NASDAQ: OTLK
outlooktherapeutics.com

OUTLOOK THERAPEUTICS

Enhancing the Standard of Care for Bevacizumab for Retina Diseases

Corporate Presentation
November 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 “expect,” “explore,” “initiate,” “intend,” “may,” “plan,” and “potential,” 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, European Commission approved and/or United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) approved ophthalmic formulation of bevacizumab for the treatment of retinal diseases in the United States, European Union and United Kingdom, plans for potential commercial launch of ONS-5010 in the United States, European Union and United Kingdom 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 NORSE EIGHT enrollment, the timing for completion of NORSE EIGHT and resubmission of the Biologics License Application (BLA) for ONS-5010, the sufficiency of our capital resources, expectations concerning decisions of regulatory bodies, and the timing thereof,, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof, expectations concerning the size of the market for ONS-5010 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, 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.

Outlook Therapeutics prepares its consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) and pursuant to accounting requirements of the Securities and Exchange Commission. In an effort to provide investors with additional information regarding the results and to provide a meaningful period-over-period comparison of Outlook Therapeutics' financial performance, Outlook Therapeutics sometimes uses non-U.S. GAAP financial measures (NGFM) as defined by the Securities and Exchange Commission. In this presentation, Outlook Therapeutics uses “adjusted net loss attributable to common stockholders,” which is defined as net loss attributable to common stockholders excluding warrant related expenses (i.e., the excess of the fair value of the warrants upon issuance over the proceeds of the private placement that closed on March 18, 2024) and changes in fair value of warrants and convertible promissory notes, as well as “adjusted net loss attributable to common stockholders per share of common stock - basic and diluted,” which is defined as net loss attributable to common stockholders per share of common stock - basic and diluted excluding warrant related expenses and changes in fair value of warrants and convertible promissory notes. Management uses these NGFMs because they adjust for certain non-cash items that impact financial results but not cash flows and that management believes are not related to its core business. Management uses these NGFMs to evaluate Outlook Therapeutics financial performance against internal budgets and targets. Management believes that these NGFMs are useful for evaluating Outlook Therapeutics' core operating results and facilitating comparison across reporting periods. Outlook Therapeutics believes these NGFMs should be considered in addition to, and not in lieu of, GAAP financial measures. Outlook Therapeutics' NGFMs may be different from the same NGFMs used by other companies. A reconciliation of these NGFMs to the most directly comparable U.S. GAAP financial measures have been provided in an appendix at the end of this presentation.

Now Approved in the EU and UK

LYTENAVA™ (bevacizumab gamma) for the Treatment of Wet AMD

Received European Commission Marketing Authorization in May 2024

Received UK MHRA Marketing Authorization in July 2024

First and Only Approved Ophthalmic Formulation of Bevacizumab for the Treatment of Wet AMD in the European Union and United Kingdom[1]

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1. European Commission Marketing Authorization May 28, 2024; United Kingdom MHRA Marketing Authorization July 8, 2024

The Anti-VEGF Retina Market

Currently Estimated to be in Excess of $15.9 Billion Worldwide[1]

Market	Number of Treated Patients	Physician Interest in an Approved Bevacizumab	Total Market Opportunity
United States	1.75 Million[2]	85%[4]	$8.5 Billion[1]
EU + UK	1.52 Million[3]	82%[4]	$3.6 Billion[1]

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
4. Navigant Quantitative Survey (n=152), 2019, Respondents who have interest or high interest in ONS-501

Why Outlook, Why Now

- Enhancing the standard of care for bevacizumab for retina diseases, including wet AMD
- First European Union and UK authorized form of bevacizumab for ophthalmology
- Opportunity to expand into DME and BRVO
- Targeting $15.9 billion global ophthalmic anti-VEGF market[4]

ONS-5010 / LYTENAVA™

(bevacizumab-vikg; bevacizumab gamma)[1]

Bevacizumab has been validated[2] in wet AMD and is used off-label as a first-line treatment[3]

Europe

LYTENAVA™ (bevacizumab gamma) received European Commission Marketing Authorization for Treatment of Wet AMD in May 2024 and UK MHRA Marketing Authorization in July 2024

Engaging with Potential Partners with Established UK and EU Infrastructure

United States

Ongoing NORSE EIGHT study

Enrollment completed first week September 2024 with top line results expected Q4 2024

US FDA Biologics License Applications (BLA) resubmission expected Q1 2025

*Dates and timelines are listed in calendar year

1. ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab in the United Sates; LYTENAVA™ (bevacizumab gamma) gained European Union marketing authorization
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
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)

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The Bevacizumab Opportunity

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

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

Outlook Therapeutics Achieved First Authorization of Ophthalmic Formulation of Bevacizumab in European Union and UK in Treatment of Wet AMD and Working to Gain Potential Approval in the United States

Current Situation

55.4% of new diagnosed wet AMD patients start with off-label, unapproved bevacizumab[1]

66.3% of US retina physicians state off-label, unapproved bevacizumab is their most commonly used first-line anti-VEGF[2]

However, switching to an FDA approved anti-VEGF may occur up to over 40% of the time by year 3 of treatment[1]

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 was reviewed as a full mixed MAA based on Article 8.3 of Directive 2001/83/EC in the EU and is being reviewed under the International Recognition Procedure in the UK and as a 351 (a) BLA submission in the US

8 Years of data exclusivity and 10 years market exclusivity received with authorization in the EU.

12 years regulatory exclusivity expected upon approval in the United States

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

1. Medicare Claims Analysis 2023: Guidehouse Analysis
2. ASRS 2022 Membership Survey Presented at ASRS NY 2022. Q: Considering all indications, what is your most commonly used first-line anti-VEGF agent?

Bevacizumab Gamma Complies to Stringent EU and US Quality Standards

Ophthalmic Solution Requirement	Off-Label Repackaged IV Solution Matches to Ophthalmic Approval Requirements	Bevacizumab gamma Ophthalmic Solution for Intravitreal Injection
Sterile per Ph. Eur. 2.6.1	Unknown	Yes
Particulates per USP <789> for ophthalmic solutions[1]	Unknown	Yes
GMP[2,3]	Unknown	Yes
Bacterial endotoxins per Ph. Eur. 2.6.14	No	Yes
EMA approved ophthalmic package consistent with Ph. Eur. 0520	No	Yes
EMA reviewed stability data supporting shelf life[2,3]	No	Yes
pH EMA approved and consistent with Ph. Eur. 0520	No	Yes
Potency EMA approved specifications for shelf life[2,3]	No	Yes
Osmolarity specification for ophthalmic solution[2,3]	No	Yes

Sources: 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. Abbreviations: EMA – European Medicines Agency; EU – European Union; FDA – Food and Drug Administration; GMP – Good Manufacturing Practice; IV – intravenous; pH – potential of hydrogen; Ph. Eur. – European Pharmacopoeia ; USP – United States Pharmacopeia

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The Limitations with Off-Label Bevacizumab

Repackaged Bevacizumab Used Off-Label is Not Held to Ophthalmic Quality Standards

Variability in Potency[1]

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

Safety and Sterility Adverse Events[2]

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

Syringe Adverse Events[3]

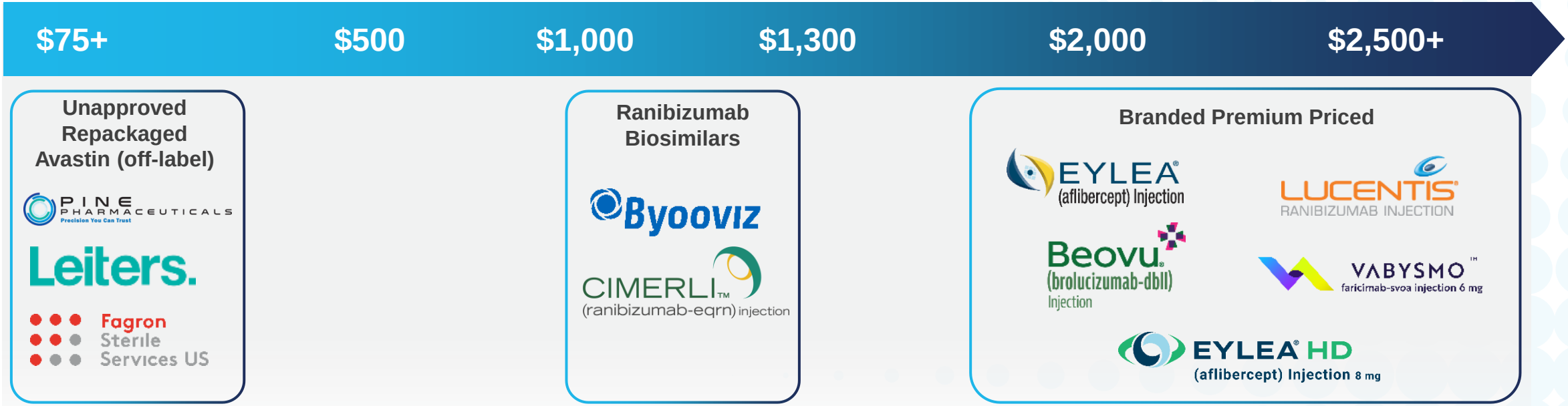
Include mechanical failures, visible particulates, and quality challenges caused by long-term storage in immediate use syringes

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

Our United States Pricing Opportunity

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

United States



EU+UK Pricing Opportunity

EU+UK Pricing spectrum of anti-VEGFs average per dose (range)[1]

AVERAGE EU+UK PRICING OF ANTI-VEGFS[1]

*Price range is based on clinician feedback for EU4+UK. The use of off-label bevacizumab varies widely across the EU4+UK

1. Local pricing sources, ex-factory prices (UK: list prices exchange rate 1EUR : 0.85GBP, February 2024
Branded products: Eylea, Beovu, Lucentis, Vabysmo)
Biosimilars included Lucentis biosimilars Byooviz (Germany, UK) Ranivisio (France, Germany , Spain, UK) and Ximluci (Germany, Spain, UK)

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Achieved First Authorized Ophthalmic Formulation of Bevacizumab for Treatment of Wet AMD in the EU and UK

Engaging with Potential Partners with Established UK and EU Infrastructure

Preparing product availability for potential launch for H1 2025

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

Key Activities in Europe to Support a Launch

Engaging with Potential Partners
with Established UK and EU Infrastructure

- Preparing product availability for potential launch for H1 2025
- Working with Cencora (formerly AmerisourceBergen) and their European Partners to support commercialization in the EU4 & UK
- Engaging with leading retina KOLs across key markets
- Pricing and reimbursement roadmaps for EU15 & UK defined, with work underway for first launch countries[1]

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*Dates and timelines are listed in calendar year
1. Switzerland, Iceland and Norway are not EU member States

Strategic Commercialization Partnership with Preeminent Leader in Specialty Pharma Distribution

cencora

(Formerly AmerisourceBergen)

- Establishes Commercial Depth in Advance of Planned LYTENAVA™ (bevacizumab gamma) Commercial Launch
- Besse Medical is One of the Largest Specialty Pharmaceutical Distributors to Retina Specialists

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

ONS-5010

Roadmap to Potential FDA Approval

Clinical Studies

Ongoing (US Only)

NORSE EIGHT

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

Study to Support Potential US Approval according to SPA Agreement

Completed

✓ Completed

NORSE ONE

Clinical Experience Trial

✓ Positive Data

NORSE TWO

Phase 3 Safety and Efficacy Trial

✓ Completed

NORSE THREE

Open-Label Safety Study

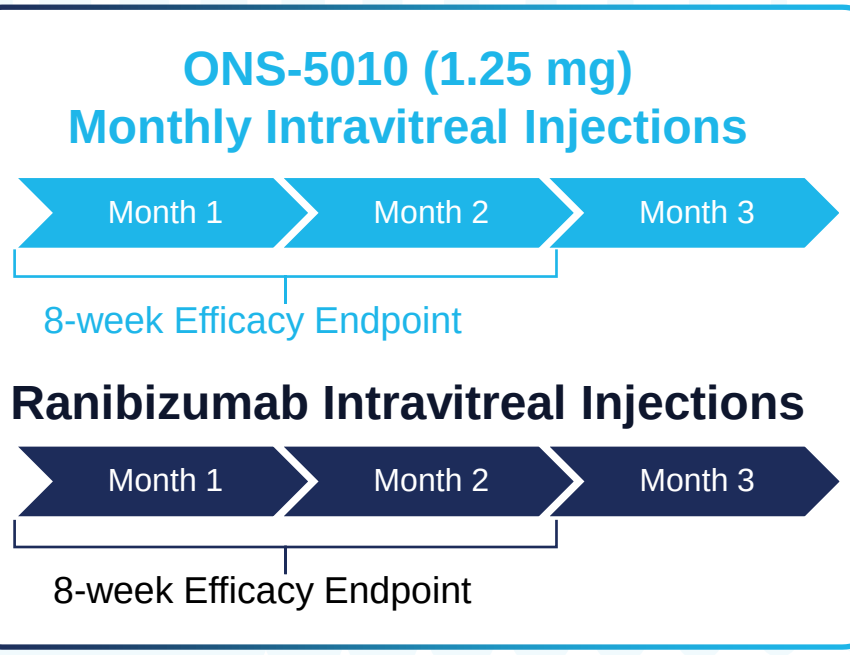
*Dates and timelines are listed in calendar year.

Ongoing Non-Inferiority Study

Enrollment Completed First Week of September 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



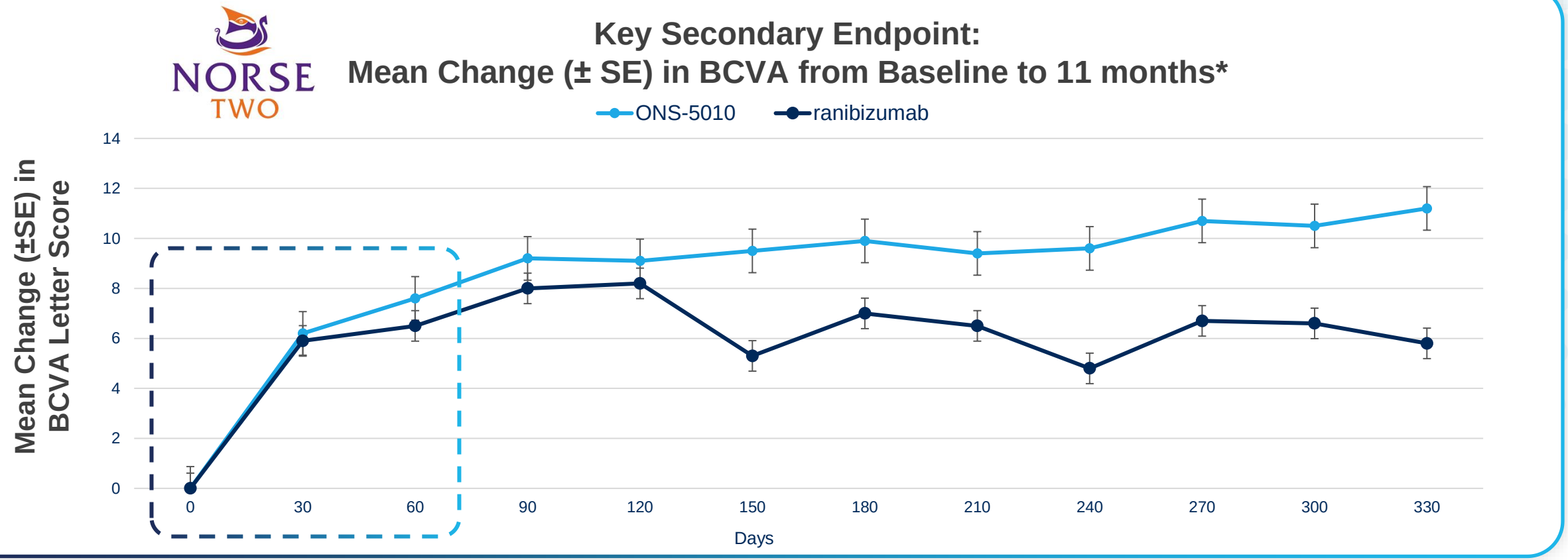
Topline Results Expected in 2024

- Study design mirrors first three months of our positive NORSE TWO Phase 3 study
- Enrolled 400 treatment naïve, wet AMD subjects across 61 US sites
- Primary endpoint of mean BCVA at 8 weeks with a non-inferiority margin of - 3.5 letters

*Dates and timelines are listed in calendar year.

Why We Believe NORSE EIGHT Will Be Successful

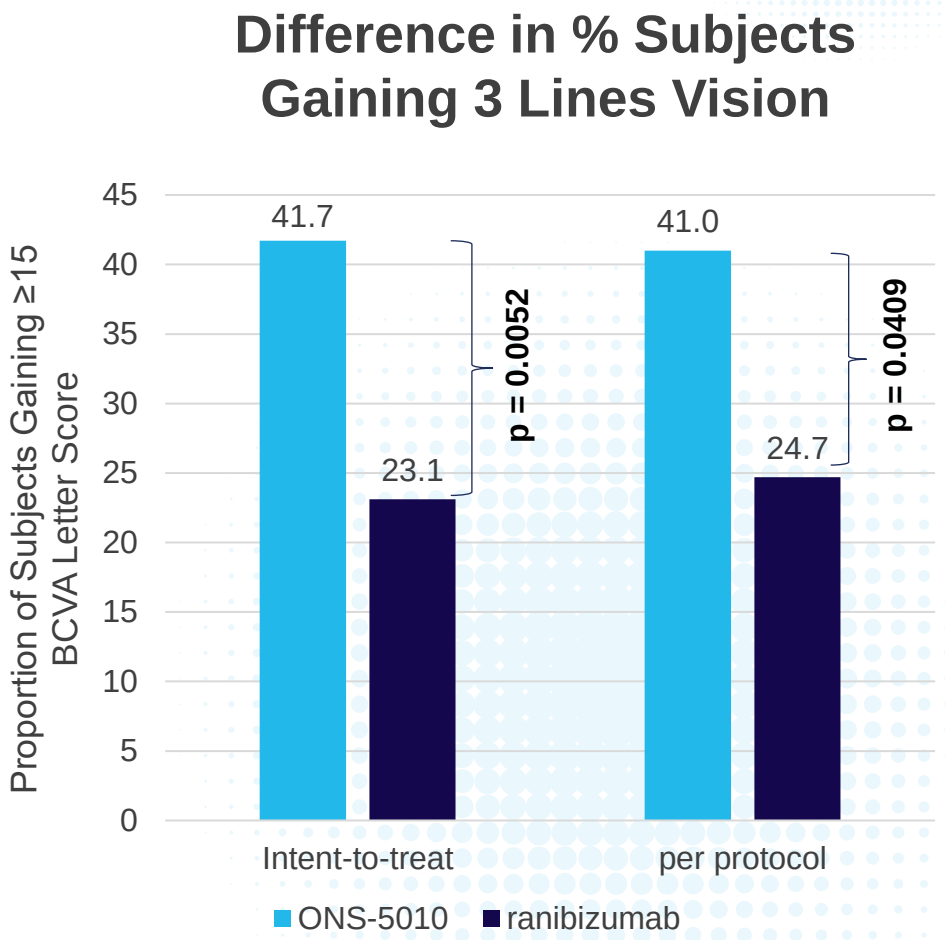
Study Design Mirrors, First Three Months of Our Statistically Significant NORSE TWO Phase 3 Study



Full NORSE TWO Data

Primary Endpoint Met with Statistically Significant, Clinically Relevant Results

Characteristic	Statistic	ONS-5010 (n=113)	Ranibizumab (n=115)
Intent-to-Treat Pop.			
Number of Subjects	n/N (%)	**45/108 (41.7)**	24/104 (23.1)
Risk Difference		0.1859	
95% CI		(0.0442,0.3086)	
p-value		**0.0052**	
Per Protocol Pop.			
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		**0.0409**	



ONS-5010 Demonstrated Comparable Safety Profile to Ranibizumab in Completed Trials

Financial Snapshot
NASDAQ: OTLK

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

- Cash and Cash Equivalents of $32.0 million as of June 30, 2024
- Outstanding debt as of June 30, 2024 is $31.8 million
- Closed Private Placements for gross proceeds of up to $172 million
  - $65 million from the issuance and sale of shares of common stock
  - Potential to receive additional gross proceeds of up to $107 million[1] upon the full cash exercise of the warrants issued
  - Led by top tier institutional investors

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1. Subject to meeting the requirements for calling these warrants.

Upcoming Potential Milestones

Targeted Europe Commercialization Timeline

European Partnering Discussions Ongoing

Q2 2024
- ✓ EU Positive CHMP Opinion
- ✓ Submission of UK MAA
- ✓ EU Marketing Authorization

H2 2024
- ✓ UK Marketing Authorization
- • Ongoing Market Access Activities

H1 2025
- • Commercial Inventory Available to Support Launch in Germany and UK

Timeline to Potential US Approval

Q1 2024
- ✓ FDA Agreement on SPA
- ✓ Commence NORSE EIGHT Study

Q2/Q3 2024
- ✓ Conduct Type C and Type D Meetings with FDA Regarding CMC

Q3 2024
- ✓ NORSE EIGHT Full Enrollment

Q4 2024
- Topline Data

Q1 2025
- Resubmit BLA

2025
- FDA Decision

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*Dates and timelines are listed in calendar year
✓ = Milestone Accomplished

Why Outlook, Why Now

2024: A Pivotal Year for Outlook Therapeutics

Achieved First Authorization of Ophthalmic Formulation of Bevacizumab for the Treatment of Wet AMD in EU and UK and Working to Gain Potential Approval in the United States

Engaging with Potential Licensing Partners for Commercial Launch in the EU and UK	Topline Data from NORSE EIGHT Expected Q4 2024	Focused on Executing NORSE EIGHT to possible resubmission of BLA to FDA in Q1 2025

Potential to Transform $15.9 Billion Global Ophthalmic Anti-VEGF Market[1]

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* Dates and timelines are listed in calendar year

1. Citeline (2023), Global Data (2023) and Market Scope (2022)

Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence

C. Russell Trenary III
President, CEO and Director

INNFOCUS · G&H ORTHODONTICS · AMO · Allergan

Lawrence Kenyon
Chief Financial Officer and Director

ARNO THERAPEUT · PAR PHARMACEUTICAL · TAMIR

Jeff Evanson
Chief Commercial Officer

NOVARTIS · Alcon · Medtronic · NAVIGANT

Joel Prieve
SVP, Licensing and M&A

AmerisourceBergen · amag · janssen

Surendra Sharma, MD
SVP, Medical Affairs

Santen · Biogen · Spark · Alcon

Jennifer Kissner, PhD
SVP, Clinical & Regulatory Affairs

CLEARSIDE BIOMEDICAL · Alcon · ACUCELA

Christopher Yonan, PhD
SVP, Technical Operations

Bristol Myers Squibb · Oncobiologics

Jedd Comiskey, PhD
SVP, Head of Europe

BAYER · Apellis · Shire · Takeda

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