# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 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): **February 9, 2015**

# OCATA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **000-50295** | **87-0656515** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **33 Locke Drive, Marlborough, Massachusetts** | **01752** |
|---|---|
| (Address of Principal Executive Offices) | (Zip Code) |

Registrant's Telephone Number, Including Area Code: **(508) 756-1212**

(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))

**Item 7.01. Regulation FD**

The following information and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

The Company will present a company overview at the 17th Annual BIO CEO and Investor Conference on Monday, February 9, 2015 at 9:30 a.m. ET in New York City. A live audio webcast of the presentation will be available via the "Investor Relations" page of the Company's website, www.ocata.com. A replay of the webcast will be archived on the Company's website for 90 days following the presentation.. A copy of the Company's presentation slides is furnished herewith as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Ocata Therapeutics, Inc. Company Presentation dated February 9, 2015 |



**SIGNATURES**

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.

**Ocata Therapeutics, Inc.**

Date: February 9, 2015

By: /s/ Edward Myles
Edward Myles
Chief Financial Officer and Chief Operating Officer


## Cautionary Statement Concerning Forward-Looking Statements

*Ocata Therapeutics Inc. ("Ocata" or "the Company") has filed a registration statement (including a prospectus and a preliminary prospectus supplement) with the Securities and Exchange Commission ("SEC") for the offering to which this presentation relates. Before you invest you should read the prospectus and the preliminary prospectus supplement in that registration statement and other documents the Company has filed with the SEC for more complete information about the Company and the offering. You may get these documents for free on the SEC's website at http://www.sec.gov*

*These slides and the accompanying oral presentation contain statements that are not historical facts and are considered forward-looking information. In some cases you can identify these statements by forward-looking words such as "anticipate," "believe," "could," "continue," "estimate," "expect," "intend," "may," "should," "will", "would," "plan," "projected," or the negative of such words or other similar words or phrases. Investors are cautioned not to unduly rely on forward-looking statements because they involve risks and uncertainties and statements related to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These statements are also subject to a number of material risks and uncertainties that are described more fully in the prospectus and the preliminary prospectus supplement filed with the SEC, including without limitation our most recently filed Report on Form 10-Q, as filed with the SEC. These forward-looking statements speak only as of the date on which the statements were made and are not guarantees of future performance. Except as may be required by applicable law, we do note undertake or indent to update any forward-looking statements contained herein or in our public filings wit the SEC.*

# The Regenerative Ophthalmology™ Company

## Addressing Macular Degeneration with Groundbreaking RPE Therapy

Safety observed, in addition to anatomical and functional evidence of repair and restoration in Phase 1 trials for dry AMD and SMD

- Data published in *The Lancet*, October 14, 2014

Initiating Phase 2 studies soon:

- Stargardt's Macular Degeneration (SMD) - Q1 2015
- Dry Age-related Macular Degeneration (AMD) - Q2 2015

Extensive proprietary position in major markets protecting the entire value chain of the cell therapy – from the origin of the stem cell to the delivery into patients' eyes

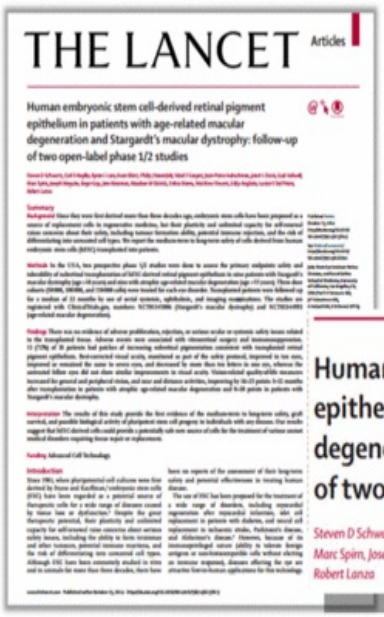


# Ophthalmology: A Large, Growing and Underserved Market (US at $12 Billion)

- **Age-Related Macular Degeneration (AMD)**
  - Approximately 15m people in the US
  - ~85-90% have dry AMD
  - No treatment available currently to prevent, effectively treat or cure dry AMD
- **Stargardt's Macular Degeneration (SMD)**
  - Leading form of inherited juvenile onset macular degeneration
  - Orphan disease indication with no available treatment
- **Myopic Macular Degeneration (MMD)**
  - Prevalent condition especially in Asia affecting up to 13m in China and Japan

**Ocata's Regenerative Ophthalmology™ R&D programs target the major forms of macular degenerative disease with potentially transformative therapies**

## The First Evidence of Long-term Safety and Efficacy Signal Following Transplantation of RPE Cells



THE LANCET Articles

Human embryonic stem cell-derived retinal pigment epithelium in patients with age-related macular degeneration and Stargardt's macular dystrophy: follow-up of two open-label phase 1/2 studies

"What we did is transplant the cells into patients who have a disease where those particular cells are dying; and we replaced those dying tissues with new tissue that's derived from these stem cells. In a way it's a retinal transplant.

*- Steven Schwartz, eye specialist, UCLA*

**Human embryonic stem cell-derived retinal pigment epithelium in patients with age-related macular degeneration and Stargardt's macular dystrophy: follow-up of two open-label phase 1/2 studies**

*Steven D Schwartz, Carl D Regillo, Byron L Lam, Dean Eliott, Philip J Rosenfeld, Ninel Z Gregori, Jean-Pierre Hubschman, Janet L Davis, Gad Heilwell, Marc Spirn, Joseph Maguire, Roger Gay, Jane Bateman, Rosaleen M Ostrick, Debra Morris, Matthew Vincent, Eddy Anglade, Lucian V Del Priore, Robert Lanza*

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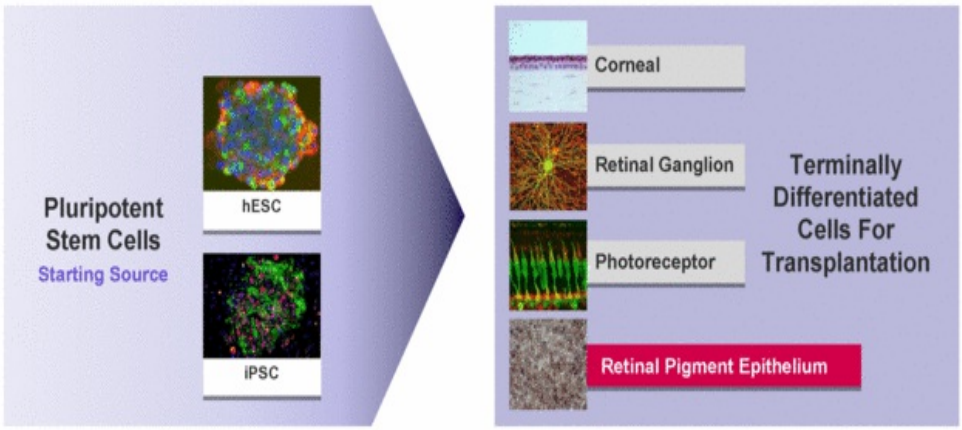
## World Leaders in Terminal Differentiation of Pluripotent to Target Cells




**Stem Cells are the Starting Material but fully Differentiated Cells are the Treatment**

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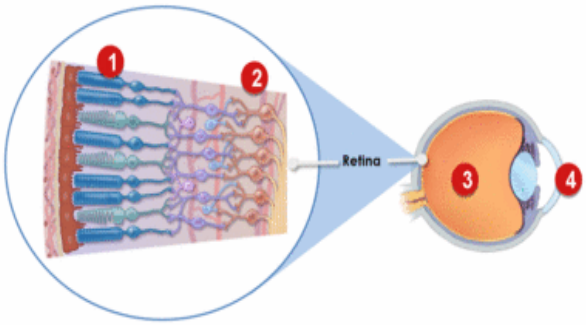
## Additional Cell Types in Development to Address a Spectrum of Ocular Disorders

1. **Photoreceptor Progenitor Cells**
   - Macular Degeneration - dry AMD, SMD, MMD
   - Retinitis Pigmentosa
2. **Retinal Ganglion Progenitor Cells**
   - Glaucoma
3. **Mesenchymal Stem Cells**
   - Uveitis
   - Management of Ocular Surfaces
4. **Corneal Endothelial Therapy**
   - Corneal Disease

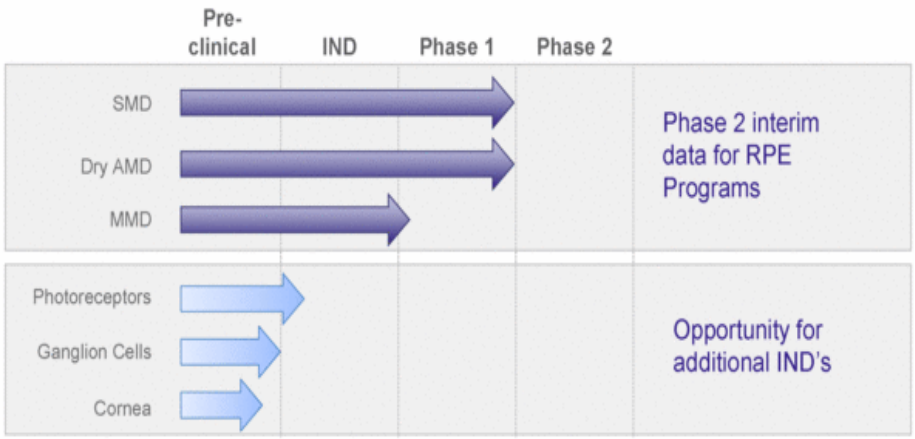



**Rich preclinical pipeline of regenerative ophthalmology product opportunities each addressing large unmet medical needs**



## Ophthalmic Development Pipeline Includes SMD, Dry AMD and MMD

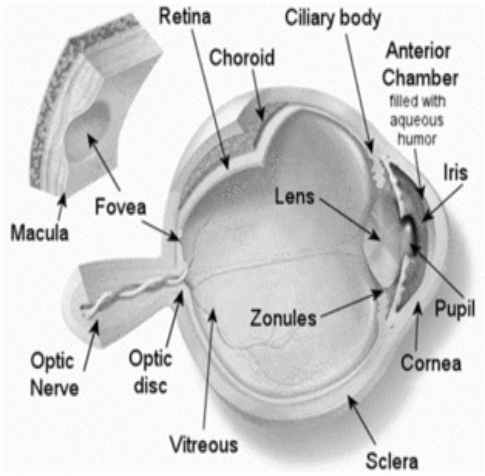
**Multiple Opportunities for Product Development and Commercialization**




**Potential European launch for Stargardt's Macular Degeneration in 2019**

# The Eye is Well-Suited for Cellular Transplantation

- Immune privileged
  - Less prone to rejection
- Compact Structure
  - Relatively small doses required to treat
- Straightforward delivery using currently available technology
- Validated tools for clinical outcome assessment






# RPE Market Dynamics for Stargardt's Macular Degeneration

## Orphan Disease with an Estimated Prevalence of 1:10,000 (~31,600 in the US)

| | | |
|---|---|---|
| Three main subtypes of patients that physicians observe | Fast deterioration | 60-70% of total Stargardt's population: symptoms present early on and progress from 20/40 to 20/200 (5-10 years) |
| | Slow deterioration | |
| | Rod and cone dystrophy | 5%-10% of total Stargardt's population: could potentially benefit from aggressive treatment |

Stargardt's patients are primarily diagnosed and managed by retinal specialists

There are no approved therapies that slow or stop the progression of Stargardt's disease; almost all patients develop 20/200 vision or worse and are managed currently with supportive therapies

Pipeline limited to a few product candidates in early stages of development:

- StarGen (Oxford Biomedica)
- ALK-001 (Alkeus)
- Emixustat (Acucela)

## Market Dynamics Age-related Macular Degeneration
### ~1.8m Dry AMD Patients Diagnosed Every Year in the USA

In the late form of dry AMD, patients can progress to geographic atrophy (GA) – GA progresses slowly and leads to the death of the photoreceptors.

Approximately 110,000-165,000 Cases of Advanced Dry AMD are diagnosed every year with central GA – our primary target indication.

Severe Dry AMD is a precursor to Wet AMD – Wet AMD is a blockbuster drug category e.g. Lucentis (Roche/Novartis) and Eylea (Regeneron)

Dry AMD patients are primarily managed by general ophthalmologists who are referred to retinal specialists when there are risks for wet AMD or severe symptoms

There are no approved therapies that slow or stop the progression of AMD; almost all patients develop 20/100 or 20/200 vision or worse and can only be managed with supportive therapies

Pipeline indicative of unmet need and commercial opportunity includes: NT-501 (Neurotech), emixustat (Acucela, Lampalizumab from (Roche) and MC-1101 from MacuCLEAR



## SMD, Dry AMD and MMD are Specialized Opportunities and Feasible for an Emerging Biotech

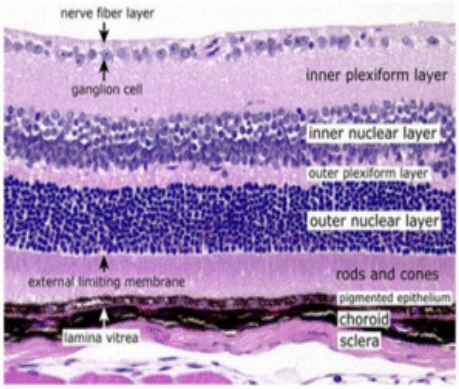
- **Well-defined prescriber base**
  - Patients are referred to retinal specialists (~2,500 in the US of which ~1,500- 2,000 are vitreoretinal [VR] surgeons) who diagnose and manage subsequent patient care
  - Targeted marketing achievable with a small and specialized technical salesforce
- **Ease of administration: cellular transplantation performed with current technology**
  - P1 utilizes pars plana vitrectomy and subretinal injection modalities scalable to VR surgeons
- **Small dosage requirement**
  - Commercial scalability of manufacturing and distribution in process
- **Significant unmet medical need – no approved treatments for dry AMD or SMD**
  - Opportunity to treat earlier stage disease

# Clinical Programs
# RPE for SMD, Dry AMD and MMD



## Retinal Pigment Epithelium: Vital for Photoreceptor Health

- Required for vision and maintenance of photoreceptor health
- Delivers and metabolizes Vitamin A
  - Recycles photopigments
- Phagocytosis of photoreceptor outer segments
- Transport of metabolic waste from retina to choriocapillaris
- Absorbs stray light for improved image resolution
- Secretes growth and survival factors needed for photoreceptor differentiation



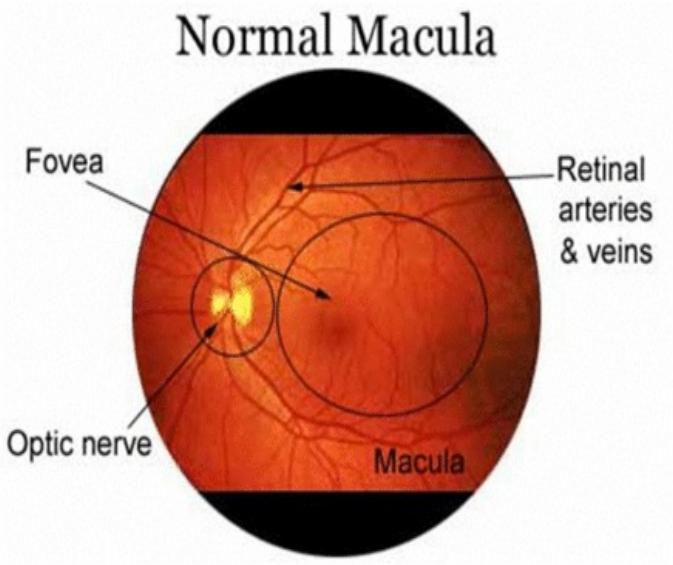
## Failure of RPE Causes Macular Degeneration regardless of etiology

| Disease | Pathophysiology | Prevalence |
|---|---|---|
| Stargardt's Macular Degeneration **(SMD)** | **Genetic** (e.g. *ABCA4* gene mutation) | **US/EU:** 80k-100k |
| Age-related Macular Degeneration **(AMD)** | **Environmental/Genetic** (e.g. smoking, obesity) and genetic (e.g. Y402H mutation in complement factor H) | **US/EU** Wet: 7.2m-11m Dry: 61m-65m |
| Myopic Macular Degeneration **(MMD)** | **Environmental/Genetic** (e.g. family history and race) | **US/EU:** 0.7m-1.3m **Asia:** 7.2-13.2m |

**Treatment of macular degeneration with Ocata Therapeutics' terminally differentiated retinal pigment epithelial cells uniquely poised to restore visual function**



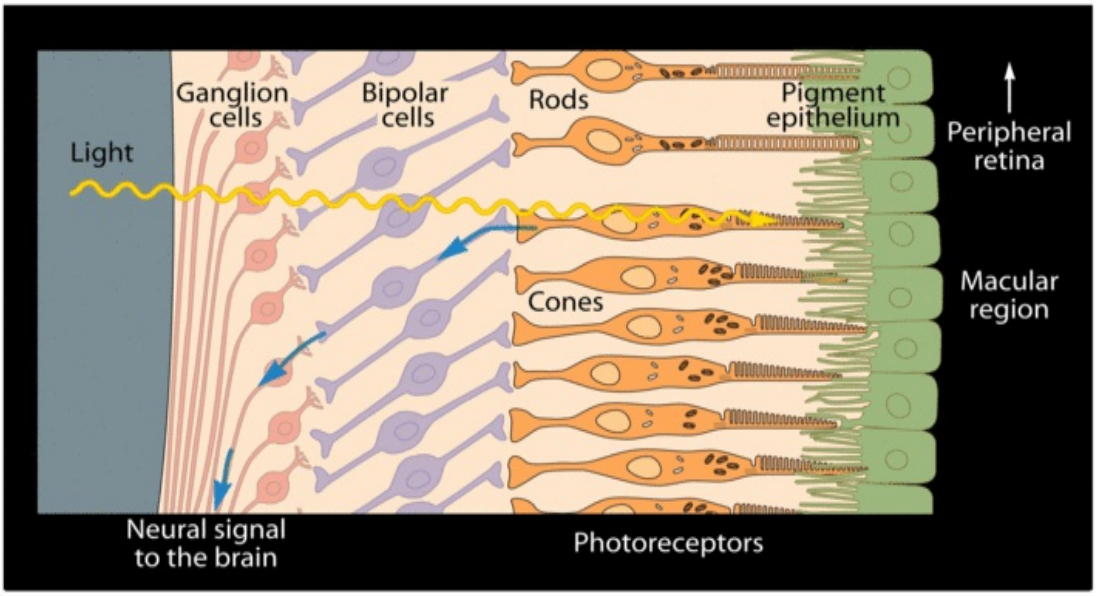
## Anatomical Overview



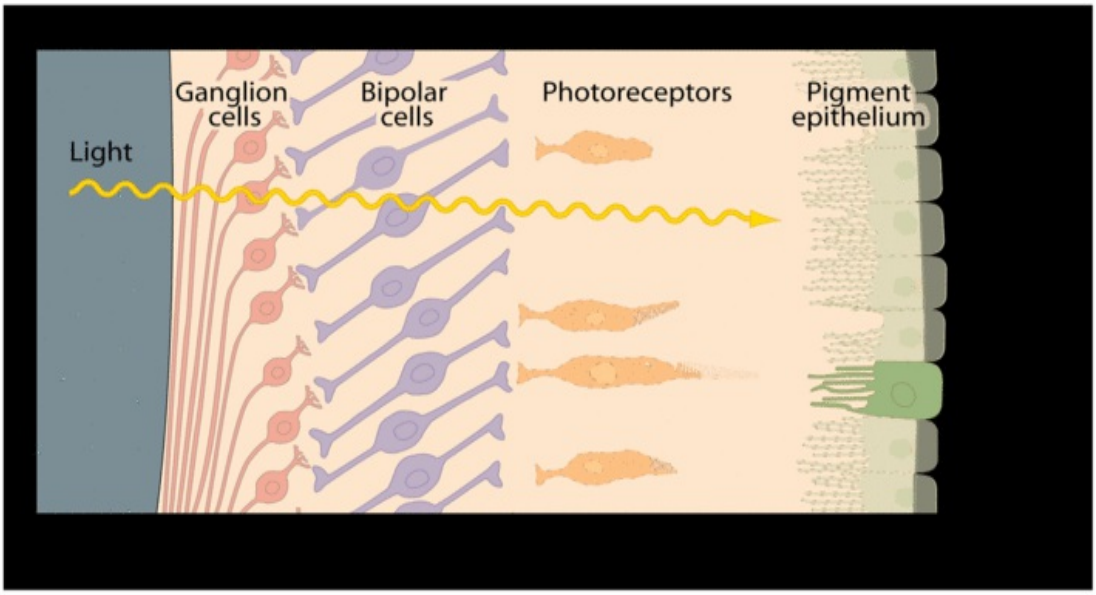
## RPE Damage and Subsequent Photoreceptor Degeneration Leads to Loss of Central Visual Acuity



## Visual Physiology: Normal

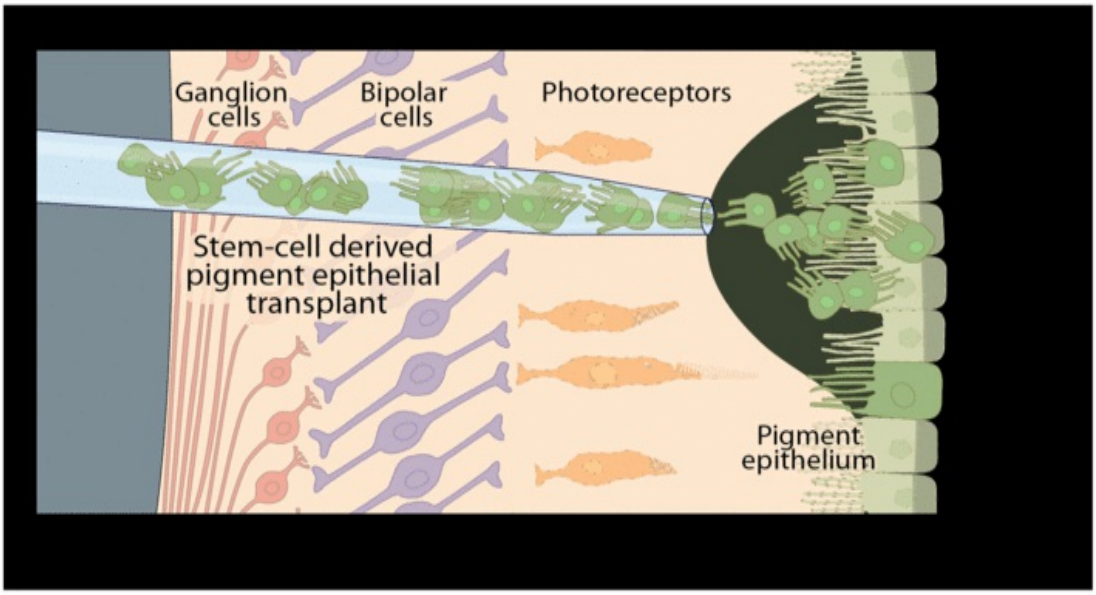


# Visual Physiology: Macular Degeneration

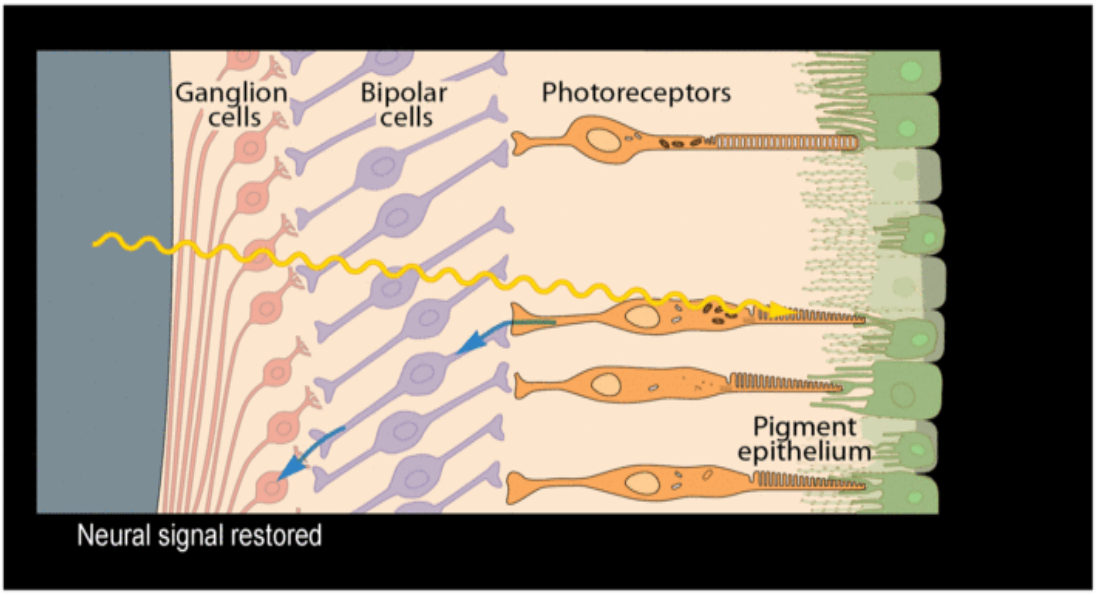





# RPE Transplantation



# Thesis of RPE Transplantation: Restoration of Anatomy & Function

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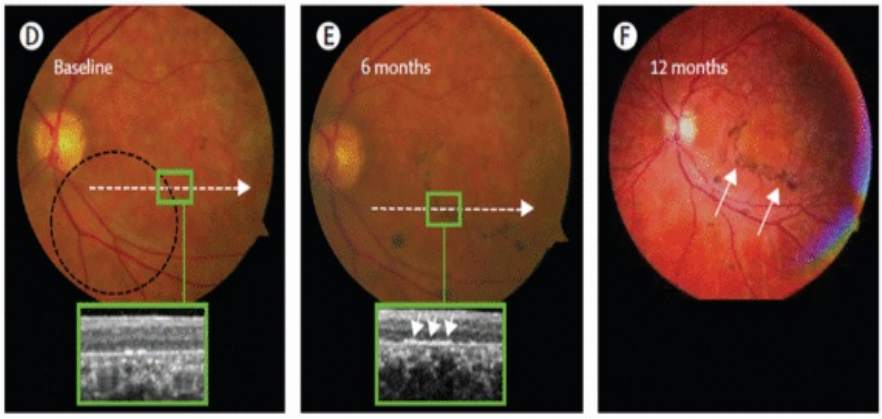
# Phase 1/2 Trials: Evidence of Engraftment (Lancet 2014)




- D. Black dashed circle outlining area of subretinal transplantation
- E. Green rectangle overlying white dashed arrow demonstrating optical coherence tomographic section (OCT) at baseline and at 6 months following subretinal MA09-hRPE injection
- F. White arrows demonstrating persistence of subretinal pigment epithelial cells 12 months post-transplantation

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**Anatomic Evidence of Successful Engraftment in 13/18 Subjects**

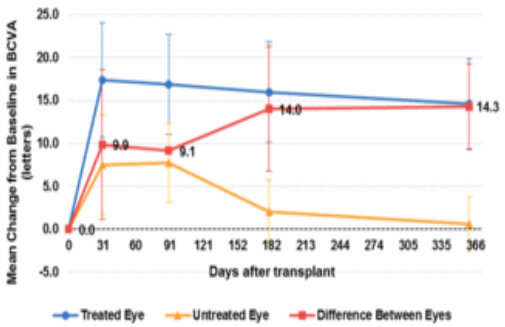
# Age-related Macular Degeneration



## AMD: BCVA Improved and Sustained At 1 Year

***Lancet* publication: May 2014**

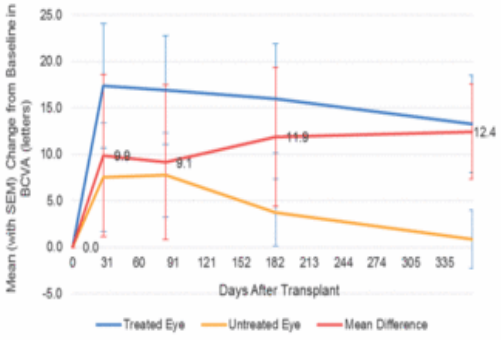
**8 Subjects with 12 Months Follow-up***




- *1 subject was excluded due to cataract formation
- *Month 6 BCVA result was carried forward to Month 12 for 2 subjects

**December 2014**

**8 Subjects with 12 Months Follow-up***




- *1 subject excluded due to cataract formation
- *1 subject excluded due to <6 months follow-up

**Persistent signal of efficacy in treated eyes & lack of improvement in untreated eyes**

# Stargardt's Macular Degeneration

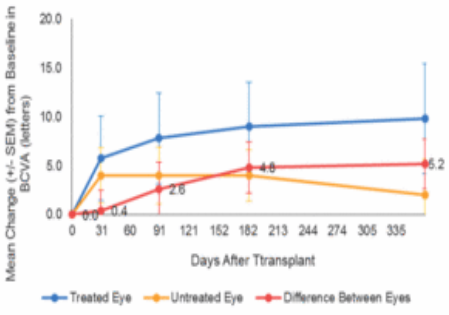


## SMD: BCVA Improved and Sustained At 1 Year

May 2014 - *The Lancet* publication

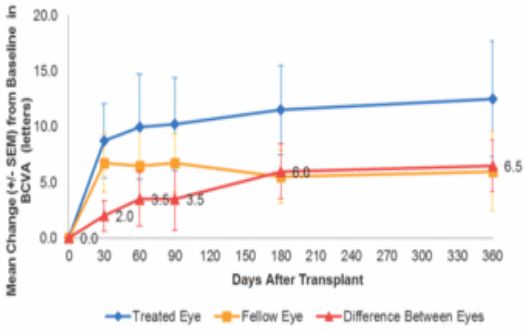
December 2014

**5 Subjects with 12 Months Follow-up***




*3 subjects excluded due to cataract formation; 1 subject excluded due to <6 months follow-up

**4 Subjects with 12 Months Follow-up***




*5 subjects excluded due to cataract formation; 1 subject excluded due to <6 months follow-up

Success in Phase 1/2 Studies Supports Investment in Proof-of-Concept Trials

# Phase 1/2 AMD & SMD Interim Data Conclusions

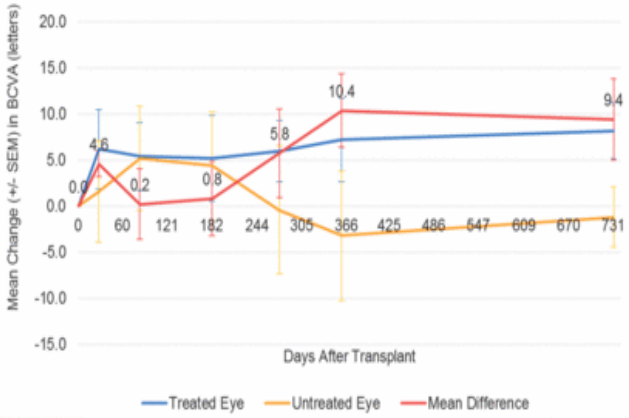
- Evidence of Engraftment
  - Patches of increasing subretinal, pigmented cellular tissue consistent with transplanted and integrated retinal pigment epithelium were observed in 13/18 subjects
- Signal of Efficacy
  - Visual acuity measures demonstrate functional improvement
  - Possible confounders
    - Placebo effect
    - Bias (selection, examiner)
    - Learning artifact due to repeat testing



# Two Year Update - BCVA Improvement Sustained

**December 2014**

**5 AMD Subjects with 24 Month Follow-Up**




**Persistent signal of efficacy in treated eyes & lack of improvement in untreated eyes maintained at 2 years**

# Operations, Finance and Corporate



## Ocata Therapeutics has Invested Heavily to Own Manufacturing Process in cGMP Environment

| Step | |
|---|---|
| Master Cell Bank of hESC's | Cryopreserved – inexhaustible replicative capacity starting material, stored at ACT and in remote location |
| Expansion of cells ~20 fold | Induction of proliferation and cell culture expansion |
| Shift to Terminal Differentiation to RPE cells | In-process assays to ensure morphology and sterility of cells |
| Purify RPE and re-passage to expand quantity | The process of re-passaging the cells can produce >1,000 fold increase of quantity of RPE cells |
| Harvest bulk material and cryopreserve RPE inventory | Available for patient dosing; one five month process typically yields ~1,000 doses |

**12 full-time employees dedicated to manufacturing, quality control, quality assurance & assay development**

FDA review of CMC accepting of release criteria and processes

Continued Investment and Advances in Manufacturing and Delivery Generates Expansion of IP Estate

# IP Coverage From Stem Cell Line to Patient Treatment

**Single Blastomere Derivation of hESCs**

1 Patent Family
- 4 Issued Patents
- 12 Pending Applications

**Expiry begins 2025**

**Methods of Manufacturing hESC-derived RPE cells**

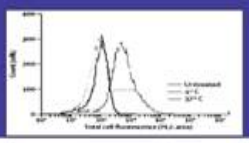
3 Patent Families
- 13 Issued Patents
- 26 Pending Applications

**Core Patent expiry – 2031 (with Patent Term Extension)**

**Product Release Assays**

2 Patent Family
- 11 Pending Applications

**Expiry will begin 2031 & 2032**



**Pharmaceutical Preparations**

5 Patent Families
- 2 Issued Patents
- 34 Pending Applications

**Core Patents - 2031**
**Formulation Improvements - 2032**
**Shipping Medium –2035**

**Methods-of-Treatment**

3 Patent Families
- 4 Issued Patents
- 26 Pending Applications

**Core Patents - 2031**
**Improvements - 2032**

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# Potential Milestones: Next 12- 24 Months

| Year | Quarter | Milestone |
|---|---|---|
| 2015 | Q1 | • SMD P2: First subject treated<br>• Up-listing of company stock to Nasdaq<br>• Publication of data in Asian patients (SMD & AMD) |
| | Q2 | • AMD P2: First subject treated<br>• Partnership of non-core asset (e.g. platelet program) |
| 2016 | Q1 | • AMD P2: First 15 subjects with 3 month data |
| | Q3 | • SMD P2: interim read<br>• AMD P2: interim read |

Continually build corporate awareness (conferences, presentations, expansion of IP estate)

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# The World Leader in Regenerative Ophthalmology

- Initiating Phase 2 with novel, potentially curative therapy in areas where no approved products exist today (Dry AMD/SMD)
- Dry AMD is a potential blockbuster indication – a precursor to Wet AMD where Treatments include Eylea (Regeneron) and Lucentis (Novartis/Roche)
- Safety observed, in addition to anatomical and functional evidence of repair and restoration; data published in *The Lancet*, October 14, 2014
- Established IP position in major markets protecting the life span of the cell therapy – from the origin of the cell to the delivery into patients' eyes