

NASDAQ: OTLK  
outlooktherapeutics.com



# OUTLOOK THERAPEUTICS

*Redefining the Standard of  
Care for Ophthalmic Therapies*

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Corporate Presentation  
April 2024

# Disclaimer

This presentation contains forward-looking statements about Outlook Therapeutics, Inc. (“Outlook Therapeutics” or the “Company”) based on management’s current expectations, which are subject to known and unknown uncertainties and risks. Words such as “anticipate,” “believe,” “estimate,” “expect,” “explore,” “initiate,” “intend,” “may,” “plan,” “potential,” “seek,” “target,” “will,” and variations of these words or similar expressions are intended to identify forward-looking statements. These forward-looking statements include, among others, statements about ONS-5010’s potential as the first U.S. Food and Drug Administration (FDA)-approved and/or European Medicines Agency (EMA) approved ophthalmic formulation of bevacizumab-vikg, our expectations for ONS-5010 market exclusivity, expectations concerning our ability to remediate or otherwise resolve deficiencies identified in our Complete Response Letter (CRL) issued by the FDA, including with respect to an additional clinical trial and chemistry, manufacturing and controls (CMC) issues, expectations concerning the NORSE EIGHT trial design, the timing for initiation and completion of NORSE EIGHT and resubmission of the Biologics License Application (BLA) for ONS-5010, expectations concerning decisions of regulatory bodies, including the FDA and EMA, and the timing thereof, plans for potential commercial launch of ONS-5010 in the United States and European Union, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof, ONS-5010’s ability to replace and address issues with off-label use of Avastin, other drug candidates in development, commercial drivers for ONS-5010 and its potential, the success of ongoing ONS-5010 trials for wet age-related macular degeneration (AMD), planned trials for ONS-5010 for diabetic macular edema (DME) and branch retinal vein occlusion (BRVO), expectations concerning the size of the market for, and potential issuers of ONS-5010, the sufficiency of our capital resources and other statements that are not historical fact. Our actual results could differ materially from those discussed due to a number of factors, including, but not limited to, the risks inherent in developing pharmaceutical product candidates, conducting successful clinical trials, and obtaining regulatory approvals, including our ability to resolve issues identified in the CRL issued by the FDA, as well as our ability to raise additional equity and debt financing on favorable terms, among other risk factors. These risks are described in more detail under the caption “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended September 30, 2023, and other filings with the Securities and Exchange Commission, which include the uncertainty of future impacts related to macroeconomic factors, including as a result of the ongoing overseas conflict, high interest rates, inflation and potential future bank failures on the global business environment. Moreover, Outlook Therapeutics operates in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied.

# Why Outlook, Why Now

- ▶ Redefining the standard of care for retina disorders, including wet AMD, DME and BRVO
- ▶ Working to achieve the first approval for bevacizumab in ophthalmology

\*Dates and timelines are listed in calendar year

1. ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab
2. 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 / LYTENAVA™

(bevacizumab-vikg; bevacizumab gamma)<sup>1</sup>

*Ophthalmic formulation of bevacizumab in development for the treatment of wet AMD*

- ▶ **Positive European CHMP Opinion**  
Serves as basis for final decision of potential EU market approval targeted Q2 2024
- ▶ US FDA Biologics License Applications (BLA) resubmission expected before year end 2024
- ▶ Bevacizumab has been validated<sup>2</sup> in wet AMD and is used off-label as a first-line treatment<sup>3</sup>
- ▶ Targeting \$15.9 Billion global ophthalmic anti-VEGF market<sup>4</sup>

3. ASRS 2022 Membership Survey Presented at ASRS NY 2022. Q: Considering all indications, what is your most commonly used first-line anti-VEGF agent?
4. Citeline (2023), Global Data (2023) and Market Scope (2022)

# The Bevacizumab Opportunity

**Bevacizumab (Brand Name Avastin®) Approved as an Oncology Drug in 2004**

*Not Approved for Ophthalmic Use*

*Most Commonly Used First-Line Anti-VEGF for Treatment of Wet AMD*

## Current Situation

55.4% of new diagnosed wet AMD patients start with off-label, unapproved bevacizumab<sup>1</sup>

66.3% of US retina physicians state off-label, unapproved bevacizumab is their most commonly used first-line anti-VEGF<sup>2</sup>

However, switching to an FDA approved anti-VEGF may occur up to over 40% of the time by year 3 of treatment

This may be occurring due to the limitations of off-label (non-ophthalmic) repackaged bevacizumab, specifically:

- Lack of potency,
- Significant safety issues
- Quality and supply issues

## Outlook Therapeutics Opportunity

Ophthalmic formulation of bevacizumab is a 351 (a) BLA submission in the US and a full mixed MAA application based on Article 8.3 of Directive 2001/83/EC in the EU

12-years regulatory exclusivity expected upon approval in the United States

10 years market exclusivity expected upon approval in the EU

Potential to eliminate safety risks associated with repackaged bevacizumab, impurities, particulates, and lack of drug potency

# The Anti-VEGF Retina Market<sup>1</sup>

*Currently Estimated to be in Excess of \$15.9 Billion Worldwide<sup>1</sup>*

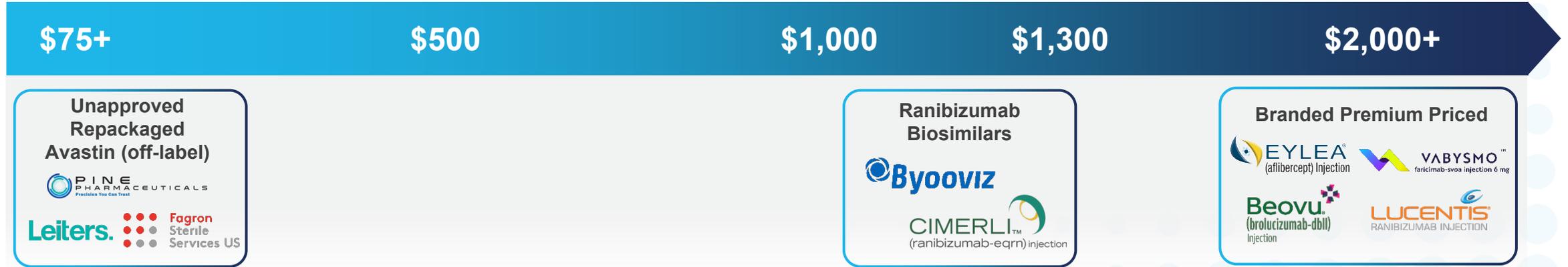
Market	Number of Treated Patients	Physician Interest in an Approved Bevacizumab	Total Market Opportunity
United States	1.75 Million <sup>2</sup>	85%	\$8.5 Billion <sup>1</sup>
EU + UK	1.52 Million <sup>3</sup>	82%	\$3.6 Billion <sup>1</sup>

1. Citeline (2023), Global Data (2023) and Market Scope (2022)
2. Triangulation of Global Data, Market Scope Data, CDC Vision and Eye Health Surveillance System (VEHSS)
3. Guidehouse Triangulation of Global Data, Market Scope 2022 Retinal Pharmaceuticals Market Report

# Our Pricing Strategy

Price according to what payers and retina specialists have indicated is reasonable

United States 



EU     + UK 



# The Limitations with Off-Label Bevacizumab

*Repackaged at Compounding Pharmacies*

*Not Held to FDA Ophthalmic Quality Standards When Repackaged*

## Variability in Potency<sup>1</sup>

81% of samples had lower protein concentrations than required.  
Demonstrated inconsistencies of compounded Avastin from syringe to syringe

## Safety and Sterility Adverse Events<sup>2</sup>

Frequent recalls and compliance issues by compounders cause service interruptions and endanger patient safety and consistency of treatment

## Syringe Adverse Events<sup>3</sup>

Include mechanical failures, visible particulates, and quality challenges caused by long-term storage in immediate use syringes

1. JAMA Ophthalmol. 2015 Jan;133(1):32-9. doi: 10.1001/jamaophthalmol.2014.3591
2. Goldberg, Roger A et al. "An outbreak of streptococcus endophthalmitis after intravitreal injection of bevacizumab." American Journal of Ophthalmology vol. 153,2 (2012): 204-208.e1. doi:10.1016/j.ajo.2011.11.035
3. ASRS Member Alert, April 2019

# We Are Held to Stringent FDA and EU Quality Standards

Ophthalmic Solution Requirement	Off-Label Compounded Repackaged IV Solution Matches to Ophthalmic Approval Requirements	FDA Approved Ophthalmic Solution for Intravitreal Injection
Sterile USP <71> <sup>1</sup>	Unknown	Yes
Particulates per USP <789> for ophthalmic solutions <sup>1</sup>	Unknown	Yes
GMP <sup>2,3</sup>	Unknown	Yes
Bacterial endotoxins USP <85> <sup>1</sup>	No	Yes
FDA approved ophthalmic package consistent with USP <771> <sup>1</sup>	No	Yes
FDA reviewed stability data supporting shelf life <sup>2,3</sup>	No	Yes
pH FDA approved and consistent with USP <771> <sup>1,2,3</sup>	No	Yes
Potency FDA approved specifications for shelf life <sup>2,3</sup>	No	Yes
Osmolarity specification for ophthalmic solution <sup>2,3</sup>	No	Yes

1. USP general Chapter <771> OPHTHALMIC PRODUCTS—QUALITY TESTS USP40-NF35, second supplement, June 1, 2017; 2. Aldrich, Dale S., Bach, Cynthia M., Brown, William, Chambers, Wiley, Fleitman, Jeffrey, Hunt, Desmond, Marques, Margareth R. C., Mille, Yana, Mitra, Ashim K., Platzer, Stacey M., Tice, Tom, Tin, George W.; Ophthalmic Preparations USP STIMULI TO THE REVISION PROCESS Vol. 39(5) [Sept.–Oct. 2013]; 3. Missel PJ, Lang JC, Rodeheaver DP, Jani R, Chowhan MA, Chastain J, Dagnon T. Design and evaluation of ophthalmic pharmaceutical products. In: Florence, AT, Siepmann J. Modern Pharmaceutics—Applications and Advances. New York: Informa; 2009:101–189.

# ONS-5010 “Start and Stay”

- ▶ **ONS-5010** must meet or exceed ophthalmic standards
- 

- ▶ Ensuring quality (e.g. cold chain) from “dock to doctor”

## **ONS-5010**<sup>1</sup>:

Achieved ~42% 3-line gainers  
Achieved 11.2 BCVA letters

Allowed ~85% of patients to “gain or maintain” vision through every study endpoint through 11 months

- ▶ This allows physicians to “**Start and Stay**” on ONS-5010, if approved, avoiding the need to switch to a new anti-VEGF

*Up to 40.7% of patients switch to an approved ophthalmic anti-VEGF agent by year 3 of treatment<sup>2</sup>*

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# Why We Believe Physicians Will Switch

*Ophthalmologists Have Told Us...*

**77%** Surveyed Believe an FDA Approved Bevacizumab for Wet AMD is Important<sup>1</sup>

**71%** Surveyed Said They are Likely to Prescribe ONS-5010 if Approved<sup>1</sup>



*“Repackaging a drug or biological product could change its characteristics in ways that have not been evaluated during the approval process and that could affect the safety and effectiveness of the product. Improper repackaging of drugs and biological products can cause serious adverse events.<sup>2</sup>”*

# ONS-5010

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## Positive CHMP Opinion

*Preparing for Potential Commercial Launch  
in EU in Q4 2024 / Q1 2025*

*Staging for a Potential Commercial  
Launch in the United States in 2025*

# Key Activities in Europe to Support a Launch

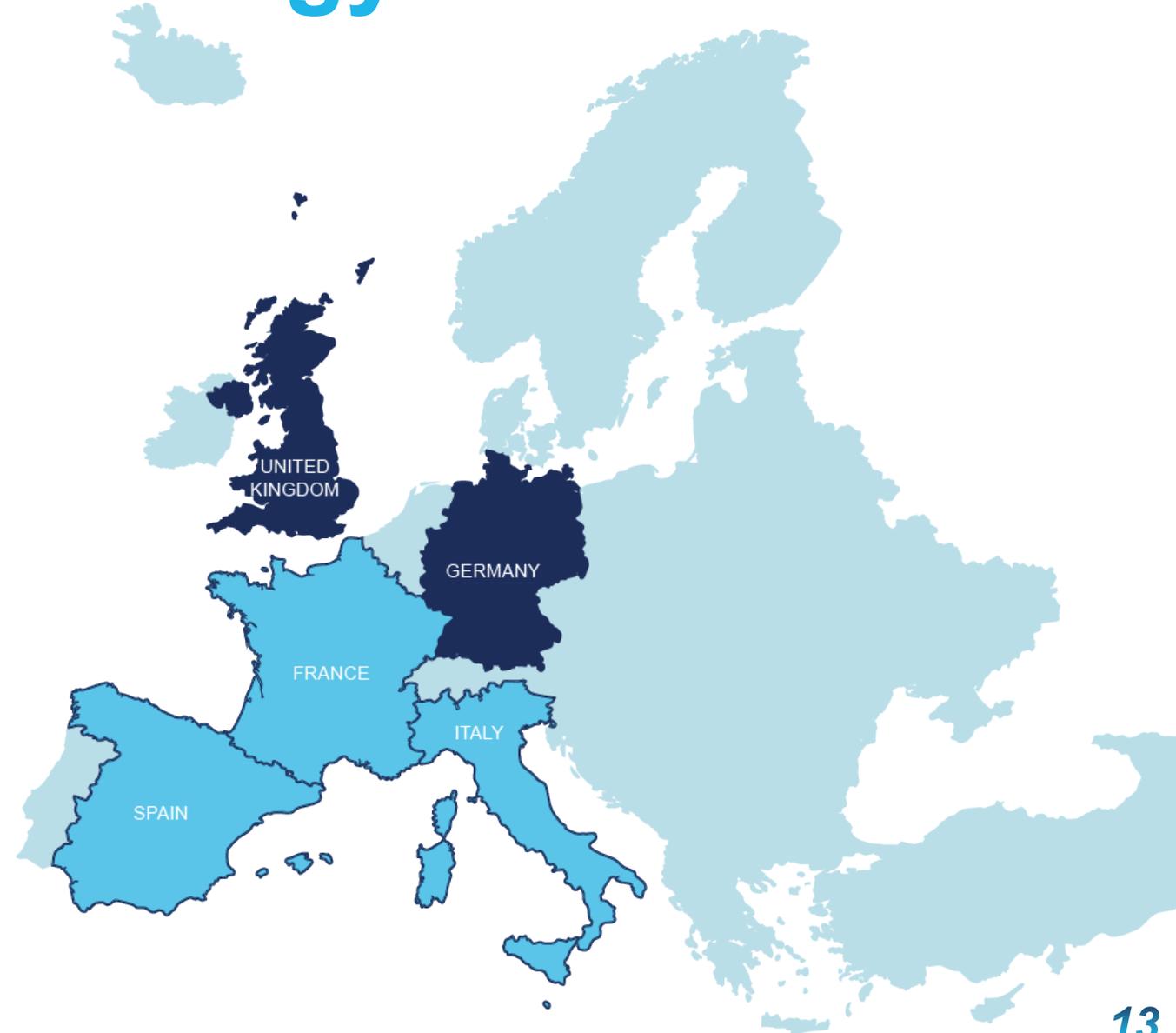
*First EU and UK Launch Expected Q4 2024 / Q1 2025*

- ▶ Ongoing business development discussions with EU partners
- ▶ Engaging with leading retina KOLs across key markets
- ▶ Advanced discussions with Cencora (formerly AmerisourceBergen) and their European Partners to support commercialization in the EU4 & UK
- ▶ Pricing and reimbursement roadmaps for EU4 & UK defined, with work underway for first launch countries

# UK and EU Launch Strategy

## Initial Target Markets

<i>Market</i>	<i>Targeted Launch</i>	<i>Sales / Marketing Team</i>	<i>Anti-VEGF Treated Patients</i>
Germany	Q4 2024 / Q1 2025	10	<b>231k</b>
United Kingdom	Q4 2024 / Q1 2025	6	<b>365k</b>
France	Q4 2025	11	<b>342k</b>
Italy	Q4 2025	8	<b>440k</b>
Spain	Q4 2025	8	<b>103k</b>



# Strategic Commercialization Partnership in US with Preeminent Leader in Specialty Pharma Distribution

- ▶ Establishes Commercial Depth in Advance of Potential ONS-5010 Commercial Launch
- ▶ Besse Medical is One of the Largest Specialty Pharmaceutical Distributors to Retina Specialists

**cencora**  
(Formerly **AmerisourceBergen**)



- ▶ Third-Party Logistics Services and Distribution
- ▶ Pharmacovigilance Services and Medical Information

# ONS-5010

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*Roadmap to Potential FDA Approval*

# Clinical Studies

## Ongoing (US Only)



**3-Month Non-Inferiority Study with 8-Week Efficacy Endpoint  
Per Special Protocol Assessment (SPA) Agreed with FDA**

**Study to Support Potential US Approval according to SPA Agreement**

## Completed

✓ **Completed**



**Clinical  
Experience Trial**

✓ **Positive Data**



**Phase 3  
Safety and Efficacy Trial**

✓ **Completed**



**Open-Label  
Safety Study**

# Ongoing Non-Inferiority Study

First Subject Dosed in January 2024

3-Month Non-Inferiority Study with 8-Week Efficacy Endpoint

SPA Agreement with FDA Confirms, if Successful, NORSE EIGHT would Satisfy FDA's Requirement for a Second Adequate and Well-Controlled Clinical Trial Needed for US Approval



## ONS-5010 (1.25 mg) Monthly Intravitreal Injections



8-week Efficacy Endpoint

## Ranibizumab Intravitreal Injections



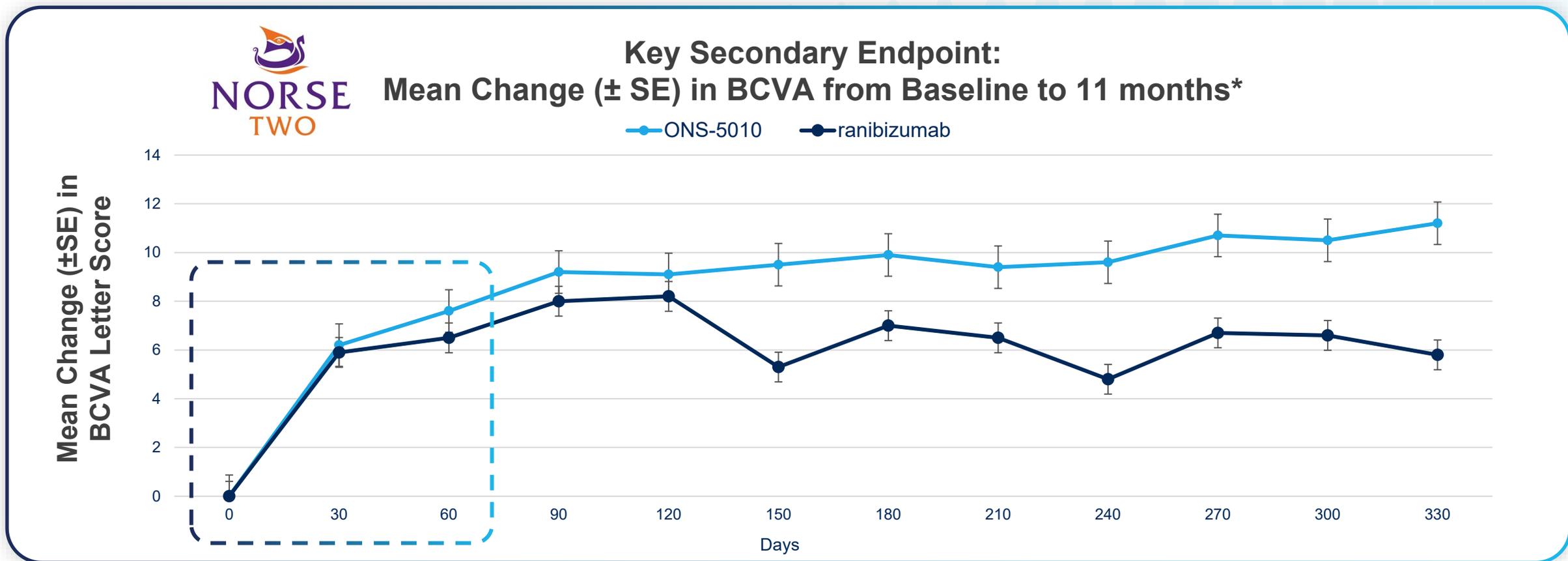
8-week Efficacy Endpoint

## Topline Results Expected in 2024

- Study design mirrors first three months of our positive NORSE TWO Phase 3 study
- 400 treatment naïve, wet AMD subjects to be enrolled at 60 US sites
- Primary endpoint of mean BCVA at 8 weeks with a non-inferiority margin of - 3.5 letters

# Why We Believe NORSE EIGHT Will Be Successful

*Study Design Mirrors, First Three Months of Our Statistically Significant NORSE TWO Phase 3 Study*

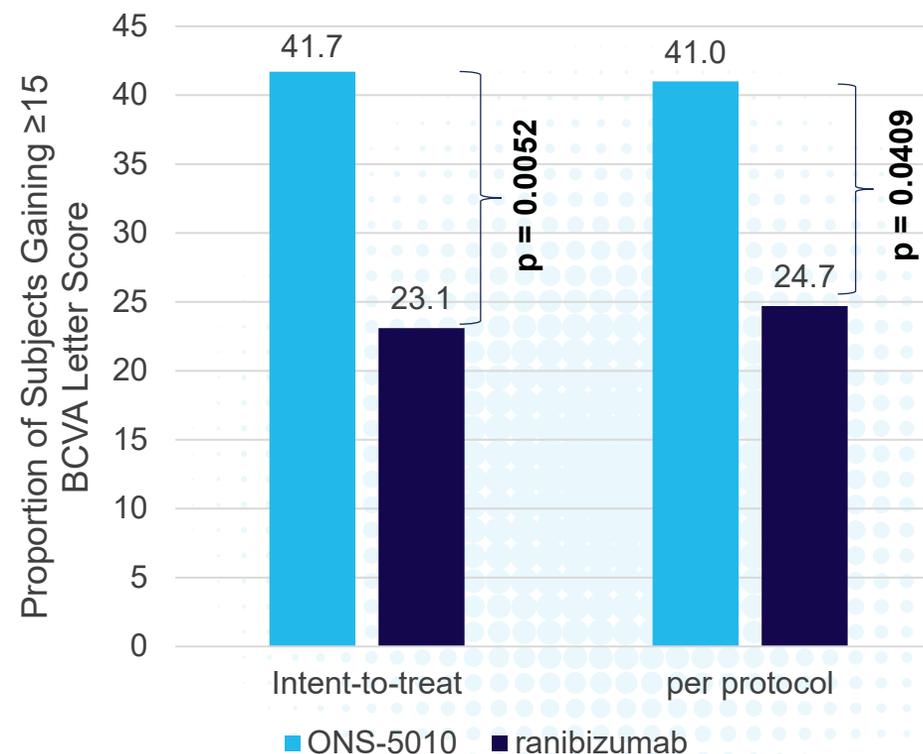


# Full NORSE TWO Data

*Primary Endpoint Met with Statistically Significant, Clinically Relevant Results*

Characteristic	Statistic	ONS-5010 (n=113)	Ranibizumab (n=115)
<b>Intent-to-Treat Pop.</b>			
Number of Subjects	n/N (%)	<b>45/108 (41.7)</b>	24/104 (23.1)
Risk Difference		0.1859	
95% CI		(0.0442, 0.3086)	
p-value		<b>0.0052</b>	
<b>Per Protocol Pop.</b>			
Number of Subjects	n/N (%)	34/83 (41.0)	18/73 (24.7)
Risk Difference		0.1631	
95% CI		(0.0120, 0.3083)	
p-value		<b>0.0409</b>	

## Difference in % Subjects Gaining 3 Lines Vision



# Promising Safety Package

*Integrated Safety Summary of NORSE ONE, NORSE TWO, & NORSE THREE*

Characteristic	Statistic	ONS-5010 (n=341)	Ranibizumab (n=145)
≥ 1 Adverse Event	n (%)	168 (49.3)	85 (73.9)
≥ 1 ocular Adverse Event	n (%)	98 (28.7)	70 (48.3)
≥ 1 ocular AE in the study eye	n (%)	73 (21.4)	52 (35.9)
≥ 1 ocular AE in the non-study eye	n (%)	48 (14.1)	39 (26.9)
≥ 1 Serious Adverse Event	n (%)	29 (8.5)	18 (12.4)
≥ 1 related Serious Adverse Event	n (%)	4 (1.2)	1 (0.7)

**No Cases of Retina Vasculitis or Optic Ischemic Neuropathy Occurred**

# Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence



**C. Russell Trenary III**  
President, CEO and Director



**Lawrence Kenyon**  
Chief Financial Officer  
and Director



**Jeff Evanson**  
Chief Commercial Officer



**Joel Prieve**  
SVP, Licensing and M&A



**Surendra Sharma, MD**  
SVP, Medical Affairs



**Jennifer Kissner, PhD**  
SVP, Clinical & Regulatory  
Affairs



**Christopher Yonan, PhD**  
SVP, Technical Operations



**Jedd Comiskey, PhD**  
SVP, Head of Europe



# Financial Snapshot

## NASDAQ: OTLK

Access to Sufficient Capital to Take ONS-5010 Through Potential FDA Approval and Fund Commercial Launch

**\$10.4 Million**

**Cash on Hand**  
As of December 31, 2023

Cash Position Does Not Include  
Proceeds from Recent Financing

Closed Private  
Placement for Up to

**\$159  
Million**

- Received upfront gross proceeds of ~\$60 million from issuance and sale of common stock and accompanying warrants
- Up to additional \$99 million upon cash exercise of warrants issued in the private placement
- BofA Securities and BTIG acted as co-placement agents

Private Placement Led by Great Point Partners, LLC, with Participation Included from GMS Ventures, Altium Capital, Armistice Capital, Caligan Partners LP, Schonfeld Strategic Advisors, Sphera Healthcare, Velan Capital and Woodline Partners LP

# Upcoming Potential Milestones

## EU and UK Approval and Commercial Launch



### Additional Activities

Ex-US Partnering Discussions | EU and US Commercial Planning | Completion of NORSE 7, Prefilled Syringe

\*Dates and timelines are listed in calendar year

# Why Outlook, Why Now

*2024 Has the Potential to be a Pivotal Year for Outlook Therapeutics*

## Positive CHMP Opinion

Driving Towards Potential EU Market Approval in late Q2 2024

Top Line Read Out on NORSE 8, as early as Q4, 2024

Focused on Executing NORSE EIGHT to Resubmit BLA to US FDA Expected in Q4 2024

**Potential to Transform \$15.9 Billion Global Ophthalmic Anti-VEGF Market<sup>1</sup>**

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