United States
Healthcare

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Outlook Therapeutics, Inc.

Reports Q1. Expect EU and UK launch in 1H 25. On track for ONS-5010 BLA FDA resubmission in Q1 2025. Lowering P/T to $24.

COMPANY UPDATE

Rating: BUY

Ticker: OTLK

Price: $1.56

Target: $24 (from $33)

Q1 about inline: Outlook recently (on February 14) reported its Q1 FY25 (ending December) results. EPS of $(0.89) compared with our and consensus estimates of $(0.78) - (0.93). There was no Q1 guidance. Outlook is a clinical stage medical device development and early stage commercialization company so it currently generates no revenue.

Adjusting estimates: We are adjusting our FY25 estimates for revenue to $5 million, from $4 million, and for EPS to $(2.52) from $(3.01).

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).

FDA BLA resubmission on track in Q1 2025: NORSE EIGHT started in February 2024 and mostly positive top-line data was reported in January 2025. The resubmission of the ONS-5010 BLA expected in Q1 2025.

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, Outlook plans to resubmit the Biologics License Application (BLA) to FDA for ONS-5010 in Q1 2025.

EU and UK launches in 1H 25: In 2024, the company received European Union (EU) and United Kingdom (UK) Marketing Authorization for LYTENAVA (bevacizumab gamma) for the treatment of wet AMD. Initial commercial launches in Europe is planned to start in first half of CY2025.

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 if found.

Balance sheet: Outlook has $6 million in cash and $31 million in debt as of Q1. With its recent (in the current Q2) capital raise ($18 million in stock/warrants and $33 million debt swap), we believe it has enough cash into mid-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 $24 from $33. 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.

Stock Data

Exchange:	NasdaqCM
52-week Range:	$0.87 – 12.85
Shares Outstanding (million):	32
Market cap ($million):	$50
EV ($million):	$75
Debt ($million):	$31
Cash ($million):	$6
Avg. Daily Trading Vol. ($million):	$4
Float (million shares):	24
Short Interest (million shares):	3
Dividend, annual (yield):	$0 (NA%)

Revenues (US$ million)

	2025E (Cur.)	2025E (Old)	2026E (Cur.)	2026E (Old)
Q1 Dec	0A	0E	5E	
Q2 Mar	0E		6E	
Q3 Jun	1E		7E	
Q4 Sep	4E	3E	7E	
Total	**5E**	**4E**	**25E**	
EV/Revs	15x		3x	

Earnings per Share (pro forma)

	2025E (Cur.)	2025E (Old)	2026E (Cur.)	2026E (Old)
Q1 Dec	(0.89)A	(0.93)E	(0.48)E	
Q2 Mar	(0.61)E	(0.75)E	(0.45)E	
Q3 Jun	(0.58)E	(0.71)E	(0.42)E	
Q4 Sep	(0.51)E	(0.64)E	(0.42)E	
Total	**(2.52)E**	**(3.01)E**	**(1.77)E**	
P/E	N/A		N/A	

Important Disclosures

Ascendiant 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

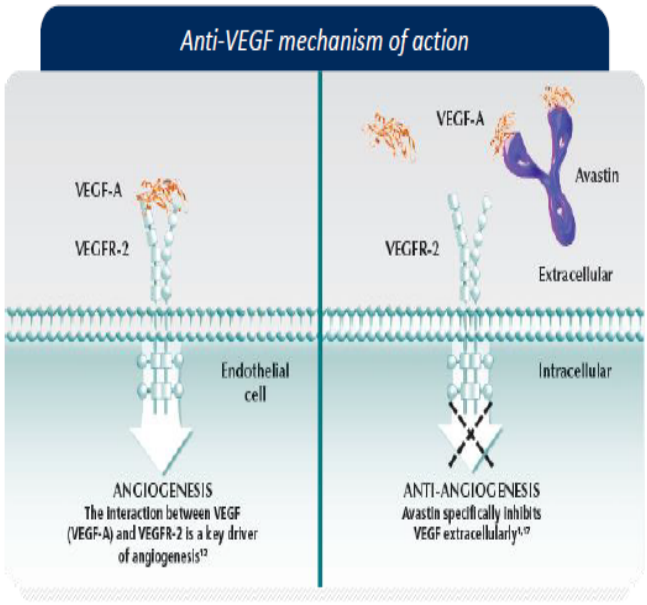
Source: Company reports.

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

Standard of Care in Wet AMD

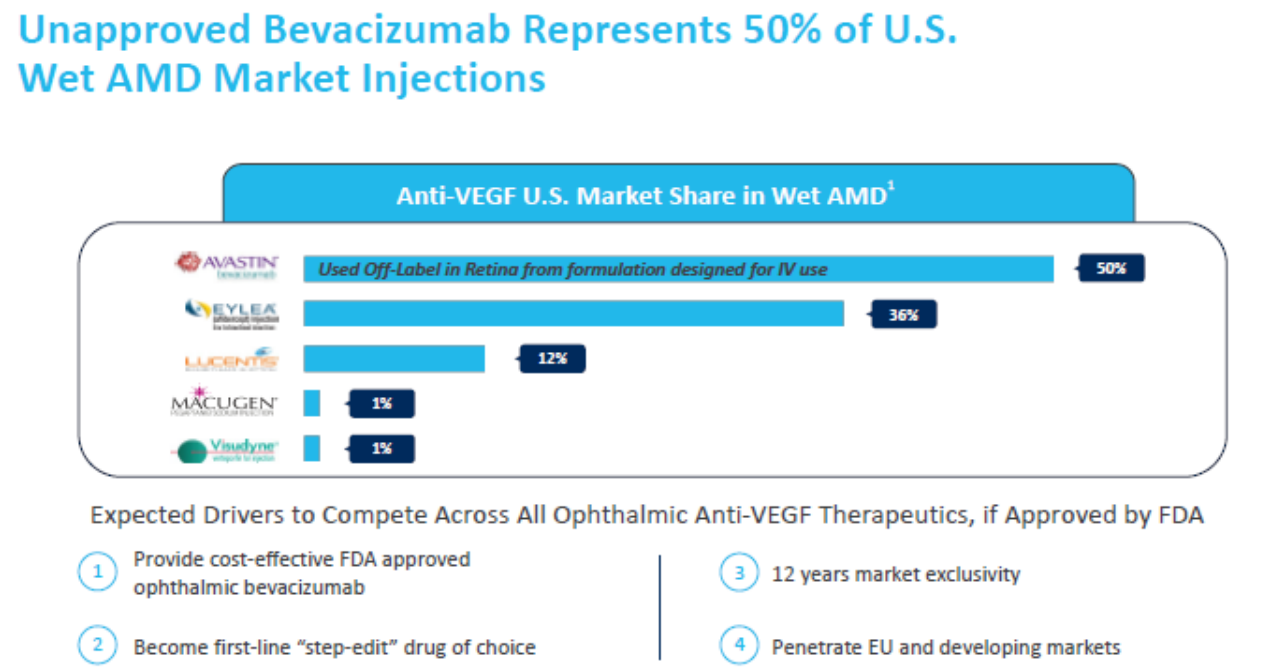
ONS-5010 / LYTENAVA™, if approved, will be the first on-label ophthalmic formulation of bevacizumab-vikg

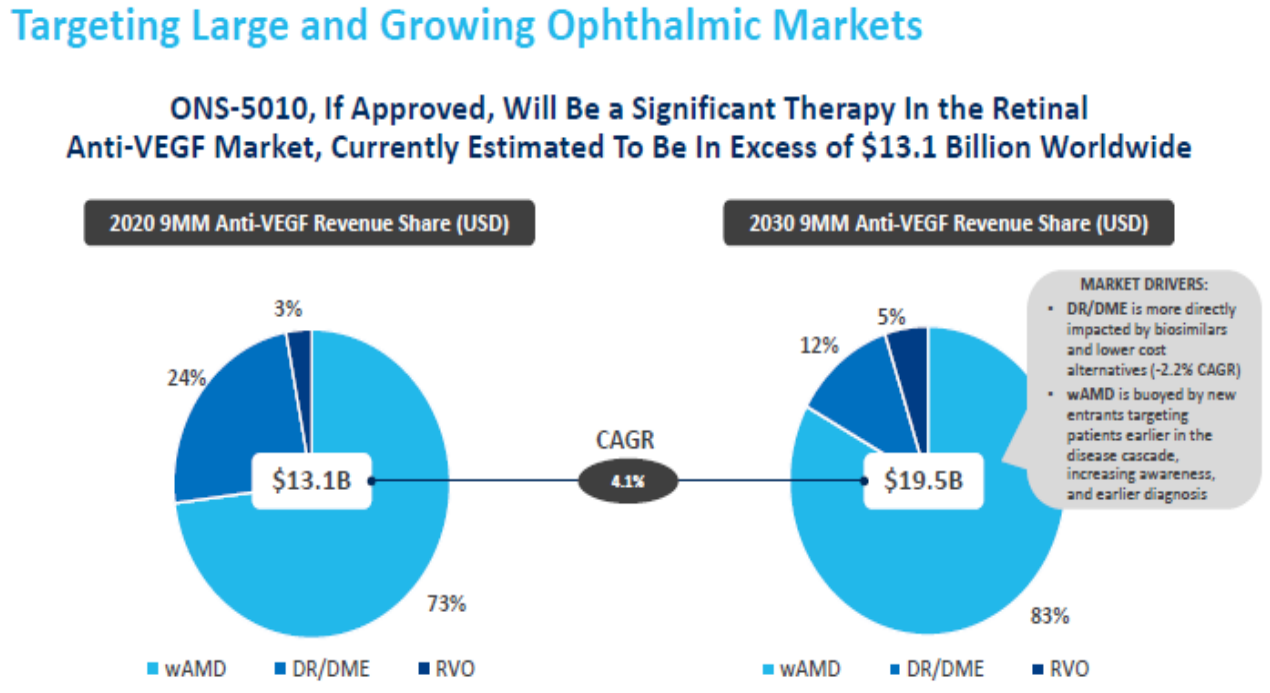
- Anti-VEGF drugs have been standard of care since 2006
  - Block growth of abnormal blood vessels and leakage of fluid from the vessels behind the retina
- Several new clinical-stage anti-VEGF drugs, including biosimilars, in development and/or recently approved
  - Require significant time and capital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



Source: Company reports.

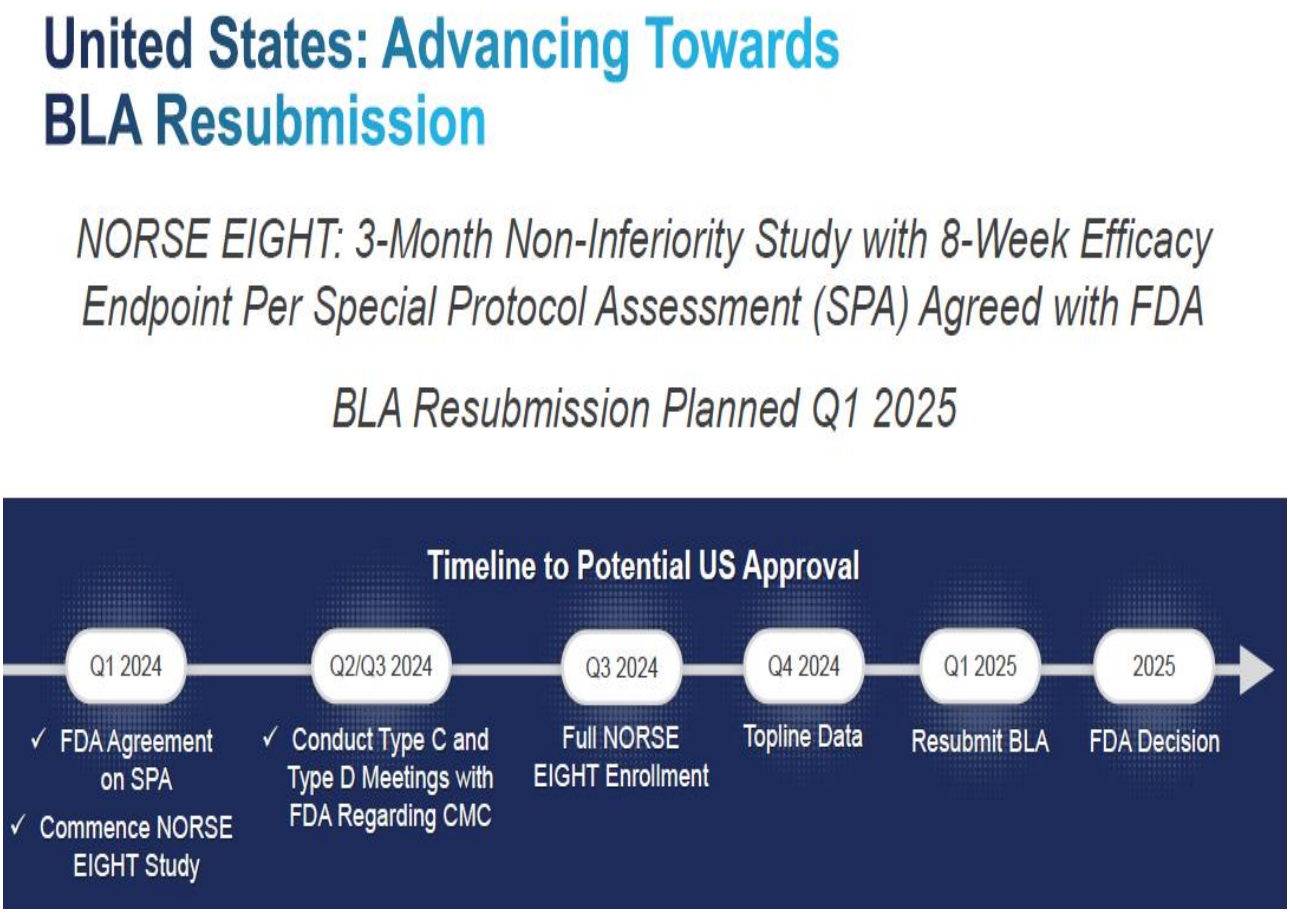
Exhibit 3: ONS-5010 (LYTENAVA) Market Opportunities





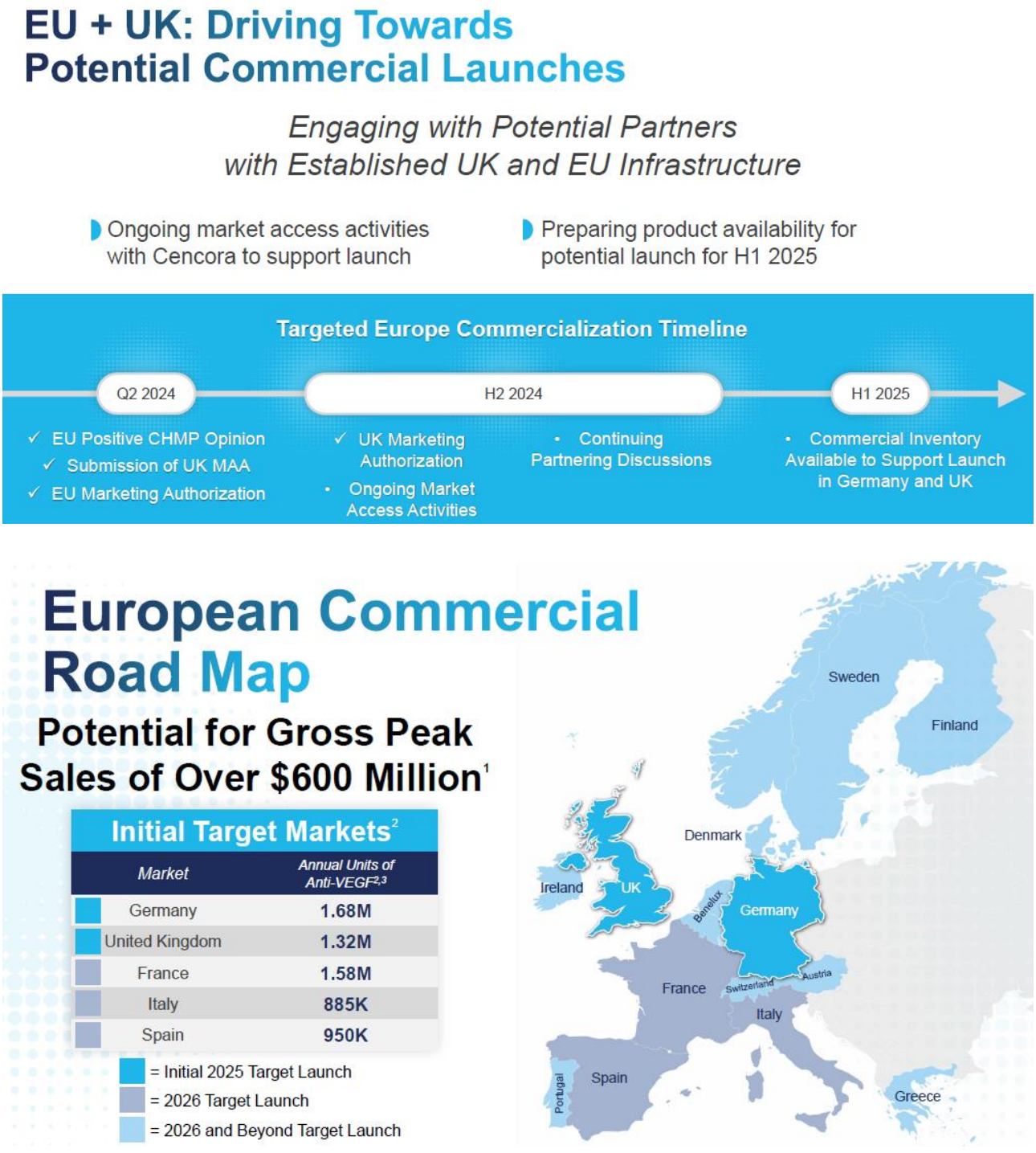
Source: Company reports.

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



Source: Company reports.

Exhibit 5: ONS-5010 (LYTENAVA) Commercial Strategy



Source: Company reports.

Exhibit 6: Recent Highlights and Upcoming Milestones (as of February 14, 2025)

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

February 14, 2025

- **ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Biologics License Application (BLA) resubmission on track to meet target of Q1 CY2025**
- **LYTENAVA™ (bevacizumab gamma) on track for first commercial launches inGermany and the United Kingdom (UK) planned for Q2 CY2025**

ISELIN, N.J., Feb. 14, 2025 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company that achieved regulatory approval in the European Union (EU) and the United Kingdom (UK) for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD), today announced financial results for the first quarter of fiscal year 2025 and provided a corporate update.

"With all of the recent progress made at Outlook Therapeutics and the upcoming milestones over the next few months, we expect to be a very different company by the end of 2025," commented Lawrence Kenyon, Chief Financial Officer and Interim Chief Executive Officer of Outlook Therapeutics. "In 2025, we plan to start realizing our goal of providing patients, physicians and payers with an approved ophthalmic formulation of bevacizumab. This year, we anticipate beginning to generate the first revenue for Outlook Therapeutics with the launch of LYTENAVA™ inGermany and the UK and our BLA is on track for resubmission this quarter."

Upcoming Anticipated Milestones

- Resubmission of the ONS-5010 BLA targeted for Q1 CY2025;
- Initial commercial launches in Germany and the UK planned to commence in Q2 CY2025; and
- Potential for US FDA approval of ONS-5010 in Q3 CY2025.

Source: Company reports.

Exhibit 7: Clinical Trials

Source: Company reports.

Exhibit 8: NORSE EIGHT Pivotal Trial

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

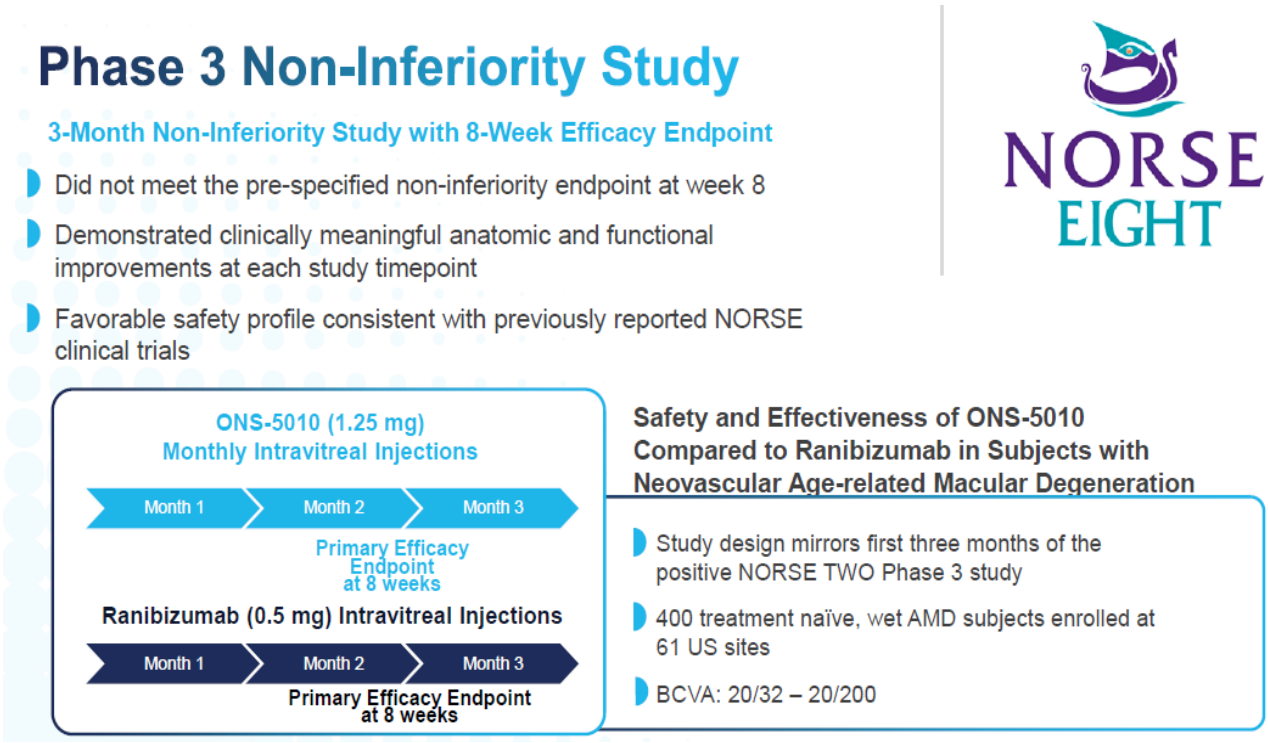
January 16, 2025

- **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.

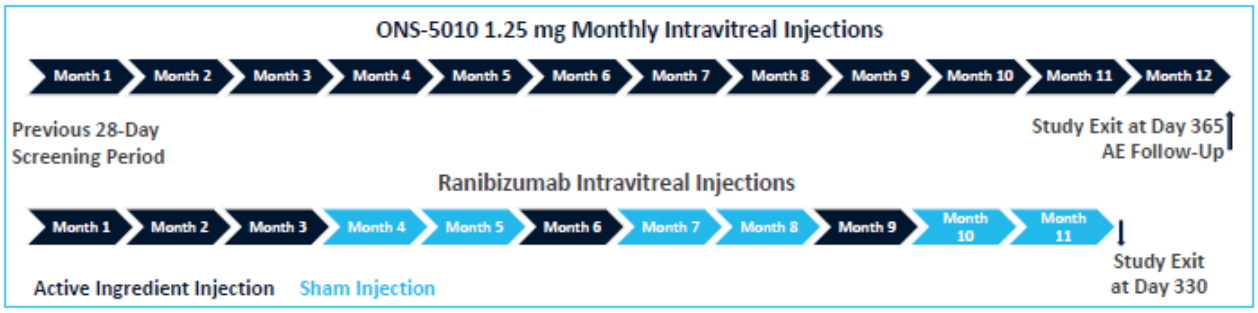


Source: Company reports.

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

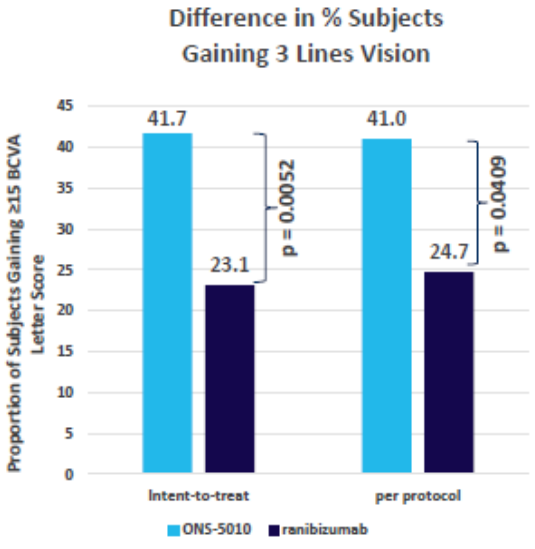
- Active, primary CNV due to wet AMD
- Treatment-naïve
- BCVA: 20/50 – 20/320

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 Results[1]

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.

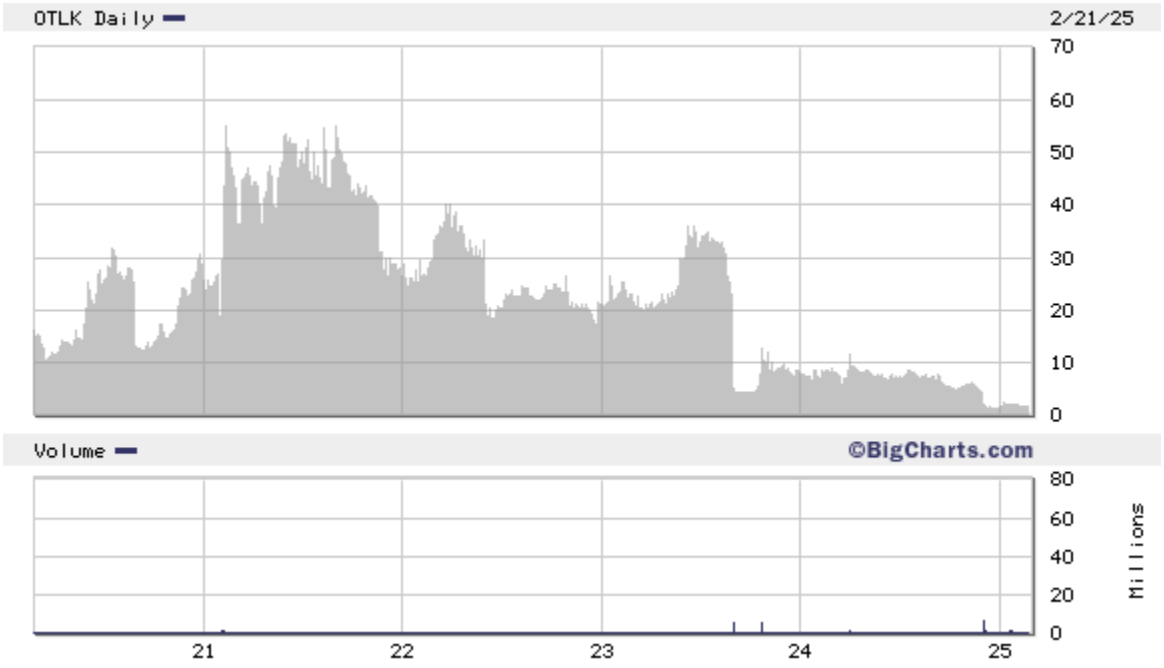
"The SPA increases our confidence that ONS-5010, if approved, will more effectively meet the needs of retina surgeons, patients and payers in the $9.5 billion ophthalmic anti-VEGF market in the United States, and the financing represents a significant commitment by our new and existing stockholders to 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 February 14, 2025)

	Revenue (mil)	
	2025E	2026E
Q1 Dec	$0.0E	
Q2 Mar	$0.7E	
Q3 Jun		
Q4 Sep		
Total	$9.9E	$49.9E

	EPS	
	2025E	2026E
Q1 Dec	$(0.78)E	
Q2 Mar	$(0.59)E	
Q3 Jun		
Q4 Sep		
Total	$(2.23)E	$(0.79)E

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

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

Source: Company report, LSEG, and Ascendiant 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	Q2E	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**	**1.0**	**4.0**	**5.0**	**5.0**	**6.0**	**7.0**	**7.0**	**25.0**
Cost of Revenues					0.0					0.0		0.0	0.3	1.2	1.5	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	0.7	2.8	3.5	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	6.0	6.0	6.0	27.7	6.0	6.0	6.0	6.0	24.0
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	11.0	11.0	11.0	44.9	11.0	11.0	11.0	11.0	44.0
Restructuring and other					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	17.0	17.0	17.0	72.6	17.0	17.0	17.0	17.0	68.0
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)**	**(17.0)**	**(16.3)**	**(14.2)**	**(69.1)**	**(13.5)**	**(12.8)**	**(12.1)**	**(12.1)**	**(50.5)**
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	(2.5)	(2.5)	(2.5)	(7.5)	(2.5)	(2.5)	(2.5)	(2.5)	(10.0)
Other income (expense)	(0.5)	(0.0)	(2.9)	(0.8)	(4.3)	(1.0)	(92.3)	63.6	28.3	(1.4)	38.9				38.9					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	(19.5)	(18.8)	(16.7)	(37.6)	(16.0)	(15.3)	(14.6)	(14.6)	(60.5)
Income taxes		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	(19.5)	(18.8)	(16.7)	(37.6)	(16.0)	(15.3)	(14.6)	(14.6)	(60.5)
Nonrecurring/noncash adjustments					0.0		92.2	(63.6)	(28.3)	0.3	(39.0)				(39.0)					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)**	**(19.5)**	**(18.8)**	**(16.7)**	**(76.6)**	**(16.0)**	**(15.3)**	**(14.6)**	**(14.6)**	**(60.5)**
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	32.0	32.5	33.0	30.4	33.5	34.0	34.5	35.0	34.3
Shares, Diluted	11.4	12.8	12.8	13.0	12.5	13.0	14.3	25.5	23.5	18.5	24.2	32.0	32.5	33.0	30.4	33.5	34.0	34.5	35.0	34.3
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)**	**($0.61)**	**($0.58)**	**($0.51)**	**($2.52)**	**($0.48)**	**($0.45)**	**($0.42)**	**($0.42)**	**($1.77)**
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)	($0.61)	($0.58)	($0.51)	($2.52)	($0.48)	($0.45)	($0.42)	($0.42)	($1.77)
Margins																				
Gross margin												70%	70%	70%	70%	70%	70%	70%	70%	70%
Research and development												#DIV/0!	600%	150%	553%	120%	100%	86%	86%	96%
General and administrative												#DIV/0!	1100%	275%	899%	220%	183%	157%	157%	176%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-1630%	-355%	-1382%	-270%	-213%	-173%	-173%	-202%
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	-1880%	-418%	-752%	-320%	-255%	-209%	-209%	-242%
Y/Y % change																				
Total Revenue																				
Gross margin																				
Research and development	0%	-96%	-1%	-45%	-38%	-54%	2379%	1%	153%	58%	113%	-56%	-46%	-52%	-34%	-38%	0%	0%	0%	-13%
General and administrative	78%	-6%	22%	50%	29%	-1%	-14%	19%	38%	12%	106%	103%	32%	6%	50%	-8%	0%	0%	0%	-2%
Operating income (loss)	19%	-64%	7%	-11%	-16%	-34%	177%	8%	84%	35%	109%	-10%	-17%	-38%	-4%	-38%	-25%	-26%	-15%	-27%
Net income (loss)	29%	-66%	18%	-9%	-11%	-40%	1618%	-315%	-144%	28%	-255%	-83%	-142%	-393%	-50%	-192%	-22%	-22%	-13%	61%
EPS Diluted (Pro forma)	7%	-71%	1%	-23%	-24%	-48%	198%	-53%	-4%	-14%	4%	-61%	-23%	-47%	-38%	-46%	-26%	-27%	-18%	-30%

Source: Company reports and Ascendiant 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	Q2E	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	7.9	(7.2)	(19.5)	(31.8)	(43.4)	(54.3)	(65.2)
Short term investments										0.0	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	0.0
Inventory									3.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1
Deferred income taxes										0.0	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	6.9	6.9	6.9	6.9	6.9	6.9	6.9
Total current assets	61.7	53.1	43.0	31.0	20.4	57.8	45.6	27.4	15.7	17.9	2.8	(9.6)	(21.8)	(33.4)	(44.3)	(55.2)
Long term securities/investments	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Property and equipment, net										(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)
Intangibles, net										0.0	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	0.0
Other	0.2	0.2	0.6	0.5	0.5	0.5	0.8	0.7	0.7	0.7	0.7	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**	**19.2**	**4.1**	**(9.0)**	**(21.3)**	**(32.9)**	**(43.9)**	**(54.8)**
Liabilities and stockholders' equity																
Accounts payable	4.2	3.6	5.1	6.6	3.5	4.4	5.6	8.0	12.2	12.2	12.2	12.2	12.2	12.2	12.2	12.2
Accrued expenses	9.0	6.2	8.3	2.7	4.1	3.1	2.7	3.2	3.4	3.4	3.4	3.4	3.4	3.4	3.4	3.4
Deferred revenue										0.0	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	0.1	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	30.7	30.7	30.7	30.7	30.7	30.7	30.7
Total current liabilities	**15.1**	**43.5**	**49.9**	**46.7**	**46.0**	**54.1**	**42.6**	**42.6**	**48.2**	**48.2**	**48.2**	**48.2**	**48.2**	**48.2**	**48.2**	**48.2**
Deferred income taxes										0.0	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	18.8	18.8	18.8	18.8	18.8	18.8	18.8
Deferred revenue										0.0	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									0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total other liabilities	**31.8**	**0.0**	**0.0**	**0.0**	**0.1**	**139.2**	**88.2**	**59.3**	**19.1**	**19.1**	**19.1**	**19.1**	**19.1**	**19.1**	**19.1**	**19.1**
Preferred stock										0.0	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	3.9	7.6	11.3	14.9	18.6	22.3	26.0
Additional paid-in capital	440.8	442.2	446.8	450.9	452.2	458.9	465.1	470.0	475.4	475.4	475.4	475.4	475.4	475.4	475.4	475.4
Retained earnings	(427.6)	(434.3)	(454.9)	(467.9)	(479.1)	(593.4)	(549.0)	(543.3)	(525.9)	(545.4)	(564.2)	(580.9)	(596.9)	(612.2)	(626.8)	(641.4)
Treasury stock										0.0	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	0.0
Other										18.0	18.0	18.0	18.0	18.0	18.0	18.0
Total stockholders' equity	**15.8**	**10.5**	**(5.5)**	**(14.4)**	**(24.3)**	**(134.2)**	**(83.7)**	**(73.1)**	**(50.3)**	**(48.1)**	**(63.2)**	**(76.3)**	**(88.6)**	**(100.2)**	**(111.2)**	**(122.1)**
Total stockholders' equity and liabili	**62.7**	**54.0**	**44.4**	**32.3**	**21.7**	**59.0**	**47.1**	**28.8**	**17.0**	**19.2**	**4.1**	**(9.0)**	**(21.3)**	**(32.9)**	**(43.9)**	**(54.8)**

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	Q2E	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	-$1.50	-$1.95	-$2.31	-$2.64	-$2.95	-$3.22	-$3.49
Cash per Share (diluted)	$4.68	$3.46	$2.69	$1.86	$0.86	$3.36	$1.28	$0.66	$0.26	$0.27	-$0.20	-$0.57	-$0.93	-$1.26	-$1.56	-$1.84
Net cash per Share (diluted)	$1.88	$0.98	-$0.02	-$0.87	-$1.95	$0.23	$0.01	-$0.59	-$1.01	-$0.69	-$1.15	-$1.50	-$1.85	-$2.16	-$2.45	-$2.72

Source: Company reports and Ascendiant 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	Q2E	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	(19.5)	(18.8)	(16.7)	(37.6)	(16.0)	(15.3)	(14.6)	(14.6)	(60.5)
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
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	3.7	3.7	3.7	14.7	3.7	3.7	3.7	3.7	14.7
Deferred income taxes					0.0					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)				(39.0)					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					0.0
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	0.0	0.0	0.0
Inventory											(3.1)				(3.1)					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	0.0	0.0	0.0	5.6	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	0.7	0.7	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	0.0	0.0	0.0	4.2	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	0.0	0.0	0.0	0.2	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	0.0
Other liabilities					0.0					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)**	**(15.8)**	**(15.1)**	**(12.3)**	**(54.2)**	**(12.3)**	**(11.6)**	**(10.9)**	**(10.9)**	**(45.7)**
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	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		0.0	0.0	0.0	0.0	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)					0.0					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	0.0	0.0	0.0	1.7	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		18.0			18.0					0.0
Other					0.0					0.0					0.0					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**	**18.0**	**0.0**	**0.0**	**19.7**	**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)**	**2.2**	**(15.1)**	**(12.3)**	**(34.4)**	**(12.3)**	**(11.6)**	**(10.9)**	**(10.9)**	**(45.7)**
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**	**7.9**	**(7.2)**	**14.9**	**(19.5)**	**(31.8)**	**(43.4)**	**(54.3)**	**(19.5)**
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**	**7.9**	**(7.2)**	**(19.5)**	**(19.5)**	**(31.8)**	**(43.4)**	**(54.3)**	**(65.2)**	**(65.2)**

Source: Company reports and Ascendiant Capital Markets estimates

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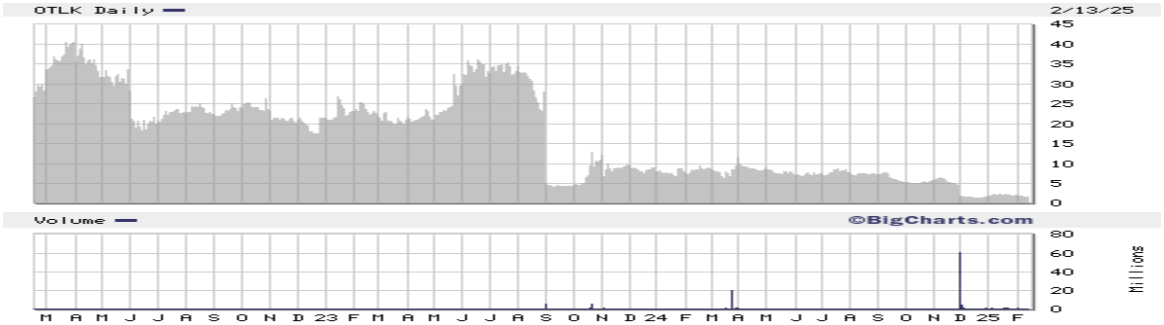
Outlook Therapeutics, Inc.



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

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

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

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Ascendiant Capital Markets, LLC Rating System

BUY: We expect the stock to provide a total return of 15% or more within a 12-month period.

HOLD: We expect the stock to provide a total return of negative 15% to positive 15% within a 12-month period.

SELL: We expect the stock to have a negative total return of more than 15% within a 12-month period.

Total return is defined as price appreciation plus dividend yield.

Ascendiant Capital Markets, LLC Distribution of Investment Ratings (as of January 10, 2025)

			Investment Banking Services Past 12 months	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy	56	98%	20	36%
Hold	0	0%	0	0%
Sell	1	2%	0	0%
Total	57	100%	20	35%

Other Important Disclosures

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