



# CORPORATE PRESENTATION

January 2019



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# INVESTMENT HIGHLIGHTS

- ❑ Clinical stage biopharmaceutical company uniquely positioned to excel in the large and growing ophthalmology market
- ❑ Lead candidate ONS-5010 is an ophthalmic formulation of bevacizumab (Avastin) with a well defined regulatory pathway
  - Streamlined clinical program allowing for potential approval in 2021/2022
- ❑ Potential for 12 years of market exclusivity protection from biosimilar competition as first approved ophthalmic bevacizumab
- ❑ ONS-5010 targets an estimated \$9.1B Anti-VEGF therapy market in wet AMD, DME, BRVO in 2018 (GlobalData 2016)
- ❑ If approved, ONS-5010 has potential to mitigate inherent risks associated with off-label compounding of drugs such as Avastin
- ❑ Management team with extensive clinical/ regulatory ophthalmology & drug development expertise

AMD = Age-Related Macular Degeneration; DME = Diabetic Macular Edema ; BRVO = Branch Retinal Vein Occlusion

# CORPORATE OVERVIEW AND RENEWED STRATEGY

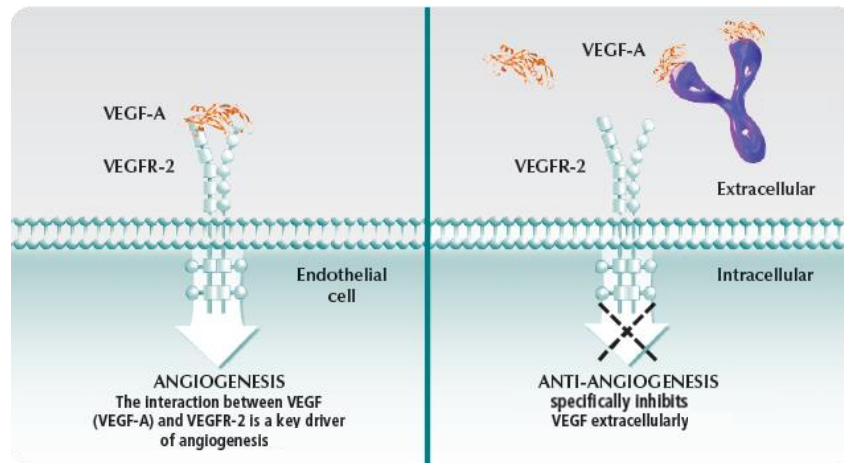
- ❑ Outlook Therapeutics (f/k/a Oncobiologics) is currently focused on the development of ONS-5010 in ophthalmic indications
  - ONS-5010 is well positioned to replace the use of off-label Avastin in ophthalmic indications such as wet AMD, DME, and BRVO
- ❑ Prioritized resources and reduced costs to support lead program
  - Recently reached agreement for \$20M equity financing and \$13.5M senior debt restructuring
- ❑ Recently expanded management team with significant experience in ophthalmic drug development
  - Jeff Evanson joined as CCO with 25+ years of commercial expertise, including Novartis (Alcon)
  - Terry Dagnon joined as COO with 20+ years of product development and regulatory experience in pharma & med tech, including Novartis (Alcon)

# PRODUCT INTRODUCTION

## ONS-5010

- ❑ ONS-5010 is an ophthalmic formulation of bevacizumab designed to replace the use of off-label Avastin
- ❑ Clinical program initiated in 2018 to evaluate ONS-5010 in first indication – wet AMD
  - Also being developed for DME and BRVO
- ❑ Avastin (bevacizumab) is an anti-VEGF monoclonal antibody (mAb)
  - It is estimated that off-label Avastin represents approximately 50% of the wet AMD market by volume
  - Avastin is approved and used widely in oncology indications but also used off-label for the treatment of several ophthalmic diseases

## Anti-VEGF mechanism of action



# COMPOUNDING PHARMACY CONCERNS

## ❑ ONS-5010 provides on-label option from current compounding of off-label Avastin

- Due to public health concerns FDA has consistently issued a Federal Register Notice upon approval of a frequently compounded drug directing physicians to use the approved drug
- ONS-5010 can provide important benefits over off-label Avastin
  - Continuity of source and quality
  - Uniformity of product
  - Supply chain integrity

## Issues with compounding pharmacies have been well-documented

### The benefits and risks of compounding pharmacies

As of the end of October, 20 deaths resulting from the use of poorly prepared compounded medications by a Massachusetts-based compounding pharmacy have been reported. These deaths have focused increased attention on the role and safety of compounded specialized medicines and dosage forms in the United States.

Pharmaceutical compounding is defined as the combining or mixing of pharmaceutical ingredients to create a customized medication product for a specific patient by a practitioner's order or prescription. Inherent in this definition is the notion that the final product is not tested for safety and efficacy by data that the FDA normally uses to assess a product. Because pharmacy school curricula include training in the science and art of compounding, pharmacists are generally well trained in how to compound many medicines. More advanced training is also available for post-graduate pharmacists and pharmacy technicians. By organizations such as the Professional Compounding Centers of America. Although most independently owned and chain pharmacies (eg, Walgreens) do not prepare many compounded products, specialized compounding pharmacies are available that do prepare many compounded products.

### SEE ALSO

FDA draft guidance on drug compounding (see link)  
 Addition of inactive substances requires scrutiny  
 FDA warns against using sterile drugs from...

The FDA has received reports describing adverse effects from other inappropriately prepared compounded medicines in past years, but the recently reported deaths from poorly prepared injectable methylprednisolone products prepared by the New England Compounding Center has focused attention on pharmaceutical compounding (see [www.fda.gov/Drugs/DrugSafety/ucm323431.htm](http://www.fda.gov/Drugs/DrugSafety/ucm323431.htm)). The New England Compounding Center (NECC) is a specialized compounding pharmacy located in Framingham, Mass., a suburb of Boston. NECC is no longer operating, as its license to practice was suspended on Oct. 3. The product prepared by NECC that has been reported to result in significant adverse effects was methylprednisolone 80 mg/mL, intended for epidural use.

...such errors may adversely affect many patients. Published reports of independent testing by the FDA, state agencies, and other consumers show that compounded drugs fail to meet specifications at a considerably higher rate than FDA-approved drugs. Compounded sterile preparations show the additional risk of microbial contamination to patients. In the last 11 years, three separate meningitis outbreaks have been traced to purportedly sterile steroid solutions contaminated with fungus or bacteria, which were made by compounding pharmacies. The most recent 2012 outbreak has resulted in intense scrutiny of pharmacy compounding practices and increased recognition of the need to ensure that compounding is limited to appropriate circumstances. Patients and healthcare practitioners need to be aware that compounded drugs are not the same as generic drugs, which are approved by the FDA. The risk-benefit ratio of using traditionally compounded medicines is favorable for patients who require specialized medications that are not commercially available, as they would otherwise not have access to suitable treatment. However, if an FDA-approved drug is commercially available, the use of an unapproved compounded drug confers additional risk with no commensurate benefit.

...the 2012 meningitis outbreak was linked to contaminated methylprednisolone acetate prepared by the New England Compounding Center (NECC) in Framingham, Mass. This outbreak was the first of its kind in the United States. The outbreak was caused by a large number of cases from a compounding pharmacy. Patients who received the medicine that is linked to the outbreak in the United States, including the United Kingdom, and other countries, should be notified and should seek to advise to improve safety and efficacy of the medicine.

As a result of this case, some patients, people may use the medicine in a different way to the medicine that is being prepared and that the product should be used in a different way to the medicine that is being prepared. Some patients may use the medicine in a different way to the medicine that is being prepared and that the product should be used in a different way to the medicine that is being prepared.

...that are not needed. Traditional by pharmacists and prepare quality oversight of food and drug new pose additional risks to with good manufacturing the production and testing of all from clinical, and testing to pharmacy-compounded in compounded preparations recommendations for safe use. In the FDA, which is practices engaging in a compounding such as a patient preparation, and creating issues of FDA, poses the potential for

### A Visible Opito

...the use of a specific compounding pharmacy for their patients, and they placed the commercial responsibility in a soft-shell case. Dr. Gosselink "They were told to get their Avastin from a specific pharmacy, for this subset of their patients. The samples were labeled for each patient but were stamped in the doctor's office as a patient of the doctor. The patient expected to only need an injection in one eye, so a sample was sent for that patient. On exam, the patient had a new intravitreal injection in both eyes and no more treatment in the other eye. The doctor had no idea what the patient had received from another source, and this case did not develop immediately, despite being treated in the same way. As we know it, we know the doctor's reaction technique that caused the infection."

### REVIEW of Ophthalmology

#### Compounded Drugs: Understand the Risks

Ask questions—ask a lot of questions—before you rely on a compounding pharmacy to supply drugs.

During the past few years, compounding pharmacies have received a lot of press. In 2012, a study involving a compounding pharmacy involved national attention when in nearly an 18,000 cases received compounded injections of a steroid medication. A total of 171 patients contracted meningitis or other infections from the injections, and 20 patients died as a result.

A year before this nationwide outbreak, ophthalmologists at Beacon Patient Eye Institute in Miami were treating patients who had received intravitreal injections of Avastin. As with the November 2011, Page 4, Gosselink, MD, MHA, reported a series of 12 patients who developed endophthalmitis after injections with intravitreal Avastin. Of these 12 patients, 10 patients presented to Beacon Patient Eye Institute with endophthalmitis. The reactions occurred at four different clinics in South Florida, but all of these (endophthalmitis) were prepared by the same compounding pharmacy in Broward County.

None of the patients received injections at Beacon Patient Eye Institute. Some patients presented to tertiary care centers emergency rooms for treatment, and three others were seen in consultation. Initially, all patients were treated with vitrectomy and injections, and eight patients later received a vitrectomy. Microbiology cultures for 10 patients were positive for *Staphylococcus epidermidis*. Seven unpaired samples of intravitreal injections prepared by the compounding pharmacy at the same time as those prepared for the affected patients were also positive for *S. epidermidis*. After four months of follow-up, all but one patient had clear vision or worse visual acuity, and seven ultimately required enucleation or amputation.

Dr. Gosselink, who is now in practice at Tufts New England Eye Center in Boston. Consistent of other, systems that many of the patients in the above outbreak of endophthalmitis were part of the same health insurance group.

They revealed the use of a specific compounding pharmacy for their patients, and they placed the commercial responsibility in a soft-shell case. Dr. Gosselink "They were told to get their Avastin from a specific pharmacy, for this subset of their patients. The samples were labeled for each patient but were stamped in the doctor's office as a patient of the doctor. The patient expected to only need an injection in one eye, so a sample was sent for that patient. On exam, the patient had a new intravitreal injection in both eyes and no more treatment in the other eye. The doctor had no idea what the patient had received from another source, and this case did not develop immediately, despite being treated in the same way. As we know it, we know the doctor's reaction technique that caused the infection."

# PREVALENCE IN TARGET INDICATIONS (2018)<sup>(1)</sup>

ONS-5010 has the potential to address large markets in wet AMD, DME and BRVO

Assumption	U.S.	EU5 <sup>(2)</sup>	Japan
Prevalence: Wet AMD Patients	697,041	1,724,946	365,709
Diagnosed: DME Patients	324,064	338,011	376,414
Prevalence: BRVO Patients	119,042	135,206	61,852

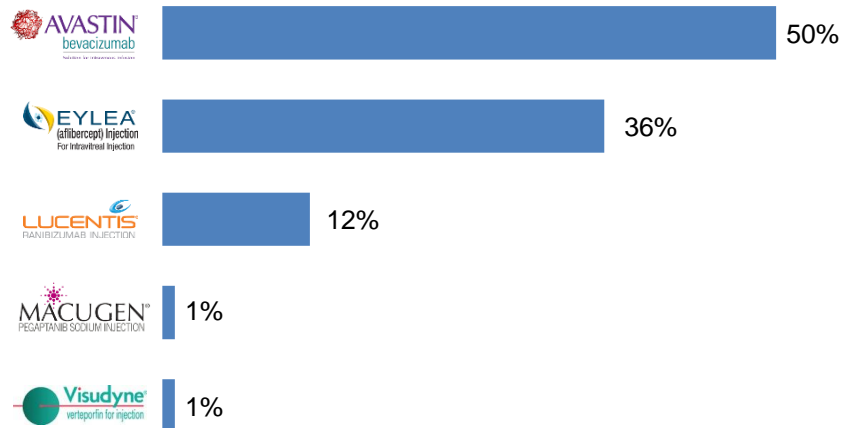
(1) Source: Global Data estimates, 2016

(2) EU5 consists of the UK, France, Germany, Spain, and Italy

# SIGNIFICANT OPPORTUNITY IN TARGET INDICATIONS

- ❑ \$9.1 Billion estimated 2018 anti-VEGF market in wet AMD, DME and BRVO
  - As Avastin, Eylea and Lucentis lose patent protection, we believe emerging therapies such as ONS-5010 have the potential to capture significant market share in wet AMD

## Wet AMD U.S. treated patient market share (est 2018) and ONS-5010 opportunity



### Expected demand drivers for ONS-5010

1. Convert off-label Avastin
2. Penetrate EU and developing markets
3. Become first line "step edit" drug of choice
4. Support emerging home Optical Coherence Tomography (OCT) care model (vis-à-vis Notal and Acucela)

Source: GlobalData 2016



# ANTI-VEGF DEVELOPMENT LANDSCAPE

- While there are a number of approved anti-VEGF drugs currently on the market, most will run into IP expiration in the U.S. in the coming years
- Other clinical-stage anti-VEGF players will require significant time and capital to achieve commercialization

## Anti-VEGF development landscape

Phase 2

Phase 3

Approved



IP Expiration		
U.S.	EU5	Japan
2020	2022	2023
2026	2025	2023
2019	2019	2023



IP Expiration		
U.S.	EU5	Japan
2011	NA	NA
2017	2017	2017
2026	2023	2023

**ONS-5010 represents a first mover with potential approval by 2021/2022**

NA = Not publicly disclosed

# COMPARISON OF AMD TREATMENTS TRIALS (CATT)

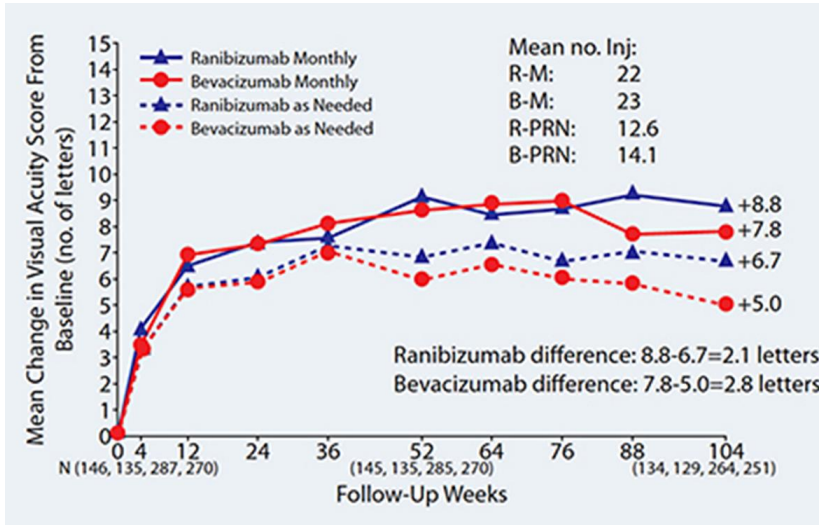
- ❑ Multicenter, randomized clinical trial (N = 1,107)
- ❑ Year 1: patients were assigned randomly to 1 of 4 arms
  - Ranibizumab 0.5 mg monthly
  - Bevacizumab 1.25 mg monthly
  - Ranibizumab 0.5 mg PRN
  - Bevacizumab 1.25 mg PRN
- ❑ Year 2: patients assigned to monthly dosing retained their drug but were randomly reassigned to monthly or PRN
- ❑ Primary endpoint: mean change in visual acuity

Source: \*Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Daniel F. Martin, Ophthalmology, July 2012 Volume 119, Issue 7, Pages 1388–1398

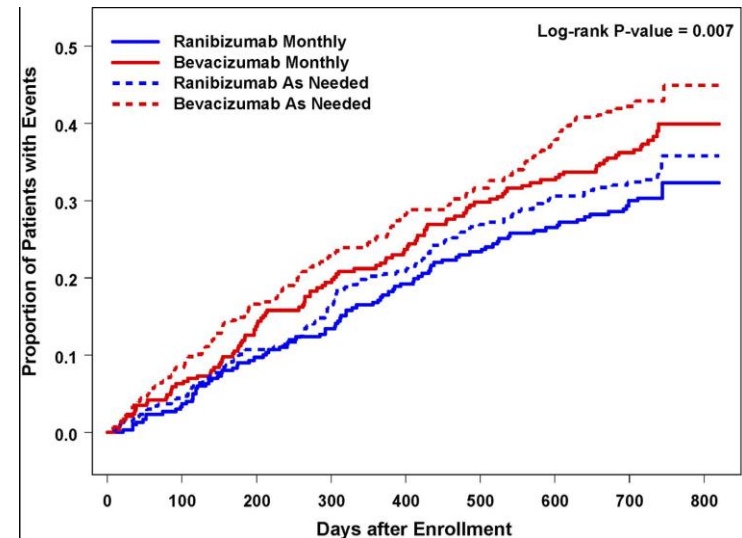
# CATT DATA

- ❑ The CATT Study data demonstrated that bevacizumab is safe and effective for the treatment of age-related macular degeneration and non-inferior to Lucentis

## Efficacy



## Safety



Source: Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Daniel F. Martin, Ophthalmology, July 2012 Volume 119, Issue 7, Pages 1388–1398

# ONS-5010 CLINICAL PROGRAM DESIGN

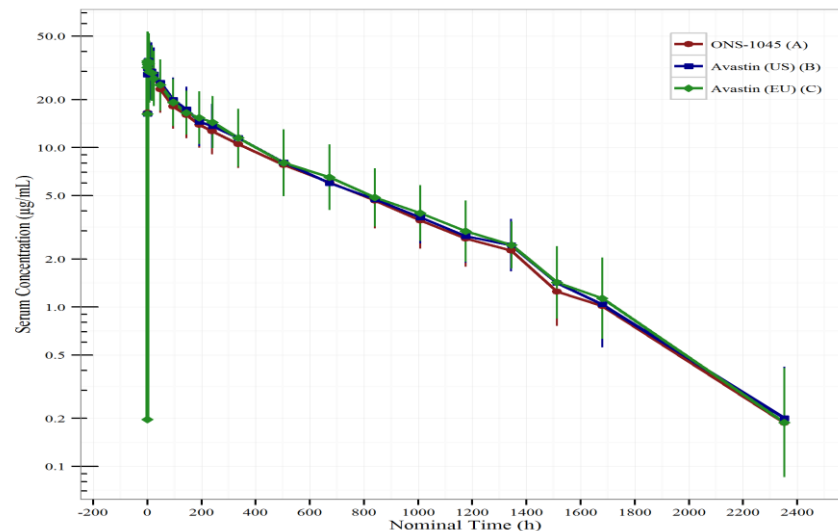
- ❑ Two registration studies have been initiated in wet AMD
  - ONS-5010-001: Currently dosing patients in first adequate and well controlled study in wet AMD ex-U.S.
  - ONS-5010-002: Second wet AMD study initiated with enrollment anticipated to begin in 2019
- ❑ Clinical program for wet AMD, DME & BRVO reviewed by FDA at End-of-Phase 2 meeting in 2018
  - FDA has indicated the study design would be acceptable for registration
- ❑ Completed Phase 1 pharmacokinetic (PK) study comparing to Avastin
- ❑ Intravitreal pharmacokinetic and immunogenicity being collected in ongoing registration trial
- ❑ U.S. IND expected to be filed in Q1 2019 for U.S. portion of second wet AMD study
- ❑ DME and BRVO clinical studies planned to begin later in 2019

# BEVACIZUMAB PHASE 1 PK

Phase 1 PK data demonstrated biosimilarity between Outlook's formulation of bevacizumab vs. U.S. and EU versions of Avastin

- Phase 1 PK study was conducted using ONS-1045, a formulation of bevacizumab developed by Outlook Therapeutics
- Randomized, double blind, single dose study vs U.S. and EU Avastin
- Met primary and secondary endpoints
  - Biosimilar PK
  - Low immunogenicity
- High degree of similarity to Avastin

Mean ( $\pm$ SD) bevacizumab serum concentration - log scale



# ONS-5010-001 CLINICAL TRIAL DESIGN

- ❑ First of two adequate and well controlled trial designs in wet AMD subjects
  - Both studies will be used for registration
- ❑ Study is being conducted outside the U.S.
- ❑ Enrollment: 50% complete
- ❑ Safety and efficacy data to be collected
  - Safety data expected to support U.S. IND filing anticipated in Q1 2019
  - Safety & efficacy data expected to support U.S. BLA filing expected in 2020

# REGULATORY STRATEGY

- ❑ Outlook Therapeutics has met with FDA and confirmed an innovative clinical trial strategy, which we believe will expedite the clinical development of ONS-5010 for wet AMD
  - PHSA 351 (a) New BLA regulatory pathway
  - FDA End-of-Phase 2 meeting completed
  - Recommendations have been implemented
  - Protocols reflect FDA feedback
- ❑ New BLA expected to have 12 years of regulatory exclusivity as first approved ophthalmic bevacizumab
- ❑ EU agency meetings planned in Q2 2019
- ❑ Additional Ex-U.S. regulatory agency meetings expected in Q3 & Q4 2019

# COMMERCIAL STRATEGY

- ❑ Convert off-label Avastin use to ONS-5010
  - Pricing to maximize launch velocity and peak share
  - Pre-filled syringe provides convenience and safety (post-approval change)
  - Collaborative payor strategy (e.g., “not to exceed” per patient agreements)
- ❑ Become first-line “step edit” drug of choice for branded (Eylea, Lucentis) and long acting options (e.g., brolucizumab, abicipar, GNE PDS)
- ❑ Support emerging at home OCT care model (e.g., Notal and Acucela)
- ❑ Penetrate EU5 and developing markets where off-label Avastin use has been restricted



# LEADERSHIP TEAM: GLOBAL OPHTHALMOLOGY DEVELOPMENT & COMMERCIAL EXECUTION



**LAWRENCE KENYON**

President, CEO, CFO



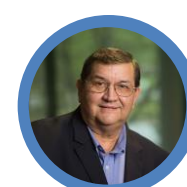
**JEFF EVANSON**

Chief Commercial Officer



**TERRY DAGNON**

Chief Operating Officer



**KENNETH M. BAHRT, M.D.**

Chief Medical Officer



**RANDY THURMAN**

Executive Chairman of the Board

# DEEP EXPERIENCE IN RETINA

- **Jeff Evanson** has extensive experience in all aspects of Commercial and Strategy in retina
- Former VP and Global Commercial Head of \$4.2B Division Ophthalmic Pharmaceuticals of Alcon (Novartis), had responsibilities for all strategy and execution, acquisitions, global launches and campaigns
- Co-Led Global collaboration of Alcon Pharmaceuticals and Novartis Lucentis Franchises specifically in retina
- Significant depth in enabling payor strategies that enable successful commercial launch
- Has consulted to the major Pharma companies targeted as Strategics for ONS-5010
- **Terry Dagnon** has been working with biologics for over two decades and has been working in retina therapeutic area since the 1990's
- Former North America Head of Regulatory Affairs for Alcon (Novartis) with previous global role for all Alcon 'back of the eye' products including Retina Pharmaceuticals and vitreoretinal surgical franchises
- Extensive product development experience that has resulted in 100's of product approvals
- Product development, operations, quality and regulatory executive
- General Manager of consulting service line with recent direct experience working with targeted Strategics

# MILESTONES

Milestone	Target
U.S. IND submission	Q1 2019
Enrollment begins in 2nd Wet AMD clinical trial	Q1 2019
Meet with European regulatory authorities	Q2 2019
Initiate DME and BRVO clinical trials	H2 2019
ONS-5010-001 primary outcome data	Q1 2020
ONS-5010-002 primary outcome data	Q3 2020
BLA submission	Q4 2020

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