

Outlook Therapeutics, Inc.

Reports Q2. EU and UK markets just launched. ONS-5010 BLA filed with PDUFA date 8/27. Lowering P/T to \$21.

Q2 about inline: Outlook recently (on May 15) reported its Q2 FY25 (ending March) results. EPS of \$(0.40) compared with our and consensus estimates of \$(0.60) - (0.61). There was no Q2 guidance. Outlook is a clinical stage drug development and early stage commercialization company so it currently generates no revenue. However, with its recent commercial launch, revenue is expected to grow quickly going forward.

Adjusting estimates: We are adjusting our FY25 estimates for revenue to \$3 million, from \$5 million, and for EPS to \$(2.08) from \$(2.52).

ONS-5010 development: Outlook has one main therapeutic candidate, ONS-5010 (named LYTENAVA) which is a proprietary ophthalmic formulation of bevacizumab (Avastin) product for the treatment of wet AMD and other eye diseases. Avastin is FDA approved and used widely in oncology indications but is also used off-label for the treatment of several ophthalmic diseases. Outlook is developing LYTENAVA as a replacement for the use of off-label Avastin in the treatment of wet AMD.

FDA issued CRL: On August 30, 2023, Outlook announced that the FDA issued a Complete Response Letter (CRL) for the BLA for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD. While the FDA acknowledged the NORSE TWO pivotal trial met its safety and efficacy endpoints, it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence.

Received FDA confirmation: The company met with and agreed to additional trials and data to addresses the FDA's requirement for BLA approval. The FDA agreed to the SPA (Special Protocol Assessment) in January 2024. If the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter (CRL).

NORSE EIGHT mostly positive data: In January 2025, the company announced that ONS-5010 demonstrated noninferiority to ranibizumab at week 12 in the NORSE EIGHT trial. In November 2024, the company reported top-line results from the 90-day non-inferiority NORSE EIGHT clinical study that it failed to meet the pre-specified non-inferiority endpoint at week 8. However, based on the 12-week results, the data was positive and satisfies the FDA requirements.

FDA BLA PDUFA date of 8/27: The company resubmitted its ONS-5010 BLA in February 2025. The FDA formally accepted the BLA in April and has set a Prescription Drug User Fee Act (PDUFA) goal date of August 27, 2025.

EU and UK launched: In June, the company has formally launched commercially LYTENAVA (bevacizumab gamma) for the treatment of wet AMD in U.K. and Germany.

New CEO: In December, Outlook announced that Russell Trenary has stepped down as CEO. Lawrence Kenyon, CFO, has been appointed Interim CEO until a replacement is found.

Balance sheet: Outlook has \$8 million in cash and \$33 million in debt as of Q2. With its recent (in the current Q3) capital raise (\$13 million in stock), we believe it has enough cash into late-2025.

Significant upside potential: We believe that a FDA approval for ONS-5010 is likely and that the current depressed share price is not reflective of that and represents significant upside potential.

Current valuation attractive: Maintaining our BUY rating, but lowering our 12-month price target to \$21 from \$24. This is based on a NPV analysis, representing significant upside from the current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities.

Company Description

Based in Iselin, NJ, Outlook Therapeutics is a clinical-stage biopharmaceutical company focused on developing ONS-5010, a proprietary ophthalmic bevacizumab (Avastin) product for the treatment of wet AMD.

COMPANY UPDATE

Rating: **BUY**

Ticker: OTLK

Price: \$1.91

Target: \$21
(from \$24)

Stock Data

Exchange:	NasdaqCM
52-week Range:	\$0.87 – 9.25
Shares Outstanding (million):	35
Market cap (\$million):	\$67
EV (\$million):	\$92
Debt (\$million):	\$33
Cash (\$million):	\$8
Avg. Daily Trading Vol. (\$million):	\$2
Float (million shares):	21
Short Interest (million shares):	3
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	<u>2025E</u> (Cur.)	<u>2025E</u> (Old)	<u>2026E</u> (Cur.)	<u>2026E</u> (Old)
Q1 Dec	0A		5E	
Q2 Mar	0A	0E	6E	
Q3 Jun	0E	1E	7E	
Q4 Sep	<u>3E</u>	<u>4E</u>	<u>7E</u>	
Total	3E	5E	25E	
EV/Revs	31x		4x	

Earnings per Share (pro forma)

	<u>2025E</u> (Cur.)	<u>2025E</u> (Old)	<u>2026E</u> (Cur.)	<u>2026E</u> (Old)
Q1 Dec	(0.89)A		(0.42)E	(0.48)E
Q2 Mar	(0.40)A	(0.61)E	(0.40)E	(0.45)E
Q3 Jun	(0.45)E	(0.58)E	(0.37)E	(0.42)E
Q4 Sep	<u>(0.44)E</u>	<u>(0.51)E</u>	<u>(0.37)E</u>	<u>(0.42)E</u>
Total	<u>(2.08)E</u>	<u>(2.52)E</u>	<u>(1.55)E</u>	<u>(1.77)E</u>
P/E	N/A		N/A	

Important Disclosures

Ascendant Capital Markets LLC seeks to do business with companies covered by its research team. Consequently, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making an investment decision.

For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 17.

Exhibit 1: Outlook's Investment Highlights

Investment Highlights

Commercial biopharmaceutical company dedicated to developing therapies for the preservation of vision

Lead product is an ophthalmic formulation of Bevacizumab for treatment of wet AMD

Bevacizumab has been validated² in wet AMD and is used off-label as a first-line treatment³

ONS-5010 / LYTENAVA™

(bevacizumab-vikg; bevacizumab gamma)

Europe

Commercial Launch Underway

Initial Launch Territories are Germany and the United Kingdom

United States

Driving Towards Potential Approval

**Prescription Drug User Fee Act (PDUFA)
Goal Date of August 27, 2025**

Investment Summary

Europe: Now Commercially Available in Germany and the United Kingdom

US: PDUFA Goal Date of August 27, 2025

Targeting >\$15.9 Billion Global Anti-VEGF Retina Market Opportunity¹

Approved in European Union
and United Kingdom
Covering 31 Countries

Positive NICE Recommendation

Received 10 Years Market
Exclusivity in Europe

U.S. FDA has Accepted
Resubmission of BLA and
set PDUFA Goal Date of
August 27, 2025

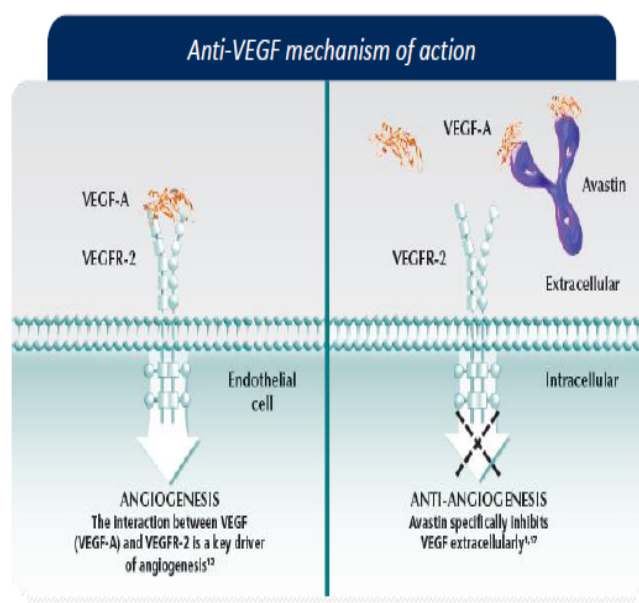
Source: Company reports.

Exhibit 2: Outlook's ONS-5010 (LYTENAVA)

Standard of Care in Wet AMD

ONS-5010 / LYTENAVA™, if approved, will be the first on-label ophthalmic formulation of bevacizumab-vikg

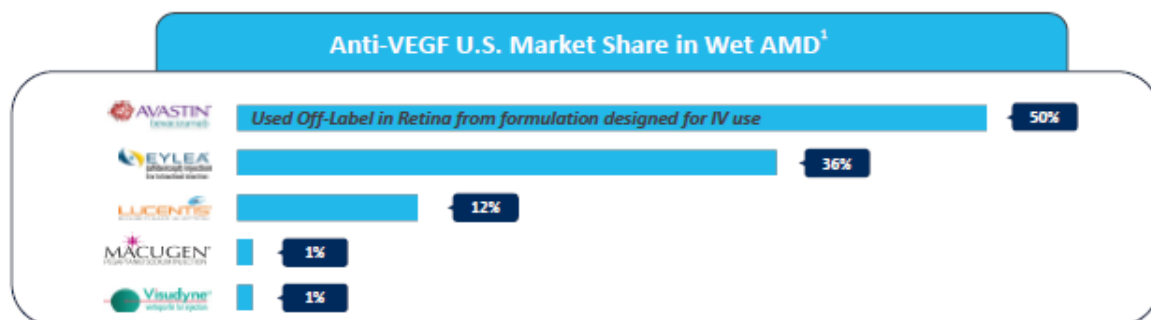
- ❑ Anti-VEGF drugs have been standard of care since 2006
 - Block growth of abnormal blood vessels and leakage of fluid from the vessels behind the retina
- ❑ Several new clinical-stage anti-VEGF drugs, including biosimilars, in development and/or recently approved
 - Require significant time and capital to achieve commercialization
 - New drugs expected to price at or near the high price points of current approved therapies



Source: Company reports.

Exhibit 3: ONS-5010 (LYTENAVA) Market Opportunities

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

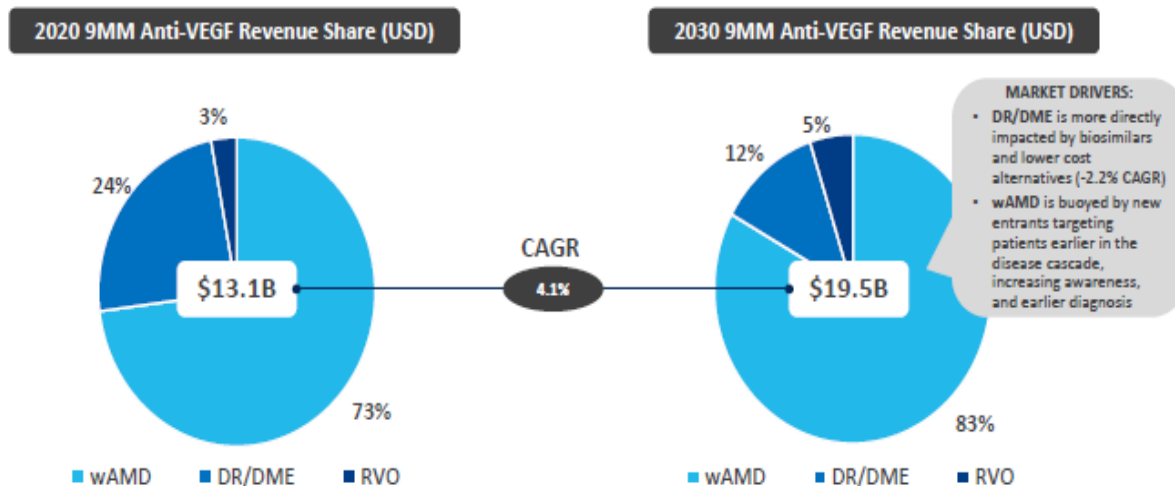


Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics, if Approved by FDA

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

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



Source: Company reports.

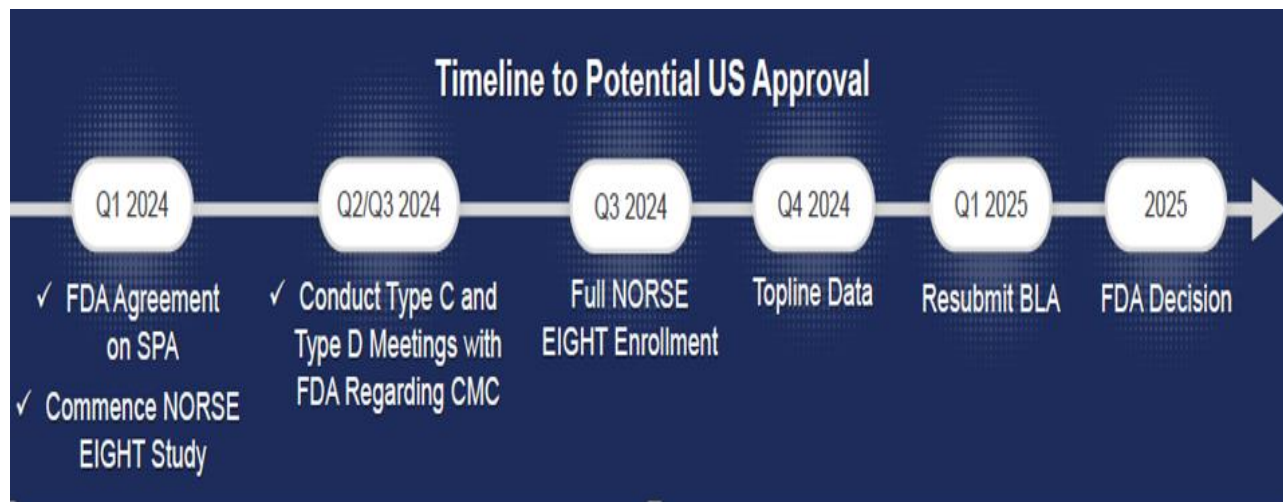
Exhibit 4: ONS-5010 ((LYTENAVA) Planned FDA Milestones

Next Steps in the United States

**BLA Resubmitted
to US FDA**

PDUFA Goal Date of August 27, 2025

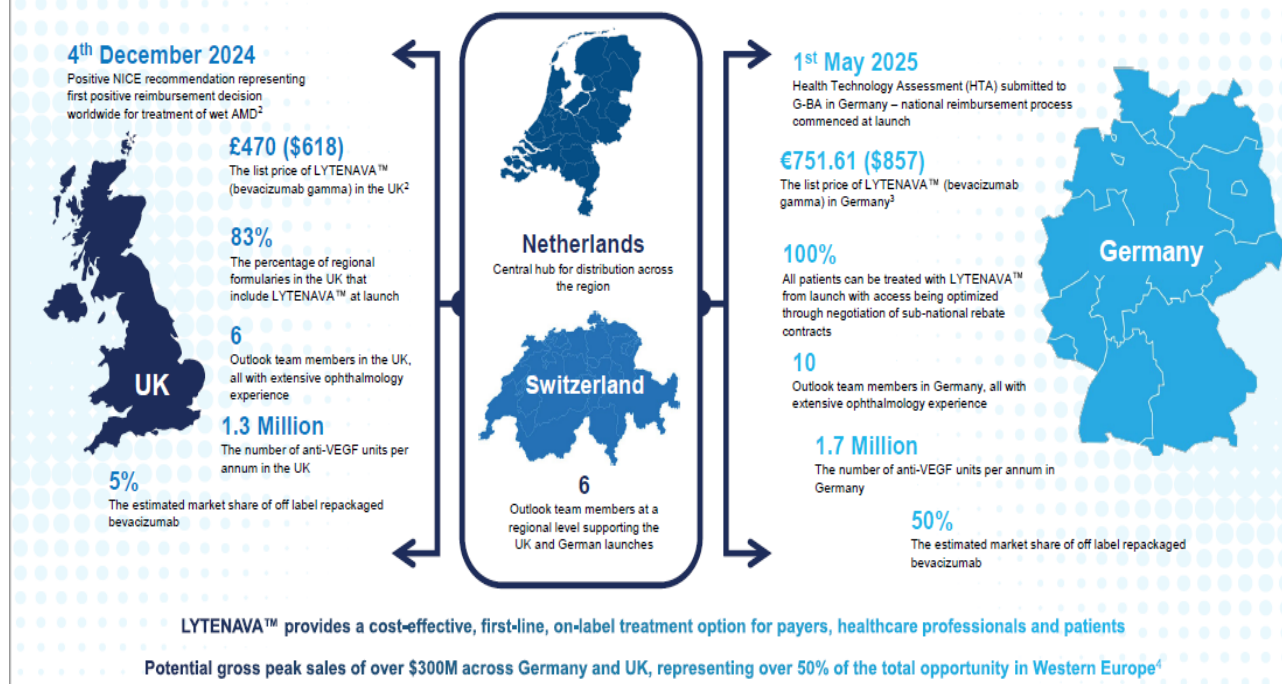
Supporting BLA Submission with Current Data Set



Source: Company reports.

Exhibit 5: ONS-5010 (LYTENAVA) Commercial Strategy

Now Launched in Germany and the United Kingdom¹



European Commercial Road Map

Potential for Gross Peak Sales of Over \$600 Million¹

Initial Target Markets ²	
	Germany
	United Kingdom
	Ireland
	Austria
	France
	Italy
	Netherlands
	Spain

Initial 2025 Target Launch
 2026 Target Launch
 2027 and Beyond Target Launch



¹Dates and timelines are listed in calendar year

Source: Company reports.

Exhibit 6: Recent Highlights and Upcoming Milestones (as of May 15, 2025)

Outlook Therapeutics Reports Financial Results for Second Quarter Fiscal Year 2025 and Provides Corporate Update

May 15, 2025

- **LYTENAVA™ (bevacizumab gamma) on track for planned first commercial launches in Germany and the United Kingdom (UK) in Q2 CY2025**
- **Prescription Drug User Fee Act (PDUFA) goal date of August 27, 2025 in the United States**

ISELIN, N.J., May 15, 2025 (GLOBE NEWSWIRE) -- [Outlook Therapeutics, Inc.](#) (Nasdaq: OTLK), a biopharmaceutical company focused on enhancing the standard of care for bevacizumab for the treatment of retina diseases, today reported financial results for the second quarter of fiscal year 2025 and provided a corporate update.

"Outlook Therapeutics remains on track in 2025 to transform into a commercial-stage company with the planned upcoming commercial launch of LYTENAVA™ (bevacizumab gamma) in Germany and the United Kingdom for the treatment of wet AMD. In addition to the commercial progress we are making in Europe, in the U.S. we are positioned to potentially receive FDA approval later this year for ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the treatment of wet AMD, with a PDUFA decision date scheduled for August 27th. We continue to build momentum and remain laser focused on our goal of providing patients, physicians and payers with a much needed, approved ophthalmic formulation of bevacizumab," commented Lawrence Kenyon, Chief Financial Officer and Interim Chief Executive Officer of Outlook Therapeutics.

Upcoming Anticipated Milestones

- Initial commercial launches in Germany and the UK planned to commence in Q2 CY2025; and
- Potential for approval from the U.S. Food and Drug Administration (FDA) of ONS-5010 in Q3 CY2025.

LYTENAVA™ (bevacizumab gamma) European Commercial Update

Outlook Therapeutics continues to advance its plans to launch LYTENAVA™ (bevacizumab gamma) in Germany and the UK, expected to take place in the second quarter of calendar year 2025. In May 2024, the European Commission granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD in the European Union (EU). Additionally, in July 2024, the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the same indication in the UK. In December 2024, the National Institute for Health and Care Excellence (NICE) recommended LYTENAVA™ (bevacizumab gamma) as an option for the treatment of wet AMD.

LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the EU and UK. Currently, off-label repackaged bevacizumab is one of the most frequently used first-line anti-VEGF treatments in Europe (approximately 2.8 million injections annually) and the United States (approximately 2.7 million injections annually) for the treatment of retinal diseases¹. ONS-5010/LYTENAVA™ has the potential to mitigate certain risks associated with the current off-label use of repackaged bevacizumab.

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

First and Only Approved Ophthalmic Formulation of Bevacizumab for the
Treatment of Wet AMD in the European Union and United Kingdom¹

Now Commercially Available in Germany and the United Kingdom (UK)

- ✓ 2.8 million injections of repackaged off-label bevacizumab in Europe each year already taking place²
- ✓ ONS-5010/LYTENAVA™ has potential to mitigate certain risks associated with the current off-label use of repackaged bevacizumab
- ✓ Positive NICE recommendation
- ✓ Received 10 years market exclusivity covering 31 countries



Source: Company reports.

Exhibit 7: U.S. Market Opportunity

Significant United States Market Opportunity

\$8.5 Billion Total US Anti-VEGF Retina Market¹

Off-Label Repackaged Bevacizumab
is Already Being Used^{1,2,3}

55%

Most Commonly
Utilized First-
Line Agent²

34%

Maintenance
Therapy³

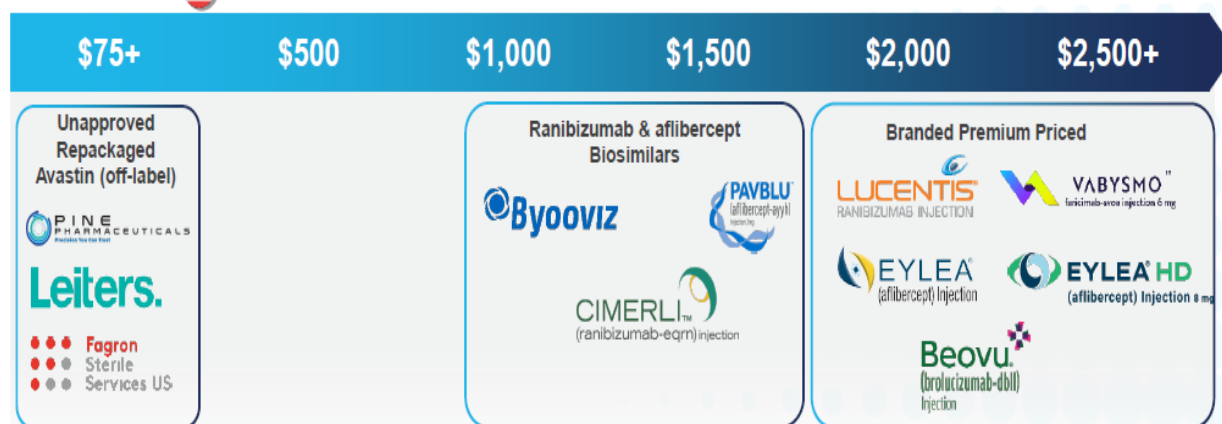
2.7 Million

Estimated Number of off-label
repackaged injections^{1,2,3,4}

Our United States Pricing Opportunity

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

United States 



Source: Company reports.

Exhibit 8: NORSE EIGHT Pivotal Trial

Outlook Therapeutics® Announces Complete Twelve Week Efficacy and Safety Results of NORSE EIGHT Clinical Trial

January 16, 2025

- **ONS-5010 demonstrated to be non-inferior to Lucentis at 12 weeks**
- **BLA resubmission on track for calendar Q1 2025**
- **Entered into agreements for warrant inducement transaction expected to result in up to \$20.4 million in gross proceeds**

ISELIN, N.J., Jan. 16, 2025 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Outlook Therapeutics, or the Company) (Nasdaq: OTLK), a biopharmaceutical company that achieved regulatory approval in the European Union and the United Kingdom for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD), today announced it has completed the analysis of the complete 12-week safety and efficacy results for NORSE EIGHT, the second of two adequate and well controlled clinical trials evaluating ONS-5010 in wet AMD patients. ONS-5010 demonstrated noninferiority to ranibizumab at week 12 in the NORSE EIGHT trial. Based on the completed analysis of the 12-week results, Outlook Therapeutics plans to resubmit the Biologics License Application (BLA) for ONS-5010 in the first quarter of calendar 2025.

Julia A. Haller, MD, Ophthalmologist-in-Chief at Wills Eye Hospital and an Outlook Therapeutics Board member, commented, "The 3-month data from NORSE EIGHT provides additional evidence to confirm what retina specialists expected. The clinical trial continues to demonstrate that ONS-5010 injections result in immediate and sustained anatomic efficacy, with steady gains in visual acuity and reliable, consistent safety."

The difference in the mean between ONS-5010 and ranibizumab was -1.009 best corrected visual acuity (BCVA) letters with a 95% confidence interval of (-2.865, 0.848) in the NORSE EIGHT trial. Applying the statistical parameters from the week 8 primary endpoint with the lower bound of the non-inferiority margin at -3.5 with a 95% confidence interval, the noninferiority margin was met at week 12 ($p=0.0043$), indicating that the two study arms are not different at this timepoint. In the intent-to-treat (ITT) population, NORSE EIGHT demonstrated a mean 5.5 letter improvement in BCVA in the ONS-5010 arm and 6.5 letter improvement in BCVA in the ranibizumab arm.

Phase 3 Non-Inferiority Study

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

- Did not meet the pre-specified non-inferiority endpoint at week 8
- Demonstrated clinically meaningful anatomic and functional improvements at each study timepoint
- Favorable safety profile consistent with previously reported NORSE clinical trials



ONS-5010 (1.25 mg) Monthly Intravitreal Injections



Primary Efficacy
Endpoint
at 8 weeks

Ranibizumab (0.5 mg) Intravitreal Injections



Primary Efficacy Endpoint
at 8 weeks

Safety and Effectiveness of ONS-5010 Compared to Ranibizumab in Subjects with Neovascular Age-related Macular Degeneration

- Study design mirrors first three months of the positive NORSE TWO Phase 3 study
- 400 treatment naïve, wet AMD subjects enrolled at 61 US sites
- BCVA: 20/32 – 20/200

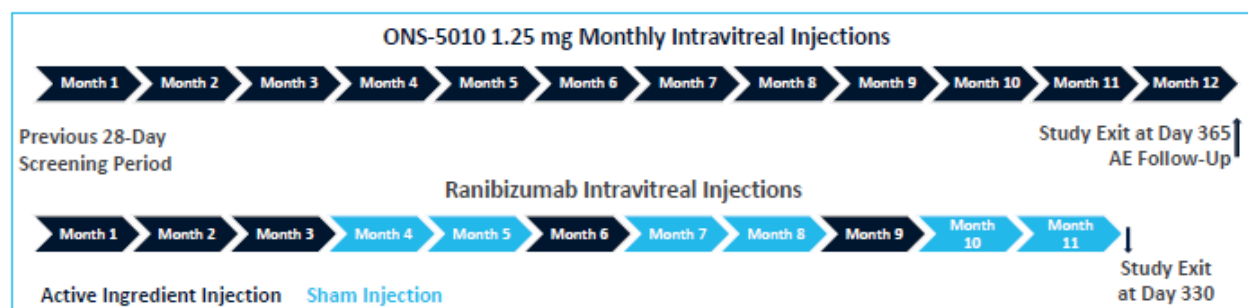
Source: Company reports.

Exhibit 9: NORSE TWO Study Conclusion



Superiority Phase 3 Pivotal Study Design

12-Month Study of Safety and Efficacy of ONS-5010 in Subjects with Wet AMD Study Design and Statistical Analysis Plan Agreed to by U.S. FDA



Study Eye Characteristics

- Active, primary CNV due to wet AMD
- Treatment-naïve
- BCVA: 20/50 – 20/320

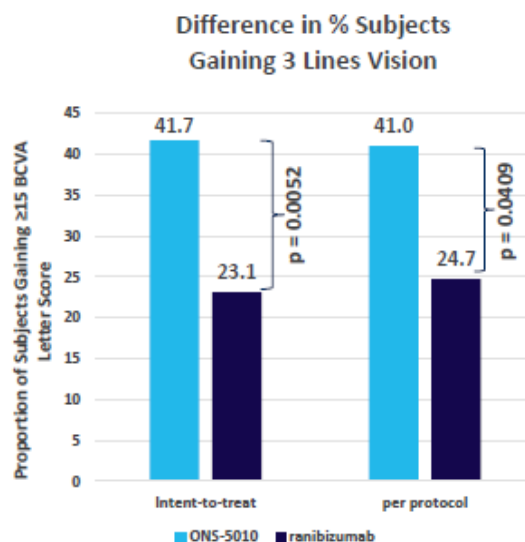
Key Study Outcomes

- Proportion of subjects who gain ≥ 15 letters in BCVA
- Mean change in BCVA from baseline to Month 11
- Frequency and incidence of AEs



Primary Endpoint Met with Statistically Significant, Clinically Relevant Results¹

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	



Source: Company reports.

Exhibit 10: FDA issues Complete Response Letter (August 30, 2023)

Outlook Therapeutics® Provides Regulatory Update on FDA Review of ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the Treatment of Wet AMD

August 30, 2023

FDA issues Complete Response Letter (CRL) for ONS-5010 BLA based on CMC and need for further confirmatory clinical evidence

Outlook Therapeutics working with FDA to address the Agency's issues

Company to host conference call and webcast, today, August 30 at 8:30 AM ET

ISELIN, N.J., Aug. 30, 2023 (GLOBE NEWSWIRE) -- [Outlook Therapeutics, Inc.](#) (Nasdaq: OTLK), a biopharmaceutical company working to achieve FDA approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced the U.S. Food and Drug Administration (FDA) has issued a CRL to the Company's BLA for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD. While the FDA acknowledged the NORSE TWO pivotal trial met its safety and efficacy endpoints, the Agency concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence.

"We continue to believe in the public health need to provide the retina community with an FDA-approved bevacizumab treatment option for wet AMD. We will request a formal meeting as soon as possible with the FDA to further understand the BLA deficiencies and how best to resolve them. Following this meeting with the FDA, the Company will be able to discuss next steps and the expected timing for resolution," said Russell Trenary, President and CEO of Outlook Therapeutics.

Julia A. Haller, MD, Ophthalmologist-in-Chief at Wills Eye Hospital and an Outlook Therapeutics Board member, commented, "The retina community needs an FDA-approved ophthalmic bevacizumab to deliver an alternative targeted on-label treatment for patients with wet AMD."

Source: Company reports.

Exhibit 11: Receives FDA Agreement for NORSE EIGHT and Capital Raise of up to \$172 Million (January 23, 2024)

Outlook Therapeutics® Receives FDA Agreement Under Special Protocol Assessment (SPA) for 90 Day Non-Inferiority Study, NORSE EIGHT, and Announces Private Placement of Up to \$172 Million to Advance ONS-5010

January 23, 2024

- Obtained clarity from U.S. Food and Drug Administration (FDA) on next steps to advance ONS-5010
- NORSE EIGHT expected to commence in the first quarter of CY2024, enabling potential resubmission of the ONS-5010 Biologics License Application (BLA) by the end of CY2024
- Private placements to top tier institutional investors and insiders include up to \$65 million in common stock and up to an additional \$107 million upon cash exercise of warrants, subject to closing conditions
- Aggregate financing, subject to achievement of milestones, is expected to be sufficient to take ONS-5010 through potential FDA approval and fund commercial launch

ISELIN, N.J., Jan. 23, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve FDA approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced that it has received written agreement from the FDA under an SPA for the NORSE EIGHT clinical trial protocol evaluating ONS-5010 in neovascular age-related macular degeneration (AMD) subjects. Additionally, Outlook Therapeutics entered into securities purchase agreements with certain institutional and accredited investors for up to \$172 million in gross proceeds to fund the advancement of ONS-5010.

"The SPA increases our confidence that ONS-5010, if approved, will more effectively meet the needs of retina surgeons, patients and payers in the \$9.5 billion ophthalmic anti-VEGF market in the United States, and the financing represents a significant commitment by our new and existing stockholders to advance this important development program," commented Russell Trenary, President and Chief Executive Officer. "We believe that the funds we expect to receive in this financing will position Outlook Therapeutics to support the ONS-5010 development pathway through potential FDA approval and launch."

The FDA has reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter (CRL).

NORSE EIGHT will be a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint will be mean change in BCVA from baseline to week 8. Outlook Therapeutics expects NORSE EIGHT topline results and resubmission of the ONS-5010 BLA by the end of calendar year 2024. In addition, through a Type A meeting and additional interactions, Outlook Therapeutics has identified the approaches needed to resolve the chemistry, manufacturing and controls comments in the CRL. Outlook Therapeutics is working to address the open items and expects to resolve these comments prior to the expected completion of NORSE EIGHT.

Source: Company reports.

Exhibit 12: Outlook Therapeutics Stock Price (5-years)



*Reflects a 1:20 reverse stock split in March 2024

Source: <https://bigcharts.marketwatch.com/>

Exhibit 13: Consensus Expectations (as of May 15, 2025)

	Revenue (mil)			EPS	
	2025E	2026E		2025E	2026E
Q1 Dec	\$0.0A		Q1 Dec	\$(0.89)A	
Q2 Mar	\$0.7E		Q2 Mar	\$(0.60)E	
Q3 Jun	\$2.3E		Q3 Jun	\$(0.49)E	
Q4 Sep			Q4 Sep		
Total	\$10.1E	\$39.4E	Total	\$(1.86)E	\$(1.05)E

*Quarterly estimates may not add to annual estimates due to variations in contributing estimates and rounding.

Source: Company report, LSEG, and Ascendant Capital Markets estimates

FINANCIAL MODEL

Outlook Therapeutics, Inc.

Income Statement (\$ mils)	Dec-22	Mar-23	Jun-23	Sep-23	2023	Dec-23	Mar-24	Jun-24	Sep-24	2024	Dec-24	Mar-25	Jun-25	Sep-25	2025	Dec-25	Mar-26	Jun-26	Sep-26	2026
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Total Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	3.0	5.0	6.0	7.0	7.0	25.0
<u>Cost of Revenues</u>					0.0					0.0			0.0	0.9	0.9	1.5	1.8	2.1	2.1	7.5
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.1	2.1	3.5	4.2	4.9	4.9	17.5
Research and development	9.9	0.5	11.1	4.9	26.5	4.5	13.5	11.2	12.5	41.8	9.7	4.4	5.0	5.0	24.1	5.0	5.0	5.0	5.0	20.0
General and administrative	5.8	6.3	7.0	7.5	26.7	5.8	5.4	8.4	10.4	29.9	11.9	8.0	8.0	10.0	37.9	11.0	11.0	11.0	11.0	44.0
<u>Restructuring and other</u>					0.0					0.0					0.0					0.0
Total operating expenses	15.7	6.8	18.1	12.5	53.1	10.3	18.9	19.6	22.9	71.7	21.6	12.4	13.0	15.0	62.0	16.0	16.0	16.0	16.0	64.0
Operating income (loss)	(15.7)	(6.8)	(18.1)	(12.5)	(53.1)	(10.3)	(18.9)	(19.6)	(22.9)	(71.7)	(21.6)	(12.4)	(13.0)	(12.9)	(59.9)	(12.5)	(11.8)	(11.1)	(11.1)	(46.5)
Interest income (expense)	(2.4)	0.2	0.4	0.3	(1.6)	0.2	(3.1)	0.4	0.2	(2.3)	0.0	(0.0)	(2.5)	(2.5)	(5.0)	(2.5)	(2.5)	(2.5)	(2.5)	(10.0)
<u>Other income (expense)</u>	(0.5)	(0.0)	(2.9)	(0.8)	(4.3)	(1.0)	(92.3)	63.6	28.3	(1.4)	38.9	(33.9)			5.0					0.0
Income before income taxes	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(11.2)	(114.3)	44.4	5.7	(75.4)	17.4	(46.4)	(15.5)	(15.4)	(59.9)	(15.0)	(14.3)	(13.6)	(13.6)	(56.5)
<u>Income taxes</u>		0.0			0.0		0.0		(0.0)	0.0		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss)	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(11.2)	(114.3)	44.4	5.7	(75.4)	17.4	(46.4)	(15.5)	(15.4)	(59.9)	(15.0)	(14.3)	(13.6)	(13.6)	(56.5)
<u>Nonrecurring/noncash adjustments</u>					0.0		92.2	(63.6)	(28.3)	0.3	(39.0)	33.9			(5.1)					0.0
Net income (pro forma)	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(11.2)	(22.1)	(19.2)	(22.6)	(75.1)	(21.6)	(12.4)	(15.5)	(15.4)	(64.9)	(15.0)	(14.3)	(13.6)	(13.6)	(56.5)
EBITDA																				
Shares, Basic	11.4	12.8	12.8	13.0	12.5	13.0	14.3	23.2	23.5	18.5	24.2	30.9	34.6	35.1	31.2	35.6	36.1	36.6	37.1	36.4
Shares, Diluted	11.4	12.8	12.8	13.0	12.5	13.0	14.3	25.5	23.5	18.5	24.2	30.9	34.6	35.1	31.2	35.6	36.1	36.6	37.1	36.4
EPS Basic (Pro forma)	(\$1.64)	(\$0.52)	(\$1.61)	(\$1.00)	(\$4.72)	(\$0.86)	(\$1.55)	(\$0.83)	(\$0.96)	(\$4.05)	(\$0.89)	(\$0.40)	(\$0.45)	(\$0.44)	(\$2.08)	(\$0.42)	(\$0.40)	(\$0.37)	(\$0.37)	(\$1.55)
EPS Diluted (Pro forma)	(\$1.64)	(\$0.52)	(\$1.61)	(\$1.00)	(\$4.72)	(\$0.86)	(\$1.55)	(\$0.75)	(\$0.96)	(\$4.05)	(\$0.89)	(\$0.40)	(\$0.45)	(\$0.44)	(\$2.08)	(\$0.42)	(\$0.40)	(\$0.37)	(\$0.37)	(\$1.55)
Margins																				
Gross margin													70%	70%	70%	70%	70%	70%	70%	70%
Research and development													#DIV/0!	167%	802%	100%	83%	71%	71%	80%
General and administrative													#DIV/0!	333%	1264%	220%	183%	157%	157%	176%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-430%	-1997%	-250%	-197%	-159%	-159%	-186%
Tax rate, GAAP	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-513%	-1996%	-300%	-238%	-194%	-194%	-226%
Y/Y % change																				
Total Revenue																				
Gross margin																				
Research and development	0%	-96%	-1%	-45%	-38%	-54%	2379%	1%	153%	58%	113%	-67%	-55%	-60%	-42%	-48%	13%	0%	0%	-17%
General and administrative	78%	-6%	22%	50%	29%	-1%	-14%	19%	38%	12%	106%	47%	-4%	-3%	27%	-8%	38%	38%	10%	16%
Operating income (loss)	19%	-64%	7%	-11%	-16%	-34%	177%	8%	84%	35%	109%	-35%	-34%	-44%	-16%	-42%	-5%	-15%	-14%	-22%
Net income (loss)	29%	-66%	18%	-9%	-11%	-40%	1618%	-315%	-144%	28%	-255%	-59%	-135%	-371%	-21%	-186%	-69%	-12%	-12%	-6%
EPS Diluted (Pro forma)	7%	-71%	1%	-23%	-24%	-48%	198%	-53%	-4%	-14%	4%	-74%	-41%	-54%	-49%	-53%	-2%	-17%	-16%	-25%

Source: Company reports and Ascendant Capital Markets estimates. Reflects a 1:20 reverse stock split in March 2024

Outlook Therapeutics, Inc.

Balance Sheet (\$ mils)	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25	Mar-26	Jun-26	Sep-26
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Assets																
Cash and cash equivalents	52.3	43.6	33.7	23.4	10.4	47.2	32.0	14.9	5.7	7.6	6.8	(6.2)	(19.4)	(32.0)	(43.8)	(55.7)
Short term investments											0.0	0.0	0.0	0.0	0.0	0.0
Accounts receivable, net											0.0	0.0	0.0	0.0	0.0	0.0
Inventory									3.1	3.6	3.6	3.6	3.6	3.6	3.6	3.6
Deferred income taxes											0.0	0.0	0.0	0.0	0.0	0.0
Prepaid expenses and other	9.3	9.4	9.3	7.6	10.0	10.6	13.6	12.5	6.9	6.6	6.6	6.6	6.6	6.6	6.6	6.6
Total current assets	61.7	53.1	43.0	31.0	20.4	57.8	45.6	27.4	15.7	17.8	17.1	4.1	(9.2)	(21.7)	(33.6)	(45.4)
Long term securities/investments	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Property and equipment, net											(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)
Intangibles, net											0.0	0.0	0.0	0.0	0.0	0.0
Deferred income tax											0.0	0.0	0.0	0.0	0.0	0.0
Other	0.2	0.2	0.6	0.5	0.5	0.5	0.8	0.7	0.7	0.6	0.6	0.0	0.0	0.0	0.0	0.0
Total assets	62.7	54.0	44.4	32.3	21.7	59.0	47.1	28.8	17.0	19.1	18.3	4.6	(8.7)	(21.2)	(33.1)	(45.0)
Liabilities and stockholders' equity																
Accounts payable	4.2	3.6	5.1	6.6	3.5	4.4	5.6	8.0	12.2	7.8	7.8	7.8	7.8	7.8	7.8	7.8
Accrued expenses	9.0	6.2	8.3	2.7	4.1	3.1	2.7	3.2	3.4	3.1	3.1	3.1	3.1	3.1	3.1	3.1
Deferred revenue											0.0	0.0	0.0	0.0	0.0	0.0
Deferred income tax	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Short term debt		31.8	34.7	35.6	36.5	44.7	32.4	29.4	30.7	12.0	12.0	12.0	12.0	12.0	12.0	12.0
Total current liabilities	15.1	43.5	49.9	46.7	46.0	54.1	42.6	42.6	48.2	24.8	24.8	24.8	24.8	24.8	24.8	24.8
Deferred income taxes											0.0	0.0	0.0	0.0	0.0	0.0
Warrant liabilities	0.0	0.0	0.0	0.0	0.1	139.2	88.0	59.1	18.8	5.5	5.5	5.5	5.5	5.5	5.5	5.5
Deferred revenue											0.0	0.0	0.0	0.0	0.0	0.0
Other long term liabilities	0.0						0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Long term debt	31.8									21.0	21.0	21.0	21.0	21.0	21.0	21.0
Total other liabilities	31.8	0.0	0.0	0.0	0.1	139.2	88.2	59.3	19.1	26.7	26.7	26.7	26.7	26.7	26.7	26.7
Preferred stock											0.0	0.0	0.0	0.0	0.0	0.0
Common stock	2.6	2.6	2.6	2.6	2.6	0.2	0.2	0.2	0.2	0.3	2.1	3.8	5.5	7.2	8.9	10.7
Additional paid-in capital	440.8	442.2	446.8	450.9	452.2	458.9	465.1	470.0	475.4	539.5	539.5	539.5	539.5	539.5	539.5	539.5
Retained earnings	(427.6)	(434.3)	(454.9)	(467.9)	(479.1)	(593.4)	(549.0)	(543.3)	(525.9)	(572.3)	(587.8)	(603.2)	(618.2)	(632.5)	(646.1)	(659.7)
Treasury stock											0.0	0.0	0.0	0.0	0.0	0.0
Accumulated other comprehensive income											0.0	0.0	0.0	0.0	0.0	0.0
Other											13.0	13.0	13.0	13.0	13.0	13.0
Total stockholders' equity	15.8	10.5	(5.5)	(14.4)	(24.3)	(134.2)	(83.7)	(73.1)	(50.3)	(32.5)	(33.2)	(46.9)	(60.2)	(72.8)	(84.6)	(96.5)
Total stockholders' equity and liab	62.7	54.0	44.4	32.3	21.7	59.0	47.1	28.8	17.0	19.1	18.3	4.6	(8.7)	(21.2)	(33.1)	(45.0)

Balance Sheet Drivers

	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25	Mar-26	Jun-26	Sep-26
	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Book & Cash Value (per share)																
Book Value per Share (diluted)	\$1.39	\$0.82	-\$0.43	-\$1.11	-\$1.87	-\$9.41	-\$3.28	-\$3.11	-\$2.08	-\$1.05	-\$0.96	-\$1.34	-\$1.69	-\$2.02	-\$2.31	-\$2.60
Cash per Share (diluted)	\$4.68	\$3.46	\$2.69	\$1.86	\$0.86	\$3.36	\$1.28	\$0.66	\$0.26	\$0.26	\$0.21	-\$0.16	-\$0.53	-\$0.87	-\$1.18	-\$1.48
Net cash per Share (diluted)	\$1.88	\$0.98	-\$0.02	-\$0.87	-\$1.95	\$0.23	\$0.01	-\$0.59	-\$1.01	-\$0.81	-\$0.74	-\$1.10	-\$1.46	-\$1.78	-\$2.08	-\$2.37

Source: Company reports and Ascendant Capital Markets estimates

Outlook Therapeutics, Inc.

Cash Flow Statement (\$ mils)	Dec-22	Mar-23	Jun-23	Sep-23	2023	Dec-23	Mar-24	Jun-24	Sep-24	2024	Dec-24	Mar-25	Jun-25	Sep-25	2025	Dec-25	Mar-26	Jun-26	Sep-26	2026
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Cash flow from operating activities																				
Net income	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(11.2)	(114.3)	44.4	5.7	(75.4)	17.4	(46.4)	(15.5)	(15.4)	(59.9)	(15.0)	(14.3)	(13.6)	(13.6)	(56.5)
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.1
Amortization	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Debt related amortization expen	1.4	0.0	0.0	0.0	1.4		2.7		0.0	2.7					0.0					0.0
Stock comp	1.4	1.4	1.4	1.4	5.5	1.3	1.3	1.4	1.4	5.4	3.7	1.7	1.7	1.7	8.8	1.7	1.7	1.7	1.7	6.9
Deferred income taxes					0.0					0.0			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Provision for bad debts					0.0					0.0					0.0					0.0
Change in fair value of warrant l	(0.0)	(0.0)	0.0	3.7	3.7	1.0	92.2	(63.6)	(28.3)	1.3	(39.0)	33.9			(5.1)					0.0
Writedowns and impairments			2.9	(2.9)	0.0					0.0					0.0					0.0
Other gains/losses	0.6	0.0	0.0	0.0	0.6	(0.0)	0.0	0.1	0.0	0.1	0.0	0.0			0.1					0.0
Other					0.0					0.0					0.0					0.0
Changes in operating assets and liabilities:																				
Accounts receivable					0.0					0.0					0.0	0.0	0.0	0.0	0.0	0.0
Inventory					0.0					0.0	(3.1)	(0.5)			(3.6)					0.0
Prepaid expenses & other curre	0.8	(0.1)	0.1	1.8	2.6	(2.4)	(0.5)	(3.0)	1.1	(4.9)	5.6	0.2	0.0	0.0	5.8	0.0	0.0	0.0	0.0	0.0
Income tax					0.0					0.0					0.0					0.0
Other assets	(0.0)	(0.0)	(0.2)	0.0	(0.2)		(0.0)	(0.0)	0.0	(0.0)	(0.0)	(0.0)	0.0	0.6	0.6	0.0	0.0	0.0	0.0	0.0
Accounts payable	0.7	(0.6)	1.2	1.8	3.1	(3.1)	0.3	1.7	2.5	1.4	4.2	(4.6)	0.0	0.0	(0.4)	0.0	0.0	0.0	0.0	0.0
Accrued expenses	5.0	(2.2)	2.1	(5.6)	(0.7)	1.3	(1.0)	(0.4)	0.6	0.5	0.2	(1.0)	0.0	0.0	(0.8)	0.0	0.0	0.0	0.0	0.0
Deferred revenue					0.0					0.0			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other liabilities					0.0					0.0			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash (used in) provided by	(8.9)	(8.1)	(13.2)	(12.7)	(43.0)	(13.0)	(19.3)	(19.5)	(17.0)	(68.8)	(11.0)	(16.6)	(13.7)	(13.0)	(54.3)	(13.2)	(12.5)	(11.8)	(11.8)	(49.5)
Cash flow from investing activities																				
Purchases of property and equipment					0.0					0.0			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Purchases of short-term investments					0.0					0.0					0.0					0.0
Acquisitions					0.0					0.0					0.0					0.0
Other					0.0					0.0					0.0					0.0
Net cash used in investing activ	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cash flow from financing activities																				
Issuance of debt	30.0				30.0					0.0		33.1	0.0	0.0	33.1	0.0	0.0	0.0	0.0	0.0
Repayment of debt	(10.8)	(0.3)	(0.0)	(0.0)	(11.1)	(0.0)	(0.0)			(0.0)		(32.9)			(32.9)					0.0
Issuance of stock	24.6	(0.3)	3.3	2.4	30.0		56.1	4.3	(0.1)	60.3	1.7	1.4	0.0	0.0	3.2	0.0	0.0	0.0	0.0	0.0
Repurchase of common stock					0.0					0.0					0.0					0.0
Proceeds from stock option exercises					0.0					0.0		16.8			16.8					0.0
Other					0.0					0.0			13.0		13.0					0.0
Dividends and distributions					0.0					0.0					0.0					0.0
Cash provided by (used in) fina	43.8	(0.6)	3.3	2.4	49.0	(0.0)	56.1	4.3	(0.1)	60.3	1.7	18.4	13.0	0.0	33.2	0.0	0.0	0.0	0.0	0.0
Effect of exchange rate on cash					0.0					0.0					0.0					0.0
Net increase (decrease) in cash	34.9	(8.7)	(9.9)	(10.3)	6.0	(13.0)	36.9	(15.2)	(17.1)	(8.5)	(9.2)	1.9	(0.7)	(13.0)	(21.1)	(13.2)	(12.5)	(11.8)	(11.8)	(49.5)
Beginning cash and equivalents	17.4	52.3	43.6	33.7	17.4	23.4	10.4	47.2	32.0	23.4	14.9	5.7	7.6	6.8	14.9	(6.2)	(19.4)	(32.0)	(43.8)	(6.2)
Ending cash and equivalents	52.3	43.6	33.7	23.4	23.4	10.4	47.2	32.0	14.9	14.9	5.7	7.6	6.8	(6.2)	(6.2)	(19.4)	(32.0)	(43.8)	(55.7)	(55.7)

Source: Company reports and Ascendant Capital Markets estimates

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Outlook Therapeutics, Inc.



*Reflects a 1:20 reverse stock split in March 2024

Source: <https://bigcharts.marketwatch.com/>

Report	Report Date	Rating	Price Target
1	4/22/2019	B	80.00
2	5/16/2019	B	60.00
3	8/20/2019	B	80.00
4	12/22/2019	B	70.00
5	1/29/2020	B	75.00
6	2/20/2020	B	70.00
7	5/21/2020	B	65.00
8	8/21/2020	B	80.00
9	8/31/2020	B	65.00
10	1/6/2021	B	70.00
11	2/17/2021	B	100.00
12	5/22/2021	B	120.00
13	9/6/2021	B	140.00
14	12/23/2021	B	145.00
15	3/2/2022	B	150.00
16	5/27/2022	B	155.00
17	8/17/2022	B	140.00
18	3/29/2023	B	145.00
19	5/30/2023	B	150.00
20	9/9/2023	B	30.00
21	12/27/2023	B	40.00
22	2/23/2024	B	45.00
23	5/22/2024	B	35.00
24	8/31/2024	B	33.00
25	2/23/2025	B	24.00

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Rating	Count	Percent	Investment Banking Services Past 12 months	
			Count	Percent
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Sell	1	2%	0	0%
Total	53	100%	21	40%

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