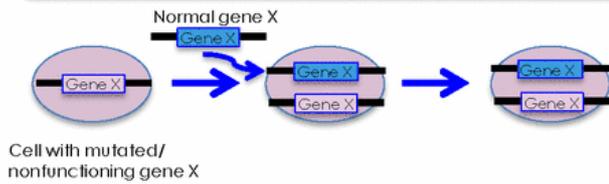
Market Potential



- 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**

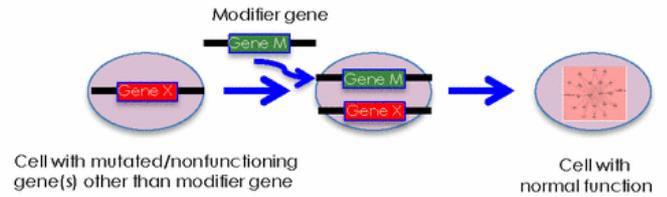
Modifier Gene Therapy Has a Broader Impact

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

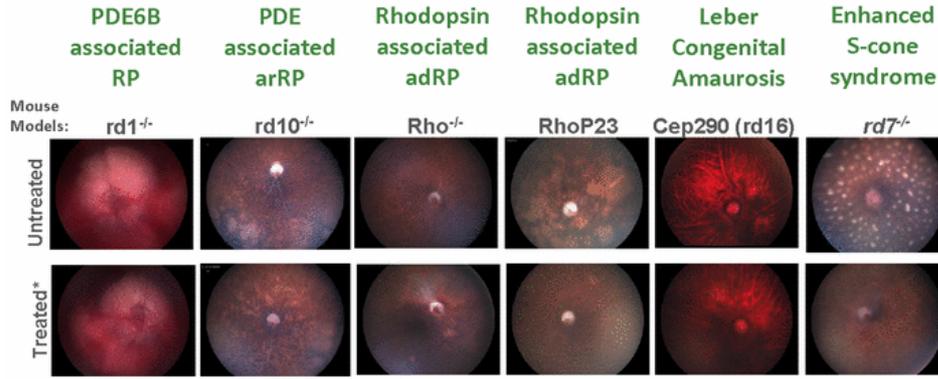
Modifier Gene Therapy: Introduce a functional gene to modify the expression of many genes, gene-networks and reset homeostasis.



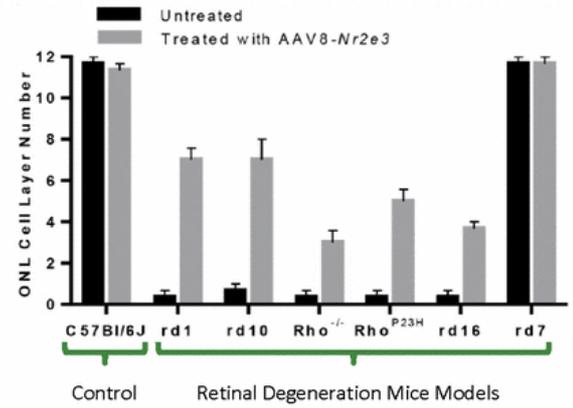
- Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina
- Smoother regulatory pathway due to ability to target multiple diseases with one product
- Ability to recoup development costs over multiple therapeutic indications

OCU400 Rescues Vision Loss in Multiple Retinal Diseases

Human Disease:



*Treated fundus photos: subretinal single injection

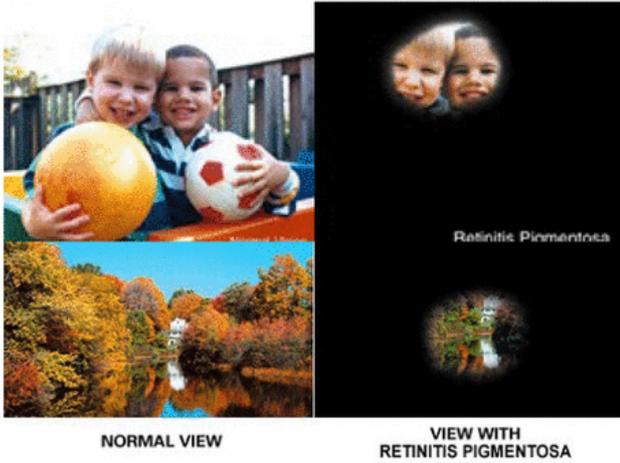


*rd16 is another name for CEP290 model
rd7 is NR2E3 mutation

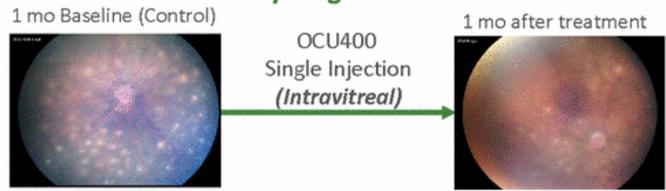
In multiple mouse models, Treatment Rescues Disease after onset

OCU400: Orphan Drug Designation

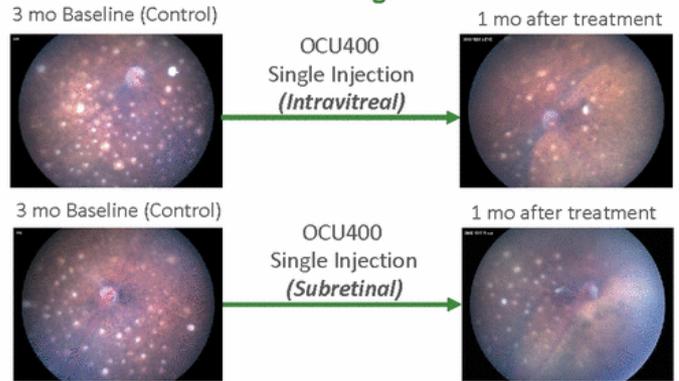
NR2E3 Mutation-Associated Retinal Degeneration



Early stage disease



Advanced stage disease



OCU400 Gene Therapy Manufacturing: Strategic Partnership with CanSinoBIO



CanSinoBIO

- Publicly-listed on Hong Kong exchange (6185.HK)
- Biotech Company with market cap of approximately \$1B
- State-of-the-art facilities with world class team

CanSinoBIO to perform CMC development & manufacturing of clinical supplies

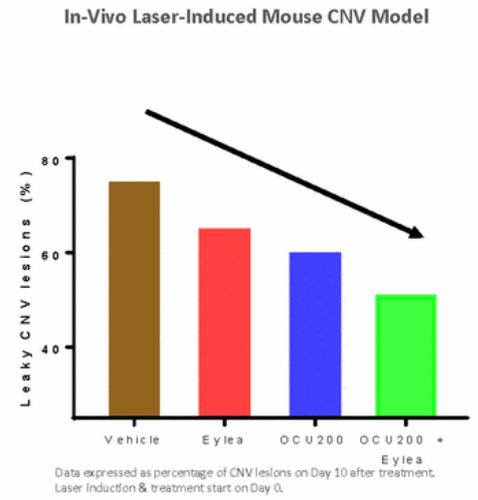
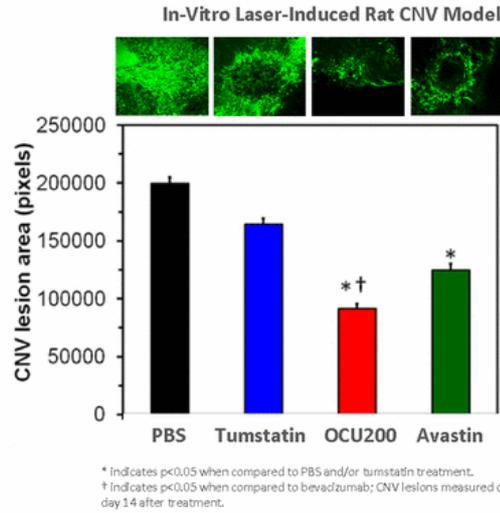
- CanSinoBIO responsible for all associated costs
- Option for commercial manufacturing agreement

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

Lead Biologic OCU200: Tumstatin-Transferrin Fusion Protein Offering Benefits Beyond 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: Sample Size re-estimation
- 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.

Kelly Beck

Vice President, Investor Relations & Administration

kelly.beck@ocugen.com