

# **Acquisition of Ocata Therapeutics**

New Step Forward in Ophthalmology with Cell Therapy Approach

November 10, 2015 Yoshihiko Hatanaka President and CEO Astellas Pharma Inc.

#### Cautionary Statement Regarding Forward-Looking Statements Fastel

Any statements made in this communication that are not statements of historical fact, including statements about the expected timetable for completing the transaction and Astellas' and Ocata's beliefs and expectations and statements about Astellas' proposed acquisition of Ocata, including the timing of and closing conditions to the acquisition, and the potential effects of the acquisition on both Astellas and Ocata are forward-looking statements that are based on management's beliefs, certain assumptions and current expectations and should be evaluated as such. These statements may be identified by their use of forward-looking terminology such as the words "expects," "projects," "anticipates," "intends" and other similar words. Forward-looking statements include statements that may relate to Astellas' or Ocata's plans, objectives, strategies, goals, future events, future revenues or performance, and other information that is not historical information. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include, but are not limited to, general economic, business and market conditions and the satisfaction of the conditions to closing of the proposed transaction. For a more complete discussion of certain of the risks and uncertainties that could cause actual results to differ from those contained in the forward-looking statements with respect to Ocata, see the discussion of risks and uncertainties in Ocata's annual report on Form 10-K for the fiscal year ended December 31, 2014, its most recent Quarterly Report on Form 10-Q, and other SEC filings. The forward-looking statements contained in this news release are made as of the date hereof, and neither Astellas nor Ocata undertakes any obligation to update any forward-looking statements, whether as a result of future events, new information or otherwise, except as required by law.

#### **Important Additional Information**

The tender offer for the outstanding common stock of Ocata has not yet commenced. This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Ocata common stock, nor is it a substitute for the tender offer materials that Astellas and its acquisition subsidiary will file with the SEC upon commencement of the tender offer. At the time the tender offer is commenced, Astellas will file a tender offer statement on Schedule TO with the SEC, and Ocata will file a solicitation/recommendation statement on Schedule 14D-9 with respect to the offer. THE TENDER OFFER STATEMENT (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND OTHER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT WILL CONTAIN IMPORTANT INFORMATION THAT SHOULD BE READ CAREFULLY AND CONSIDERED BY OCATA'S STOCKHOLDERS BEFORE ANY DECISION IS MADE WITH RESPECT TO THE TENDER OFFER. Both the tender offer statement and the solicitation/recommendation statement will be mailed to Ocata's stockholders free of charge. A free copy of the tender offer statement and the solicitation/recommendation statement will also be made available to all stockholders of Ocata by contacting Ocata at info@ocata.com or by phone at (508) 756-1212. In addition, the tender offer statement and the solicitation/recommendation statement (and all other documents filed with the SEC) will be available at no charge on the SEC's website: www.sec.gov, upon filing with the SEC.

OCATA'S STOCKHOLDERS ARE ADVISED TO READ THE SCHEDULE TO AND THE SCHEDULE 14D-9, AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME, AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC WHEN THEY BECOME AVAILABLE BEFORE THEY MAKE ANY DECISION WITH RESPECT TO THE TENDER OFFER, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES THERETO.

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- **1. Transaction Summary**
- 2. Overview of Ocata
- 3. Strategic Rationale
- 4. R&D Strategy After Acquisition

### **Transaction Summary**



#### New Step Forward in Ophthalmology with Cell Therapy Approach

Purchase Price:	\$8.50 per share in cash
	a premium of 79% to Ocata's closing share
	price of \$4.75 on November 6, 2015
Acquisition Amount*:	Approximately \$379 million
Acquisition Method:	Tender offer through Laurel Acquisition Inc.
	(a wholly-owned subsidiary of Astellas US Holding, Inc.)
Financing:	Fully financed with cash and cash equivalents
	on Astellas' balance sheet

\*Acquisition amount is including the purchase of all common shares , options, warrants and other securities.

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# **Overview of Ocata Therapeutics, Inc.**

#### > Founded in 1994

- Based in Marlborough, MA, USA
- Number of employees: 39
- Listed on NASDAQ (Ticker: OCAT)





- Focused on regenerative medicine, primarily cell therapy for ophthalmology
- Advanced technology that can establish fully-differentiated cells from pluripotent stem cells and strengths in clinical studies for cell therapy

# hES Cell Line-Derived RPE Cell Program



Retinal pigment epithelium (RPE) cells have essential roles for normal visual function and survival of retinal cells

- Provide critical nutrients, growth factors, ions and water
- ✓ Recycle photopigments and vitamin A
- Phagocytosis of photoreceptor outer segments
- ✓ Detoxify photoreceptor layer
- ✓ Prevent abnormal blood vessel growth
- ✓ Maintain Bruch's Membrane
- ✓ Absorb stray light and protects from UV ray



#### Sub-retinal injection of RPE cells

**RPE** Transplantation



(hES cell)

# **R&D** Pipelines



#### **RPE cell program at clinical stage**

Treatment with sub-retinal injection of fully differentiated cell suspension derived from hES cell line

#### Dry Age-related Macular Degeneration (AMD) : Phase II study ongoing

- AMD is the leading cause of vision loss in the US
- Dry AMD is triggered by RPE dysfunction and no approved treatments exist
- In RPE function-deficient rats, the cells prevented visual loss
- In a Phase I/II study, sub-retinal transplantation with RPE cells was well tolerated. In the exploratory evaluations for potential efficacy endpoints, engraftment of transplanted cells and recovery of vision were observed in some patients.
- Stargardt's macular degeneration : Phase I/II study ongoing
  - Juvenile macular degeneration between the ages of 6-20 (prevalence  $\sim$ 1/10K)
  - In Stargardt's macular degeneration mouse model, the cells prevented visual loss
  - Sub-retinal transplantation with RPE cells was well tolerated. While the efficacy was not the primary endpoint, engraftment of transplanted cells and recovery of vision were observed in some patients

#### Major programs at preclinical stage

#### **Photoreceptor Progenitor Cells**

- · Treatment with cells derived from pluripotent stem cell line
- Evaluation of the cells is ongoing for retinitis pigmentosa and dry AMD
- **Retinal Ganglion Progenitor Cells** 
  - Treatment with cells derived from pluripotent stem cell line

• Evaluation of the cells is ongoing for glaucoma Cell therapy programs in ophthalmology and other therapeutic areas

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# Strategic Plan 2015-2017 Advancing New Opportunities



Explore new opportunities in research for developing new drugs in new therapeutic areas and new technologies / new modalities



New therapeutic areas (Muscle diseases, Ophthalmology etc.)

#### **Rx business**

Advancing New Opportunities

#### **Existing therapeutic areas**

Urology, Oncology, Immunology, Nephrology, Neuroscience Advancing New Opportunities

#### New technologies / New modalities

(Regenerative medicine, Next-generation vaccine etc.)

# Ocata's Position in Strategic Plan 2015-2017





# **Establish Presence in Ophthalmology**



# 1. Ophthalmology: High unmet medical needs and growing opportunities



# 2. Cell therapy for ophthalmic diseases with risk of blindness:

 ✓ Eye is composed of highlydifferentiated cells

(low ability of self-regeneration)

- ✓ Degeneration of particular cell populations
- ✓ Unknown cause or multiple causes
- ✓ Real need is function recovery

Targeting function recovery using functional cells

#### 3. Potential benefits thanks to ophthalmology × cell therapy



<sup>1)</sup>Based on the data of MHLW report (中江公祐他 わが国における視覚障害の現状 厚生労働科学研究研究費補助金 難 治性疾患克服研究事業 網脈絡膜萎縮・視神経萎縮に関する研究 平成17年度 総括・分担研究報告書) <sup>2)</sup>Based on the data of National Eye Institute, Projections for Blindness (2010-2030-2050)

# **Establish Presence in Ophthalmology**



#### Pursue partnerships with leaders in cell therapy and gene therapy fields



# Establish a Leading Position in Cell Therapy



Strengthen Astellas R&D for cell therapy by Ocata's world-leading researchers and cutting-edge technologies in cell therapy Promote development and commercialization of cell therapy by combining Astellas' and Ocata's capabilities in cell therapy



\* Based on Astellas' evaluation

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# **R&D Strategy After Acquisition**



### Combine Ocata's capability of cell generation for therapy with Astellas R&D and create new value

- Continue developments of RPE program at its priority and launch the first-in-class product
- Accelerate promising pre-clinical projects and establish ophthalmic disease cell therapy franchise
- Establish and strengthen pipeline in therapeutic areas outside ophthalmology by utilizing cell therapy technology





# Summary



New Step Forward in Ophthalmology with Cell Therapy Approach

### [Strategic Rationale]

Establish presence in ophthalmology

Establish a leading position in cell therapy by obtaining Ocata's world-class capability

### [R&D Strategy After Acquisition]

Combine Ocata's capability of cell generation for therapy with Astellas R&D and create new value

### <Impact on financial results> Minor

### Strategic Plan 2015-2017 Achieving Sustainable Growth



New products will drive mid-term growth; Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening the business foundation





# **On the Forefront of Healthcare Change**