OUTLOOK THERAPEUTICS

# 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

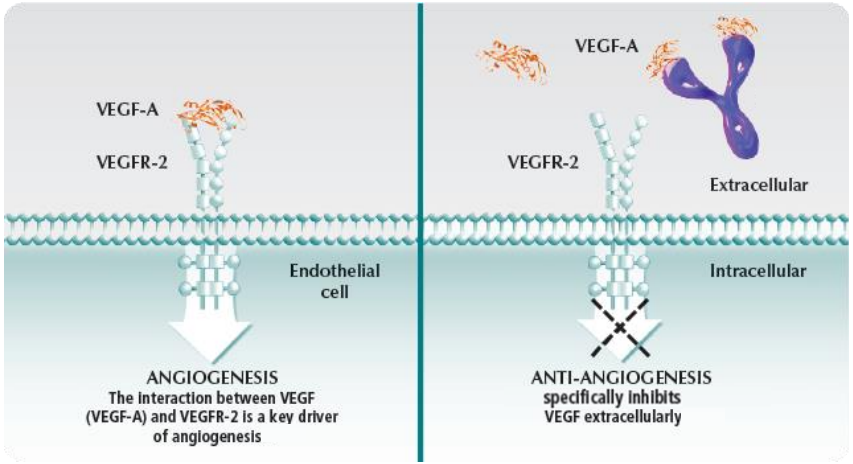
- Outlook Therapeutics (f/k/a Oncobiologics) is currently focused on the development of ONS-5010 in ophthalmic indications
  - ONS-5010 is well positioned to replace the use of off-label Avastin in ophthalmic indications such as wet AMD, DME, and BRVO
- Prioritized resources and reduced costs to support 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

# PREVALENCE IN TARGET INDICATIONS (2018)[1]

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

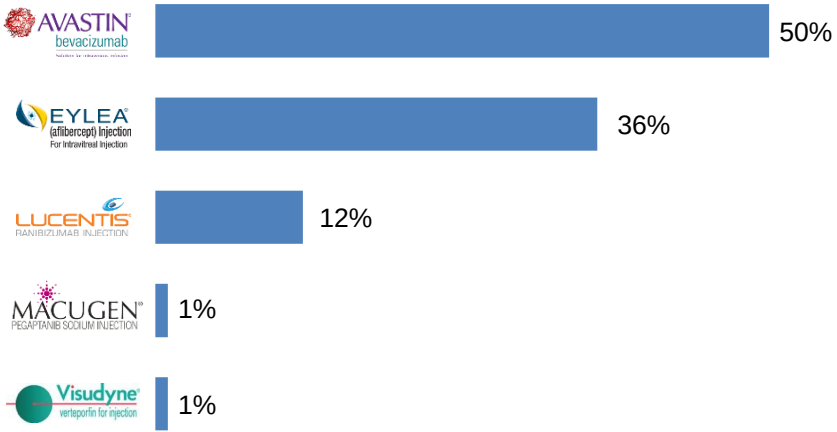
| Assumption | U.S. | EU5 [2] | Japan |
|---|---|---|---|
| Prevalence: Wet AMD Patients | 697,041 | 1,724,946 | 365,709 |
| Diagnosed: DME Patients | 324,064 | 338,011 | 376,414 |
| Prevalence: BRVO Patients | 119,042 | 135,206 | 61,852 |

(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




Source: GlobalData 2016

### 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)

# 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**

GRAYBUG VISION

OPTHEA

PANOPTICA

**Phase 3**

NOVARTIS

Genentech

Allergan

**Approved**

| | IP Expiration | | |
|---|---|---|---|
| | U.S | EU5 | Japan |
| LUCENTIS RANIBIZUMAB INJECTION | 2020 | 2022 | 2023 |
| EYLEA (aflibercept) Injection For Intravitreal Injection | 2026 | 2025 | 2023 |
| AVASTIN bevacizumab | 2019 | 2019 | 2023 |

| | IP Expiration | | |
|---|---|---|---|
| | U.S | EU5 | Japan |
| Visudyne verteporfin for injection | 2011 | NA | NA |
| MACUGEN PEGAPTANIB SODIUM INJECTION | 2017 | 2017 | 2017 |
| FOTIVDA (tivozanib hydrochloride) | 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)

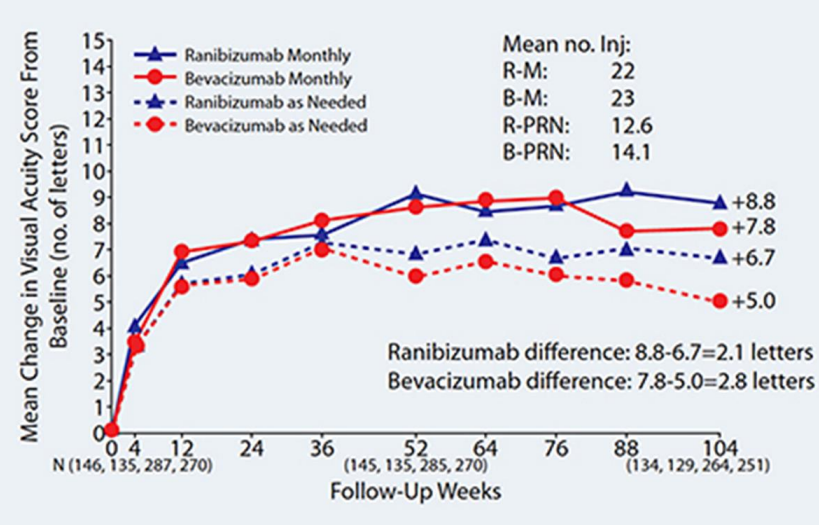
- Multicenter, randomized clinical trial (N = 1,107)
- Year 1: patients were assigned randomly to 1 of 4 arms
  - Ranibizumab 0.5 mg monthly
  - Bevacizumab 1.25 mg monthly
  - Ranibizumab 0.5 mg PRN
  - Bevacizumab 1.25 mg PRN
- Year 2: patients assigned to monthly dosing retained their drug but were 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

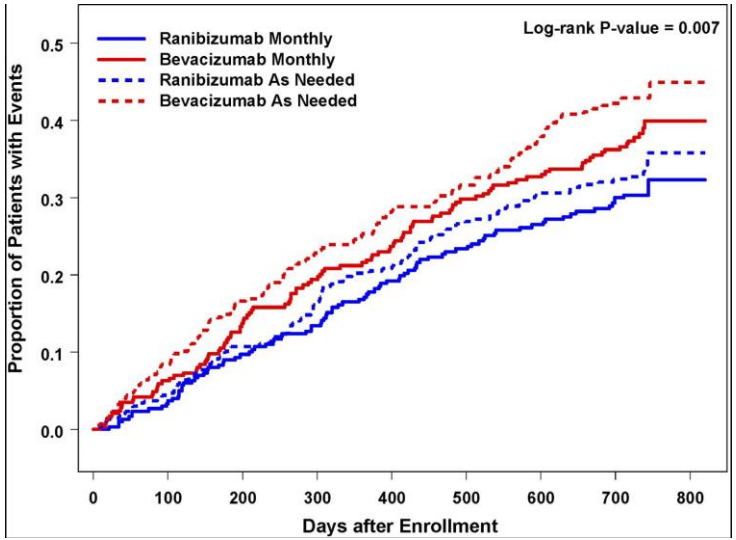
# CATT DATA

- 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

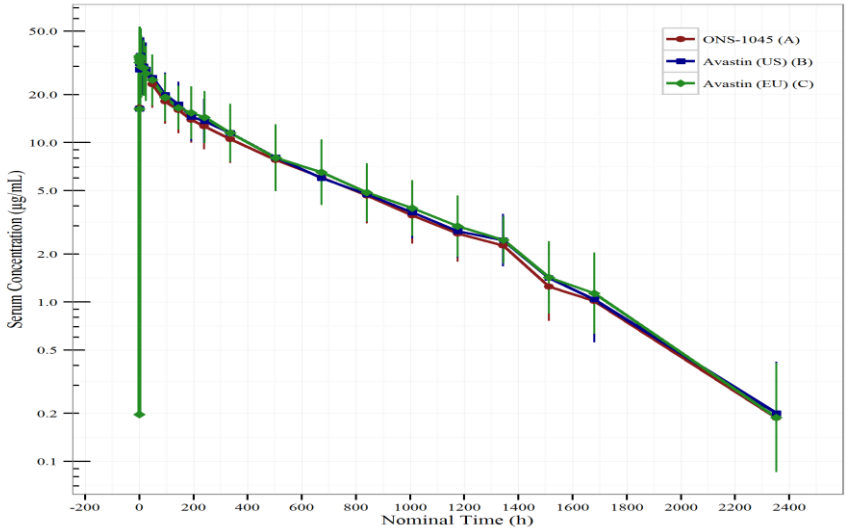
- Two registration studies have been initiated in wet AMD
  - ONS-5010-001: Currently dosing patients in first adequate and well controlled study in wet AMD ex-U.S.
  - ONS-5010-002: Second wet AMD study initiated with enrollment anticipated to begin in 2019
- Clinical program for wet AMD, DME & BRVO 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 biosimiliarity 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 (±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

ARNO THERAPEUTICS · TAMIR Targeting microRNAs · PAR PHARMACEUTICAL

**JEFF EVANSON**

Chief Commercial Officer

NAVIGANT · Medtronic · Alcon · NOVARTIS

**TERRY DAGNON**

Chief Operating Officer

Johnson & Johnson · DOHMEN LIFE SCIENCE SERVICES

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

Chief Medical Officer

Bristol-Myers Squibb · Pfizer · Genentech A Member of the Roche Group

**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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