



CORPORATE PRESENTATION

August 2021

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 “anticipated,” “initiate,” “expect,” “intend,” “plan,” “believe,” “seek,” “estimate,” “may,” “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 FDA-approved ophthalmic formulation of bevacizumab-vikg, our expectations for ONS-5010 market exclusivity, the timing of BLA submission and commercial launch of ONS-5010, 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, as well as the success of ongoing ONS-5010 trials for wet AMD and regarding planned trials for ONS-5010 for DME and BRVO. 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, 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 and other filings with the Securities and Exchange Commission (“SEC”). 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 events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied.

Except as required by law, neither Outlook Therapeutics nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We are providing this information as of the date of this presentation and do not undertake any obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise. This presentation contains trademarks, registered marks and trade names of Outlook Therapeutics and of other companies. All such trademarks, registered marks and trade names are the property of their respective holders.



*Enhancing the Standard
of Care For Retinal Disorders*

Investment Highlights

Positive Phase 3 Results Demonstrated with Lead Program, ONS-5010 (bevacizumab-vikg)¹, for Treatment of Wet AMD

U.S. FDA BLA
submission targeted
for calendar Q1 2022

Potential to be first U.S. FDA
approved ophthalmic
formulation of bevacizumab

Pre-commercialization
activities underway to
support potential launch

Targeting \$13.1 Billion Global Ophthalmic Anti-VEGF Market²

Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence



C. RUSSELL TRENARY III
President, CEO and Director

INNOVUS

G&H ORTHODONTICS®
Quality Manufacturing. Exceptional Service.

AMO
ADVANCED MEDICAL OPTICS

Allergan



LAWRENCE KENYON
Chief Financial Officer and Director

ARNO THERAPEUTICS

TAMIR
Targeting microRNAs

PAR
PHARMACEUTICAL
an endo international company



JEFF EVANSON
Chief Commercial Officer

NOVARTIS

Alcon

Medtronic

NAVIGANT



TERRY DAGNON
Chief Operating Officer

NOVARTIS

Johnson & Johnson

Alcon

DOHMEN
LIFE SCIENCE SERVICES

RANDY THURMAN
Executive Chairman of the Board



MARK HUMAYUN, MD, PhD
Medical Advisor



Goal of ONS-5010 (Bevacizumab-vikg) Program

Provide Physicians and Patients an Ophthalmic FDA Approved Alternative of a Drug Widely Used Off-Label

Deliver cGMP formulation to ensure essential drug strength, quality, and purity

Eliminate impurities and particulates from legacy re-packaging processes

Create a product offering with a differentiated delivery system to enhance physician ease of use

Provide an economically elegant anti-VEGF solution

Executing on Pathway Towards Potential FDA Approval in Wet AMD

U.S. BLA Submission Targeted Calendar Q1 2022

✓ Positive Results



Clinical Experience Trial
1st Registration Trial

✓ Positive Top-line Data



Pivotal Trial
2nd Registration Trial

✓ Completed



Open-Label Safety Study
Supports BLA Requirements



Pivotal Trial

2nd Registration Trial



Trial Highlights:

- Randomized masked controlled trial
- ONS-5010 (bevacizumab-vikg) vs LUCENTIS® (ranibizumab)
- 228 patients enrolled
- Trial conducted in the United States
- Trial arms included >95% treatment-naïve patients
- Safety & efficacy data support planned U.S. BLA submission in calendar Q1 2022

NORSE TWO Pivotal Trial Design



Randomized masked controlled trial with 228 subjects



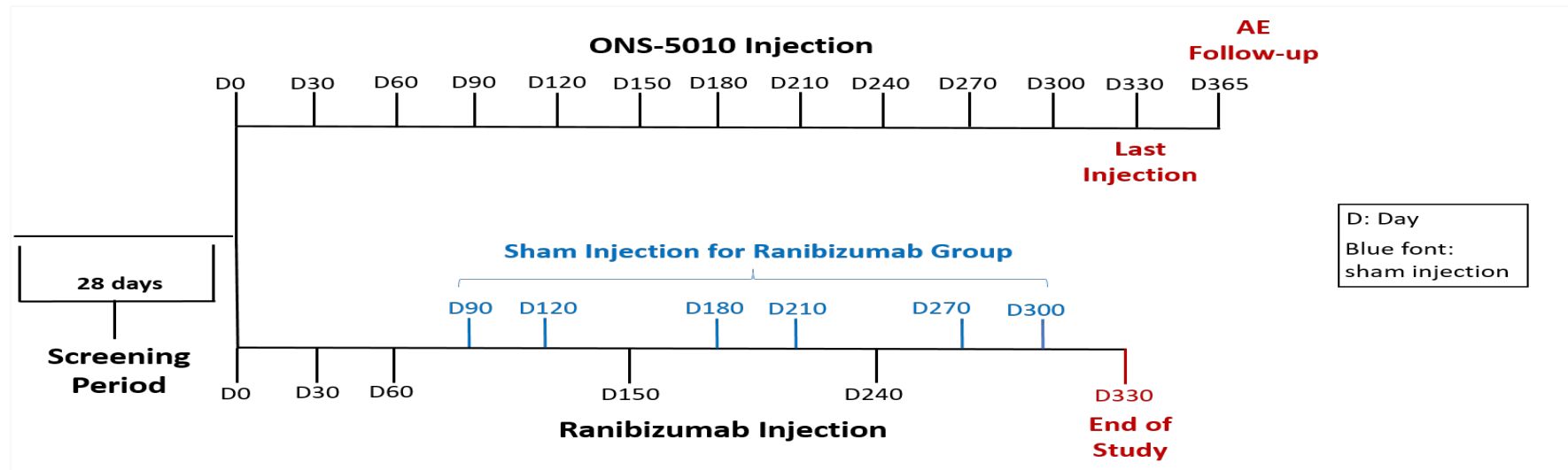
ONS-5010 (bevacizumab-vikg) administered monthly X 12



LUCENTIS dosing arm (PIER dosing) – Three initial monthly injections followed by fixed quarterly dosing



Primary endpoint difference in proportion of subjects gaining 15 letters of BCVA at Day 330



NORSE TWO: Positive Efficacy Data

Unprecedented 41% ONS-5010 with 3-Line Gainers¹

Statistically Significant Difference Across Both Primary and Key Secondary Endpoints

	ONS-5010 (bevacizumab-vikg)	LUCENTIS® (ranibizumab)	p-value
Primary Endpoint:			
Difference in subjects who gained at least 15 letters in the best corrected visual acuity (BCVA) at 11 months ²			
Intent-to-Treat (ITT) Primary Dataset	41%	23%	p = 0.0052
Secondary Per-Protocol (PP) Dataset	41%	24%	p = 0.04
Key Secondary Endpoint:			
Mean change in the BVCA through 11 months ²			
Intent-to-Treat (ITT) Primary Dataset	11.2 letters	5.8 letters	p = 0.0043
Secondary Per-Protocol (PP) Dataset	11.1 letters	7.0 letters	p = 0.05

NORSE TWO Safety Results:

Consistent with Previously Reported Results from NORSE ONE and NORSE THREE

In All Three Studies Only One Subject has Reported Ocular Inflammation

Characteristic	Statistic	ONS-5010 (Masked Data) (N=113)	Ranibizumab (N=115)	Overall (Masked Data) (N=228)
At Least 1 TEAE	n (%)	83 (73.5)	88 (76.5)	171 (75.0)
At Least 1 Related TEAE	n (%)	6 (5.3)	2 (1.7)	8 (3.5)
Maximum Severity				
CTCAE Grade 1 Mild	n (%)	46 (40.7)	45 (39.1)	91 (39.9)
CTCAE Grade 2 Moderate	n (%)	23 (20.4)	30 (26.1)	53 (23.2)
CTCAE Grade 3 Severe	n (%)	11 (9.7)	9 (7.8)	20 (8.8)
CTCAE Grade 4 Life-threatening	n (%)	0	2 (1.7)	2 (0.9)
CTCAE Grade 5 Death	n (%)	3 (2.7)	2 (1.7)	5 (2.2)
At Least 1 Ocular TEAE	n (%)	55 (48.7)	60 (52.2)	115 (50.4)
At Least 1 Ocular TEAE in Study Eye	n (%)	47 (41.6)	47 (40.9)	94 (41.2)
At Least 1 Non-Ocular TEAE	n (%)	55 (48.7)	57 (49.6)	112 (49.1)
At Least 1 >= Grade 3 Related TEAE	n (%)	2 (1.8)	1 (0.9)	3 (1.3)
At Least 1 Serious TEAE	n (%)	14 (12.4)	16 (13.9)	30 (13.2)
At Least 1 Related Serious TEAE	n (%)	2 (1.8)	1 (0.9)	2 (0.9)
At Least 1 TEAE Leading to Study Withdrawal	n (%)	2 (1.8)	4 (3.5)	6 (2.6)

NORSE TWO Safety Results: Consistent with Previously Reported Results from NORSE ONE and NORSE THREE - Frequency and Incidence of Ocular Study Eye Adverse Events $\geq 1\%$

In All Three Studies Only One Subject has Reported Ocular Inflammation

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=115)	ONS-5010 (Masked Data) [1] (N=113)	Overall (Masked Data) [1] (N=228)
At Least 1 Ocular TEAE in Study Eye	n (%)	47 (40.9)	47 (41.6)	94 (41.2)
Cataract	n (%)	1 (0.9)	2 (1.8)	3 (1.3)
Cataract nuclear	n (%)	0	3 (2.7)	3 (1.3)
Conjunctival hemorrhage	n (%)	3 (2.6)	10 (8.8)	13 (5.7)
Conjunctival hyperaemia	n (%)	2 (1.7)	0	2 (0.9)
Corneal abrasion	n (%)	1 (0.9)	4 (3.5)	5 (2.2)
Dermatochalasis	n (%)	2 (1.7)	2 (1.8)	4 (1.8)
Dry eye	n (%)	5 (4.3)	2 (1.8)	7 (3.1)
Eye irritation	n (%)	0	2 (1.8)	2 (0.9)
Eye pain	n (%)	2 (1.7)	1 (0.9)	3 (1.3)
Hordeolum	n (%)	2 (1.7)	0	2 (0.9)
Metamorphopsia	n (%)	3 (2.6)	1 (0.9)	4 (1.8)
Neovascular age-related macular degeneration	n (%)	3 (2.6)	0	3 (1.3)
Posterior capsule opacification	n (%)	2 (1.7)	1 (0.9)	3 (1.3)
Punctate keratitis	n (%)	2 (1.7)	3 (2.7)	5 (2.2)

Frequency and Incidence of Ocular Study Eye Adverse Events $\geq 1\%$

(continued)

MedDRA System Organ Class MedDRA Preferred Term	Statistic	Ranibizumab (N=115)	ONS-5010 (Masked Data) [1] (N=113)	Overall (Masked Data) [1] (N=228)
Retinal degeneration	n (%)	2 (1.7)	1 (0.9)	3 (1.3)
Retinal haemorrhage	n (%)	6 (5.2)	2 (1.8)	8 (3.5)
Retinal oedema	n (%)	2 (1.7)	0	2 (0.9)
Subretinal fibrosis	n (%)	2 (1.7)	2 (1.8)	4 (1.8)
Subretinal fluid	n (%)	3 (2.6)	2 (1.8)	5 (2.2)
Vision blurred	n (%)	0	2 (1.8)	2 (0.9)
Visual acuity reduced	n (%)	14 (12.2)	2 (1.8)	16 (7.0)
Vitreous detachment	n (%)	2 (1.7)	3 (2.7)	5 (2.2)
Vitreous floaters	n (%)	1 (0.9)	4 (3.5)	5 (2.2)
Vitreous haemorrhage	n (%)	1 (0.9)	2 (1.8)	3 (1.3)
Conjunctivitis	n (%)	0	1 (0.9)	1 (0.4)
Procedural pain	n (%)	2 (1.7)	0	2 (0.9)
Intraocular pressure increased	n (%)	1 (0.9)	7 (6.2)	8 (3.5)

NORSE ONE and NORSE THREE Results



Completed Clinical Experience Trial

Demonstrated anticipated safety and efficacy signals consistent with previously published results for ophthalmic use of bevacizumab

Trial Highlights:

- Desired proportion of 3-line visual acuity gainers achieved
- Desired mean gain in visual acuity achieved
- Zero ocular inflammation observed
- Safety was comparable to published bevacizumab studies, such as CATT



Open-Label Safety Study

Positive safety profile reinforces previously reported safety data for ONS-5010 (bevacizumab-vikg)

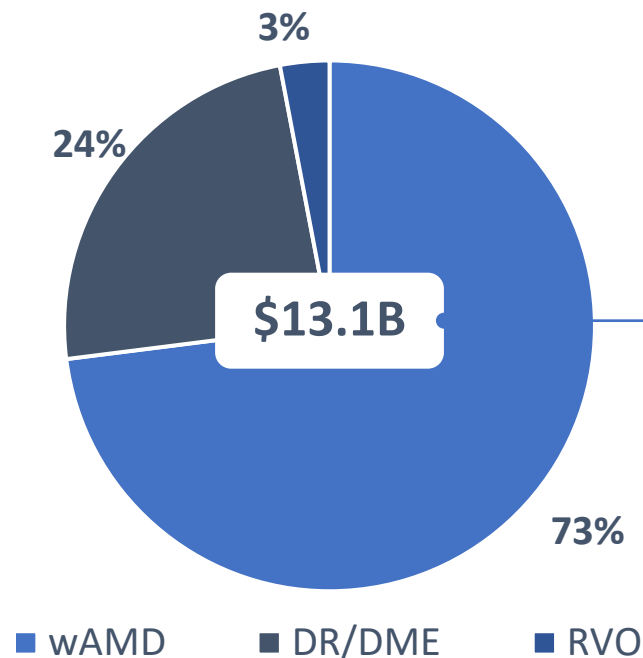
Trial Highlights:

- Provided adequate number of patient exposure required for BLA submission
- No unexpected safety trends
- Zero cases of ocular inflammation, a concern that has emerged for other anti-VEGF therapies to treat retinal conditions

Targeting Large and Growing Ophthalmic Markets

ONS-5010, if approved, will be a significant therapy in the retinal anti-VEGF market, currently estimated to be in excess of \$13.1 billion worldwide

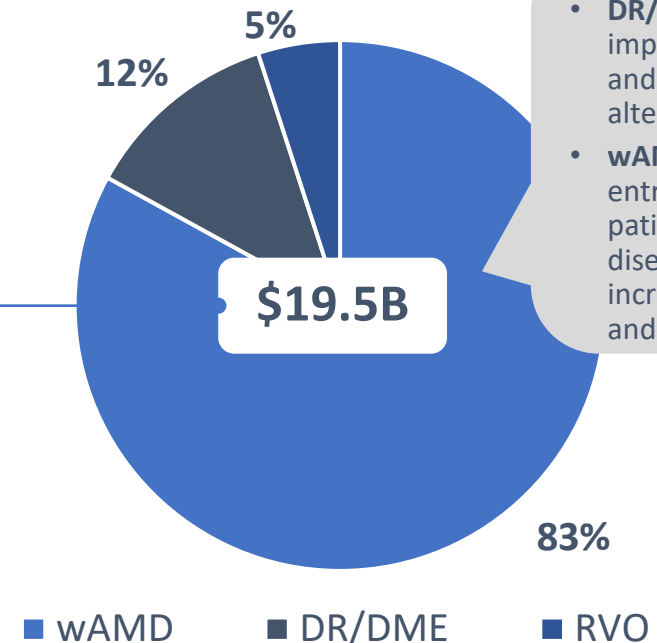
2020 9MM Anti-VEGF Revenue Share (USD)



CAGR

4.1%

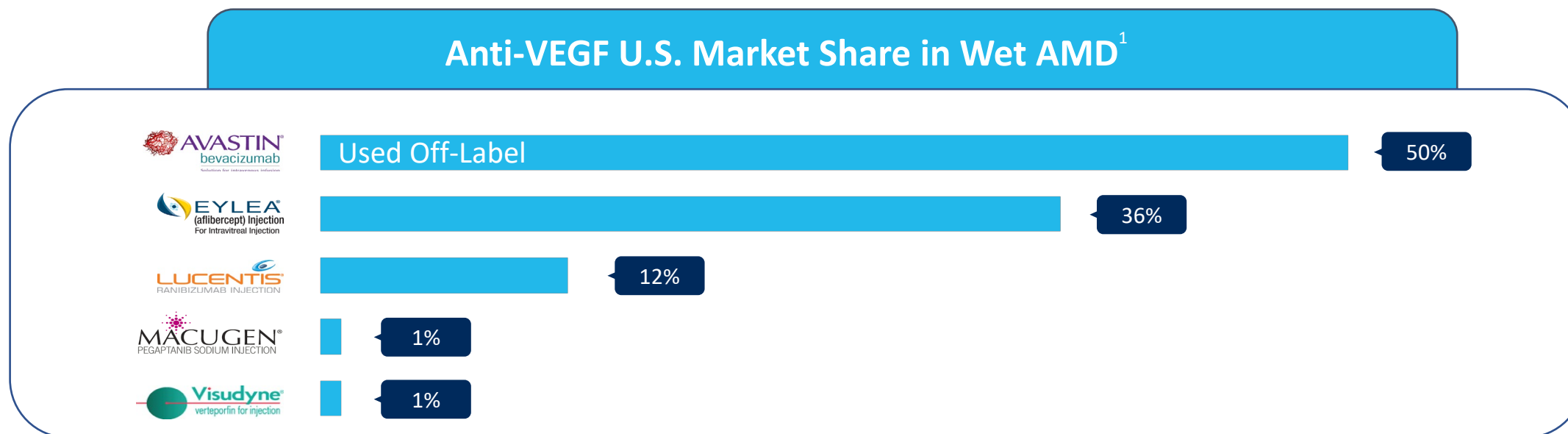
2030 9MM Anti-VEGF Revenue Share (USD)



MARKET DRIVERS:

- **DR/DME** is more directly impacted by biosimilars and lower cost alternatives (-2.2% CAGR)
- **wAMD** is buoyed by new entrants targeting patients earlier in the disease cascade, increasing awareness, and earlier diagnosis

Unapproved Bevacizumab Represents 50% of U.S. Wet AMD Market



Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics, if Approved by FDA

- 1 Provide cost-effective FDA approved ophthalmic bevacizumab
- 2 Become first-line “step-edit” drug of choice
- 3 12 years market exclusivity
- 4 Penetrate EU and developing markets

Repackaged and Off-Label Use of Bevacizumab

Variability in Potency¹

JAMA Ophthalmology

- 81% of samples had lower protein concentrations than expected
- Samples had statistically significant variations in protein concentration among samples potentially creating dosing concerns

Safety and Sterility Adverse Events²

Warning Letter FDA

- Unvalidated hold times in syringes not designed to be primary packages
- Patients have lost eyesight due to infections
- Multiple unapproved repackaged IV bevacizumab recalls due to unsterile compounding practices

Syringe Malfunctioning³

ASRS American Society of Retina Specialists

- Variability in repackaging can lower quality of syringe products, resulting in adverse events
- Silicone oil droplets may be released by the syringe into the eye

Not held to same quality standards as cGMP requirements.

Repackaging introduces potential variability.



ONS-5010 Ophthalmic Bevacizumab Target Product Profile

ONS-5010 (bevacizumab-vikg)

Patient Population

- Patients diagnosed with **wet AMD, DME, or BRVO**

Description

- Anti-VEGF **bevacizumab** designed for ophthalmic indications wet AMD, DME, and BRVO

Dosing and Administration

- Supplied either as **pre-filled ophthalmic syringe for intravitreal 1.25 mg injection** administered once monthly, **or as a glass vial**

Efficacy, Safety, and AEs

- Demonstrated efficacy and safety in NORSE TWO trial
- Comparable to data from the National Eye Institute (NEI) Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) Study as equivalent to LUCENTIS®

ONS-5010 Ophthalmic Bevacizumab Potential Value Proposition

ONS-5010 (bevacizumab-vikg)

Potential Value Proposition

- Potential FDA approved bevacizumab for the treatment of wet AMD
- **Addresses compounding pharmacy quality control issues** causing potential AEs, product shortages, and liability risks associated with off-label repackaged IV Avastin®
 - Ensures cGMP quality and delivery system designed for retinal disorders
- Addresses issue of AAO requesting that CMS modify Avastin® reimbursement rates to **protect physicians from financial risk**
- Ability for **bilateral administration with malpractice insurance coverage**
- **Priced to allow a cost-effective FDA approved option for first-line**

Do Physicians Want an Ophthalmic Approved Bevacizumab?

>80% of retinal specialists express interest/high interest in an FDA-approved ophthalmic bevacizumab to treat wet AMD, DME and BRVO



Total
(U.S. + EU)



"I do not understand how they have delayed releasing a product like this for so long. It was something retinal specialists often requested from the start"

-Retinal Specialist, ES



U.S.



"This product addresses the majority of my main concerns with using Avastin"

-Retinal Specialist, US



EU

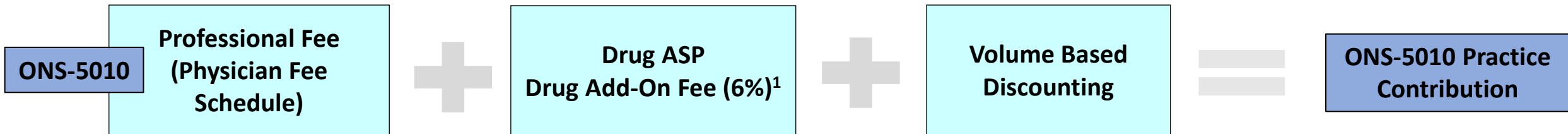


"Excellent action, reduction of costs, prefilled syringe"

-Retinal Specialist, IT

Compelling and Predictable Physician Economics Compared to Unapproved Compounded Bevacizumab

Per Injection Revenue (unilateral)



- In contrast, ASRS has identified that compounded off-label bevacizumab is not adequately reimbursed at the national level.
- Costs of compounding have continued to rise due to increased efforts to meet UPS 789 criteria. Physicians have shared that there is reduced margin for physicians choosing to compound bevacizumab due to these changes.
- Additionally, several large compounding pharmacies have either moved away from compounding (AMEX) or have had to issue recalls and product safety bulletins.
- **ONS-5010 can directly address this economic and quality dilemma for physicians and patients alike.**

Manufacturing and Regulatory Progress Towards Commercialization



Manufacturing

Best-in-class cGMP
manufacturing partners



Pre-Filled Syringes

Supply agreement for a best-in-class pre-filled ophthalmic syringe



Regulatory

Achieved clinical requirements
agreed upon with the FDA

Commercial Planning Activities Underway



If ONS-5010 (bevacizumab-vikg) is FDA approved and has a cost-effective profile, Outlook Therapeutics expects ONS-5010 to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated “step-edit” in the United States for retinal indications



**Physician and
Patient Outreach**



**Aligning Key
Opinion Leaders**



**Payor Community
Engagement**



Company Summary

- Positive Phase 3 results demonstrated with lead program, ONS-5010 (bevacizumab-vikg), for treatment of wet AMD
- Preparing U.S. FDA BLA submission targeted for calendar Q1 2022
- Potential for first FDA approved ophthalmic formulation of bevacizumab
- Targeting \$13.1 billion global ophthalmic anti-VEGF market¹
- Management team with proven ophthalmic commercial launch expertise



Thank you!

NASDAQ: OTLK
outlooktherapeutics.com

Investor Relations
JTC Team
833.475.8247
otlk@jtcir.com