



Outlook Therapeutics, Inc.

Reports Q4 about inline. On track for ONS-5010 BLA FDA resubmission by end of 2024. Raising P/T to \$2.00.

United States
Healthcare

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COMPANY UPDATE

Rating: **BUY**

Ticker: OTLK

Price: \$0.47
(intraday)

Target: \$2.00
(from \$1.50)

Q4 about inline: Outlook recently (on December 22) reported its Q4 FY23 (ending September) results. EPS of \$(0.05) compared with our and consensus estimates of \$(0.06) - (0.07). There was no Q4 guidance. Outlook is a clinical stage medical device development/commercialization company so it generates minimal revenue.

Maintaining estimates: We are maintaining our FY24 EPS estimate of \$(0.25).

FDA issues CRL: On August 30, 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.

Waiting for FDA confirmation: The company has met with and agreed to additional trials and data to address the FDA's requirement for BLA approval. The FDA is expected to provide further confirmation by early February 2024.

FDA BLA resubmission expected by end of 2024: If the FDA agrees, commencement of NORSE EIGHT is expected in Q1 2024 with completion of NORSE EIGHT in the U.S. expected in 2024, and the resubmission of the ONS-5010 BLA expected by the end of 2024.

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.

Positive clinical results: In August 2021, Outlook announced positive top-line results from its pivotal Phase 3 NORSE TWO safety and efficacy trial evaluating ONS-5010 for treatment of wet AMD. In March 2021, Outlook reported positive topline results from its NORSE THREE Open-Label Safety Study. In August 2020, Outlook reported topline results from its NORSE 1 study demonstrating safety and efficacy and positive proof-of-concept of ONS-5010 for the treatment of wet age-related macular degeneration (wet AMD).

EU MMA decision expected in early 2024: Its EU Marketing Authorization Application (MAA) decision date is anticipated in the first half of 2024.

Balance sheet: Outlook has \$24 million in cash and \$36 million in debt as of Q4 FY23. We believe it has enough cash into Q2 FY24.

Significant upside potential: Outlook's shares closed at \$1.41 on 8/29, and \$0.27 on 8/30 (-81%) and its recent price is ~\$0.47 reflecting the disappointing news. Although it will now take longer and require more investments, we believe that a FDA approval for ONS-5010 is still likely and that the current depressed share price is not reflective of that and represents significant upside potential.

Raising P/T: Maintaining our BUY rating, but raising our 12-month price target to \$2.00 from \$1.50. 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:	\$0.20 – 2.03
Shares Outstanding (million):	260
Market cap (\$million):	\$122
EV (\$million):	\$134
Debt (\$million):	\$36
Cash (\$million):	\$24
Avg. Daily Trading Vol. (\$million):	\$5
Float (million shares):	132
Short Interest (million shares):	16
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	<u>2024E</u> <u>(Cur.)</u>	<u>2024E</u> <u>(Old)</u>	<u>2025E</u> <u>(Cur.)</u>	<u>2025E</u> <u>(Old)</u>
Q1 Dec	0E		0E	
Q2 Mar	0E		0E	
Q3 Jun	0E		0E	
Q4 Sep	<u>0E</u>		<u>0E</u>	
Total	0E		0E	
EV/Revs	N/A		N/A	

Earnings per Share (pro forma)

	<u>2024E</u> <u>(Cur.)</u>	<u>2024E</u> <u>(Old)</u>	<u>2025E</u> <u>(Cur.)</u>	<u>2025E</u> <u>(Old)</u>
Q1 Dec	(0.06)E		(0.06)E	
Q2 Mar	(0.06)E		(0.06)E	
Q3 Jun	(0.06)E		(0.06)E	
Q4 Sep	<u>(0.06)E</u>		<u>(0.06)E</u>	
Total	<u>(0.25)E</u>		<u>(0.25)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 15.

Exhibit 1: Outlook’s Investment Highlights (as of December 2023)

Investment Highlights

Seeking FDA Market Approval of ONS-5010 (bevacizumab-vikg)¹, an Investigational Therapy for the Treatment of Wet AMD Targeting \$13.1 Billion Global Ophthalmic Anti-VEGF Market²

Differentiated Drug Product

- Designed to meet robust standards required for ophthalmic approval
- Potential to eliminate risks associated with off-label repackaged bevacizumab, including potential impurities and particulates from compounders re-packaging processes
- Delivery ultimately expected through a convenient pre-filled syringe

Potential for 1st Approved Ophthalmic Bevacizumab

- Potential EU Market Approval targeted for H1 2024 with up to 10 years market exclusivity
- Exploring first launches in Germany (Q3 2024) and UK (Q4 2024)
- Expected resubmission of BLA on track for the end of calendar year 2024
- Planning to commence 3-month non-inferiority study with 60-day efficacy endpoint
- Provides an economically elegant anti-VEGF solution for patients, payers and doctors

Attractive Market Opportunity

- Strategic commercialization agreement with Cencora, formerly AmerisourceBergen
- 66.3% of new patient start are off-label repackaged bevacizumab, creating a significant opportunity for ONS-5010, if approved
- 12-years US regulatory exclusivity expected upon approval
- Label expansion opportunity into DME and BRVO

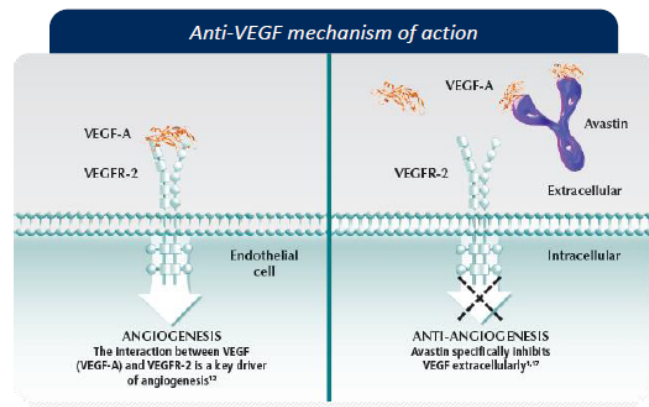
Source: Company reports.

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

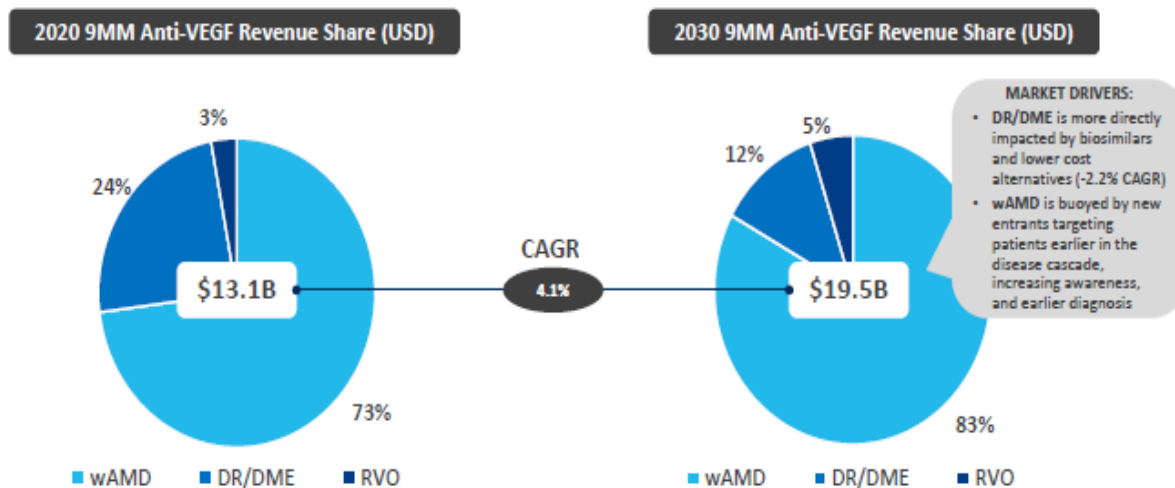


Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics, if Approved by FDA

- 1 Provide cost-effective FDA approved ophthalmic bevacizumab
- 2 Become first-line "step-edit" drug of choice
- 3 12 years market exclusivity
- 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 Milestones (as of December 2023)

Clinical Development Plan Towards FDA Approval

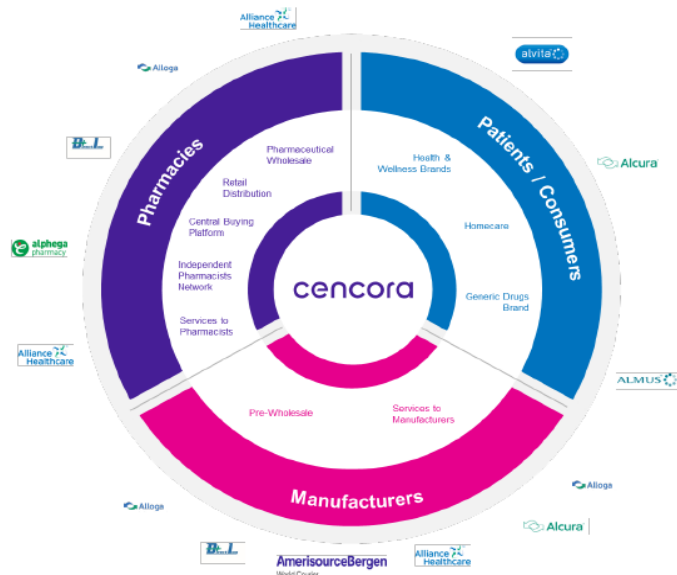


Source: Company reports.

Exhibit 5: ONS-5010 (LYTENAVA) Commercial Strategy

Key Activities Underway in Europe to Support a Successful Launch

- Advanced discussions with Cencora (formerly AmerisourceBergen) and their European Partners to support commercialization in the EU4 & UK
- Identification and engagement with leading Retinal KOLs across key markets
- Initial pricing and reimbursement roadmaps for EU4 & UK defined, with work underway for first launch countries
- Solid understanding of the Wet AMD treatment landscape across Europe and initial launch strategy defined in key markets



Source: Company reports.

Exhibit 6: Recent Highlights and Upcoming Milestones (as of December 2023)

Outlook Therapeutics® Reports Financial Results for Fiscal Year 2023 and Reiterates ONS-5010 Clinical and Regulatory Path Forward in the U.S. and EU

December 22, 2023

- Commencement of ONS-5010 NORSE EIGHT clinical trial targeted for first calendar quarter of 2024
- Company reaffirms potential for European approval for ONS-5010 with Marketing Authorization Application (MAA) decision date anticipated in the first half of 2024
- Resubmission of the ONS-5010 Biologics License Application (BLA) expected by the end of calendar year 2024

ISELIN, N.J., Dec. 22, 2023 (GLOBE NEWSWIRE) -- [Outlook Therapeutics, Inc.](#) (Nasdaq: OTLK), a biopharmaceutical company working to achieve U.S. Food and Drug Administration (FDA) approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced recent corporate highlights and financial results for its fiscal year ended September 30, 2023.

"We remain committed to working with the FDA to design and undertake the additional clinical study for ONS-5010 that, if successful, will satisfy the FDA's requirements for approval," commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics. "The patient need for an ophthalmic approved bevacizumab remains and we are steadfast in our mission to meet this need."

Upcoming Anticipated Milestones

- FDA response on NORSE EIGHT Special Protocol Assessment (SPA) in early February 2024;
- Commencement of NORSE EIGHT expected in first calendar quarter of 2024;
- MAA decision date in the EU for ONS-5010 expected targeted for first half of 2024;
- Completion of NORSE EIGHT in the U.S. anticipated in 2024; and
- Resubmission of the ONS-5010 BLA expected by the end of calendar year 2024.



Company Summary

- **Targeting \$13.1 billion global ophthalmic anti-VEGF market¹**
 - *Initial U.S. target segment worth up to billions in potential yearly revenue served by compounding pharmacies which by law should be converted to Outlook Therapeutics' LYTENAVA, if FDA approved*
- **Received validation of Marketing Authorization Application by European Medical Agency with Potential EU Market Approval targeted for H1 2024**
- **Plan to Commence 3-Month Non-Inferiority Study with 60-day Efficacy Endpoint targeted in Q1 2024 Following Type A Meeting with FDA**
- **Management team with proven ophthalmic commercial launch expertise**
 - *Leveraging strategic commercialization agreement with Cencora, formerly AmerisourceBergen, to preserve capital and enhance commercial reach*

- **Prescription Drug User Fee Act (PDUFA) goal date of August 29, 2023 for ONS-5010, an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD)**

Source: Company reports.

Exhibit 7: NORSE ONE and THREE Studies Results

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

Source: Company reports.

Exhibit 8: NORSE TWO Pivotal Trial



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

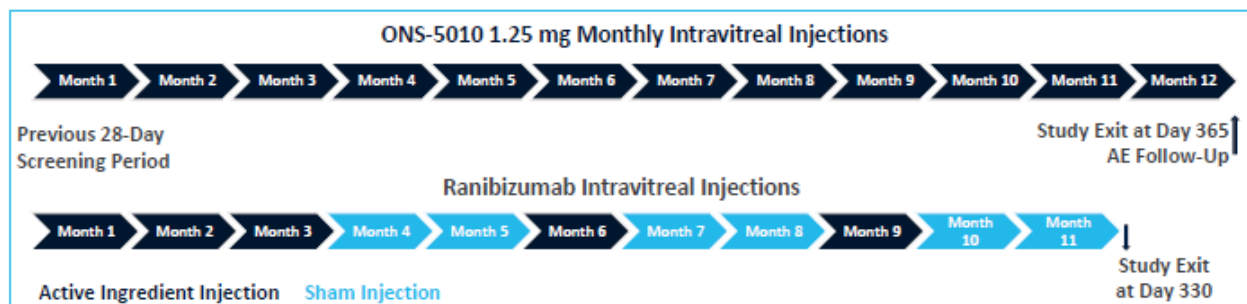
Source: Company reports.

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

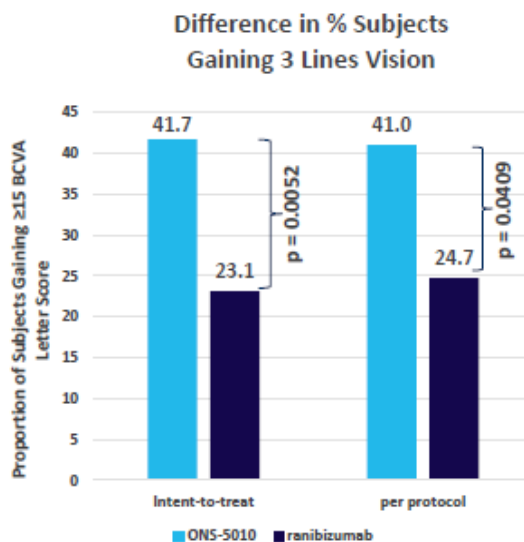
Key Study Outcomes

- 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: NORSE TWO Study Design

NORSE TWO Pivotal Trial Design



Randomized masked controlled trial with 228 subjects



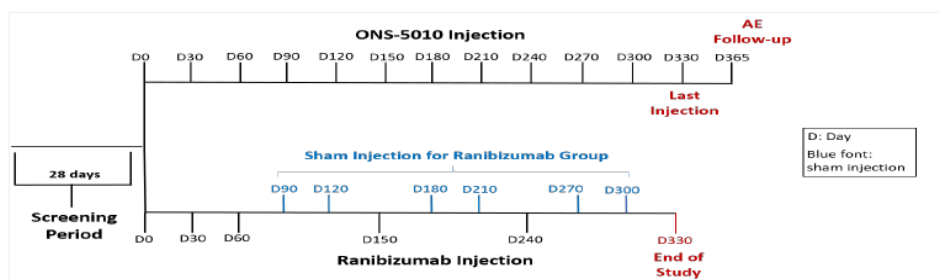
ONS-5010 (bevacizumab-vikg) administered monthly X 12



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



Source: Company reports.

Exhibit 11: NORSE ONE Study

NORSE ONE

First Registration,
Clinical Experience Study

Phase 3 Clinical Program

- Positive proof-of-concept
- Demonstrated anticipated safety and efficacy consistent with previously published results for ophthalmic bevacizumab

Study Highlights:

- Randomized Masked Controlled Trial
- ONS-5010 vs LUCENTIS® (ranibizumab)
- 61 subjects enrolled
- Study conducted in Australia
- Expected to support planned new U.S. BLA filing in 2021

Source: Company reports.

Exhibit 12: NORSE THREE Safety Study



Completed
Open-Label Safety Study
Supports BLA Requirements









Positive safety profile reported in NORSE 3 reinforces previously reported safety data for ONS-5010 ophthalmic bevacizumab

No unexpected safety trends, safety profile consistent with prior published data on the use of bevacizumab for ophthalmic conditions

Zero cases of ocular inflammation in NORSE 3, a concern that has emerged for other anti-VEGF therapies to treat retinal conditions

Trial Highlights:

- Open-label safety study
- Enrolled 197 subjects with wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) or branch retinal vein occlusion (BRVO)
- Subjects received three doses of ONS-5010 ophthalmic bevacizumab over a three-month period
- Conducted to ensure adequate number of safety exposures to ONS-5010 ophthalmic bevacizumab








Source: Company reports.

Exhibit 13: NORSE SEVEN Study (ongoing currently)

**NORSE
SEVEN**

Pre-Filled Syringe

**Vials Versus
Pre-Filled Syringe**

Trial Highlights:

- 3-month study to compare the safety of ONS-5010 in vials versus Outlook Therapeutics investigational pre-filled syringe
 - Vial arm (n= has been fully enrolled and is now complete)
- Enrolling ~120 subjects with visual impairment due to retinal disorders
 - Wet AMD
 - BRVO
 - DME

Source: Company reports.

Exhibit 14: 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 15: Outlook Therapeutics Stock Price (5-years)



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

Exhibit 16: Consensus Expectations (as of December 22, 2023)

	Revenue (mil)			EPS	
	2023E	2024E		2023E	2024E
Q1 Dec	\$0A	\$2.7E	Q1 Dec	\$(0.08)A	\$(0.05)E
Q2 Mar	\$0A		Q2 Mar	\$(0.03)A	
Q3 Jun	\$0A		Q3 Jun	\$(0.08)A	
Q4 Sep	\$2.2E		Q4 Sep	\$(0.06)E	
Total	\$2.3E	\$45.3E	Total	\$(0.25)E	\$(0.11)E

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

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

FINANCIAL MODEL

Outlook Therapeutics, Inc.

Income Statement (\$ mils)	Dec-21	Mar-22	Jun-22	Sep-22	2022	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
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1E	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<u>Cost of Revenues</u>					0.0					0.0					0.0					0.0
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	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Research and development	9.9	12.2	11.2	9.0	42.3	9.9	0.5	11.1	4.9	26.5	5.0	5.0	6.0	6.0	22.0	6.0	6.0	6.0	6.0	24.0
General and administrative	3.3	6.7	5.8	5.0	20.7	5.8	6.3	7.0	7.5	26.7	8.0	8.0	8.0	8.0	32.0	8.0	8.0	8.0	8.0	32.0
<u>Restructuring and other</u>					0.0					0.0					0.0					0.0
Total operating expenses	13.1	18.9	17.0	14.0	63.1	15.7	6.8	18.1	12.5	53.1	13.0	13.0	14.0	14.0	54.0	14.0	14.0	14.0	14.0	56.0
Operating income (loss)	(13.1)	(18.9)	(17.0)	(14.0)	(63.1)	(15.7)	(6.8)	(18.1)	(12.5)	(53.1)	(13.0)	(13.0)	(14.0)	(14.0)	(54.0)	(14.0)	(14.0)	(14.0)	(14.0)	(56.0)
Interest income (expense)	(0.4)	(0.4)	(0.4)	(0.4)	(1.5)	(2.4)	0.2	0.4	0.3	(1.6)	(2.5)	(2.5)	(2.5)	(2.5)	(10.0)	(2.5)	(2.5)	(2.5)	(2.5)	(10.0)
Other income (expense)	(1.0)	(0.4)	(0.2)	0.0	(1.5)	(0.5)	(0.0)	(2.9)	(0.8)	(4.3)					0.0					0.0
Income before income taxes	(14.5)	(19.7)	(17.5)	(14.3)	(66.0)	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(15.5)	(15.5)	(16.5)	(16.5)	(64.0)	(16.5)	(16.5)	(16.5)	(16.5)	(66.0)
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	0.0	0.0	0.0	0.0	0.0
Net income (loss)	(14.5)	(19.7)	(17.5)	(14.3)	(66.1)	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(15.5)	(15.5)	(16.5)	(16.5)	(64.0)	(16.5)	(16.5)	(16.5)	(16.5)	(66.0)
<u>Nonrecurring/noncash adjustments</u>					0.0					0.0					0.0					0.0
Net income (pro forma)	(14.5)	(19.7)	(17.5)	(14.3)	(66.1)	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(15.5)	(15.5)	(16.5)	(16.5)	(64.0)	(16.5)	(16.5)	(16.5)	(16.5)	(66.0)
EBITDA																				
Shares, Basic	188.2	219.1	220.5	220.8	212.1	227.4	256.7	256.9	259.9	250.2	260.3	260.4	260.5	260.6	260.5	260.6	260.7	260.8	260.9	260.8
Shares, Diluted	188.2	219.1	220.5	220.8	212.1	227.4	256.7	256.9	259.9	250.2	260.3	260.4	260.5	260.6	260.5	260.6	260.7	260.8	260.9	260.8
EPS Basic (Pro forma)	(\$0.08)	(\$0.09)	(\$0.08)	(\$0.06)	(\$0.31)	(\$0.08)	(\$0.03)	(\$0.08)	(\$0.05)	(\$0.24)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.25)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.25)
EPS Diluted (Pro forma)	(\$0.08)	(\$0.09)	(\$0.08)	(\$0.06)	(\$0.31)	(\$0.08)	(\$0.03)	(\$0.08)	(\$0.05)	(\$0.24)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.25)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.25)
Margins																				
Gross margin											100%	100%	100%	100%	#DIV/0!	100%	100%	100%	100%	#DIV/0!
Research and development											#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
General and administrative											#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
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	NM	NM	NM	NM	NM	NM	NM
YY % change																				
Total Revenue											#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Gross margin											#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Research and development	-17%	43%	32%	-10%	9%	0%	-96%	-1%	-45%	-38%	-49%	818%	-46%	21%	-17%	20%	20%	0%	0%	9%
General and administrative	46%	63%	97%	43%	62%	78%	-6%	22%	50%	29%	37%	27%	14%	6%	20%	0%	0%	0%	0%	0%
Operating income (loss)	-7%	50%	48%	4%	22%	19%	-64%	7%	-11%	-16%	-17%	90%	-23%	12%	2%	8%	8%	0%	0%	4%
Net income (loss)	0%	50%	44%	5%	24%	29%	-66%	18%	-9%	-11%	-17%	133%	-20%	27%	9%	6%	6%	0%	0%	3%
EPS Diluted (Pro forma)	-35%	3%	10%	-16%	-11%	7%	-71%	1%	-23%	-24%	-27%	130%	-21%	27%	4%	6%	6%	0%	0%	3%

Source: Company reports and Ascendant Capital Markets estimates.

Outlook Therapeutics, Inc.

Balance Sheet (\$ mils)	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1E	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Assets																
Cash and cash equivalents	70.2	58.4	26.0	17.4	52.3	43.6	33.7	23.4	9.3	(4.8)	(19.9)	(34.5)	(49.6)	(64.7)	(79.8)	(94.9)
Short term investments									0.0	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	0.0
Deferred income taxes									0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Prepaid expenses and other	7.3	8.1	11.5	10.1	9.3	9.4	9.3	7.6	7.6	7.6	7.6	7.6	7.6	7.6	7.6	7.6
Total current assets	77.5	66.5	37.5	27.5	61.7	53.1	43.0	31.0	16.9	2.8	(12.3)	(26.9)	(42.0)	(57.1)	(72.2)	(87.3)
Long term securities/investments	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
Property and equipment, net	0.1	0.1	0.0						(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)
Intangibles, net									0.0	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	0.0
Other	0.3	0.2	0.2	0.2	0.2	0.2	0.6	0.5	0.5	0.5	0.5	0.0	0.0	0.0	0.0	0.0
Total assets	78.7	67.7	38.6	28.5	62.7	54.0	44.4	32.3	18.2	4.1	(11.0)	(26.1)	(41.3)	(56.4)	(71.5)	(86.6)
Liabilities and stockholders' equity																
Accounts payable	2.5	4.2	2.5	3.5	4.2	3.6	5.1	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6
Accrued expenses	2.8	2.5	3.6	3.4	9.0	6.2	8.3	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7
Deferred revenue									0.0	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	0.1	0.1	0.1	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
Short term debt	12.7	22.8	10.5	10.9		31.8	34.7	35.6	35.6	35.6	35.6	35.6	35.6	35.6	35.6	35.6
Total current liabilities	19.9	31.4	18.4	19.7	15.1	43.5	49.9	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
Deferred income taxes									0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Warrant liabilities	0.3	0.3	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	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
Other long term liabilities	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
Long term debt	9.6				31.8				0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total other liabilities	9.9	0.3	0.1	0.1	31.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Preferred stock									0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Common stock	2.2	2.3	2.3	2.3	2.6	2.6	2.6	2.6	4.0	5.4	6.8	8.2	9.5	10.9	12.3	13.7
Additional paid-in capital	403.9	410.8	412.4	415.4	440.8	442.2	446.8	450.9	450.9	450.9	450.9	450.9	450.9	450.9	450.9	450.9
Retained earnings	(357.3)	(377.1)	(394.6)	(408.9)	(427.6)	(434.3)	(454.9)	(467.9)	(483.4)	(498.9)	(515.4)	(531.9)	(548.4)	(564.9)	(581.4)	(597.9)
Treasury stock									0.0	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	0.0
Other									0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total stockholders' equity	48.8	36.0	20.1	8.7	15.8	10.5	(5.5)	(14.4)	(28.5)	(42.7)	(57.8)	(72.9)	(88.0)	(103.1)	(118.2)	(133.3)
Total stockholders' equity and liabilities	78.7	67.7	38.6	28.5	62.7	54.0	44.4	32.3	18.2	4.1	(11.0)	(26.1)	(41.3)	(56.4)	(71.5)	(86.6)

Balance Sheet Drivers

	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25
	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1E	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Book & Cash Value (per share)																
Book Value per Share (diluted)	\$0.26	\$0.16	\$0.09	\$0.04	\$0.07	\$0.04	-\$0.02	-\$0.06	-\$0.11	-\$0.16	-\$0.22	-\$0.28	-\$0.34	-\$0.40	-\$0.45	-\$0.51
Cash per Share (diluted)	\$0.38	\$0.27	\$0.12	\$0.08	\$0.23	\$0.17	\$0.13	\$0.09	\$0.04	-\$0.02	-\$0.07	-\$0.13	-\$0.19	-\$0.25	-\$0.30	-\$0.36
Net cash per Share (diluted)	\$0.26	\$0.17	\$0.07	\$0.03	\$0.09	\$0.05	\$0.00	-\$0.04	-\$0.10	-\$0.15	-\$0.21	-\$0.27	-\$0.32	-\$0.38	-\$0.44	-\$0.50

Source: Company reports and Ascendant Capital Markets estimates

Outlook Therapeutics, Inc.

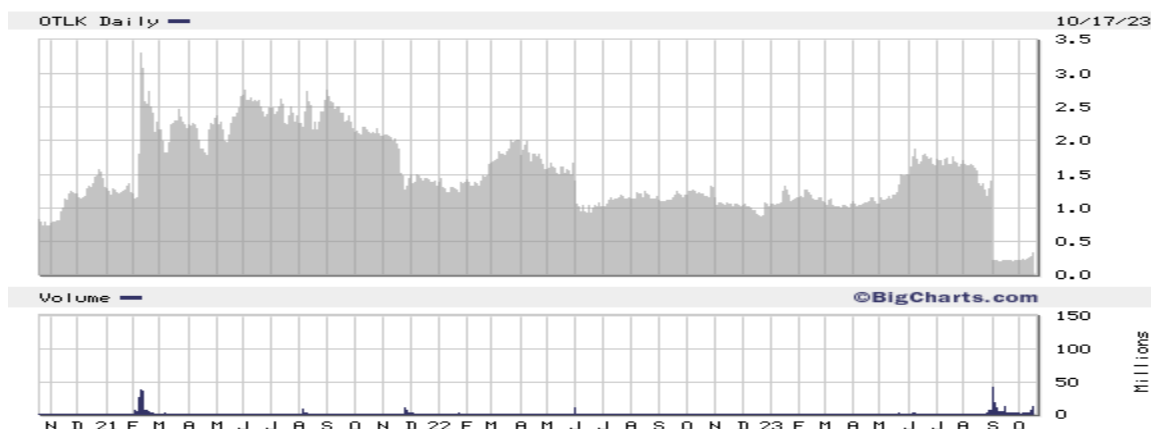
Cash Flow Statement (\$ mils)	Dec-21	Mar-22	Jun-22	Sep-22	2022	Dec-22	Mar-23	Jun-23	Sep-23	2023	Dec-23	Mar-24	Jun-24	Sep-24	2024	Dec-24	Mar-25	Jun-25	Sep-25	2025	
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1E	Q2E	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E	
Cash flow from operating activities																					
Net income	(14.5)	(19.7)	(17.5)	(14.3)	(66.1)	(18.7)	(6.7)	(20.7)	(13.0)	(59.0)	(15.5)	(15.5)	(16.5)	(16.5)	(64.0)	(16.5)	(16.5)	(16.5)	(16.5)	(66.0)	
Depreciation	0.1	0.1	0.1	0.1	0.2	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	
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	0.3	0.4	0.4	0.5	1.7	1.4	0.0	0.0	0.0	1.4	1.4	1.4	1.4	1.4	5.6	1.4	1.4	1.4	1.4	5.6	
Stock comp	1.2	3.8	1.4	1.4	7.7	1.4	1.4	1.4	1.4	5.5	1.4	1.4	1.4	1.4	5.6	1.4	1.4	1.4	1.4	5.6	
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	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	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	
Change in fair value of warrant l	(0.1)	0.4	0.1	(0.9)	(0.5)	(0.0)	(0.0)	0.0	3.7	3.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Writedowns and impairments	0.0	0.0	1.0	(0.1)	0.9	0.0	0.0	2.9	(2.9)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other gains/losses	1.0	0.0	(1.0)	1.0	1.1	0.6	0.0	0.0	0.0	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other	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	
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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Prepaid expenses & other curre	(0.3)	(0.8)	(3.4)	1.4	(3.1)	0.8	(0.1)	0.1	1.8	2.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Income tax	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	
Other assets	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.2)	0.0	(0.2)	0.0	0.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0	
Accounts payable	0.2	1.8	(1.7)	1.0	1.3	0.7	(0.6)	1.2	1.8	3.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Accrued expenses	1.0	(0.2)	(0.5)	(0.2)	0.2	5.0	(2.2)	2.1	(5.6)	(0.7)	0.0	0.0	0.0	0.0	0.0	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	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Net cash (used in) provided by	(11.0)	(14.3)	(21.1)	(10.3)	(56.7)	(8.9)	(8.1)	(13.2)	(12.7)	(43.0)	(14.1)	(14.1)	(15.1)	(14.6)	(57.9)	(15.1)	(15.1)	(15.1)	(15.1)	(60.4)	
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	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	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	
Acquisitions	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	
Other	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	
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	10.0	0.0	0.0	0.0	10.0	30.0	0.0	0.0	0.0	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	(1.0)	(0.3)	(11.6)	(0.0)	(12.9)	(10.8)	(0.3)	(0.0)	(0.0)	(11.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Issuance of stock	57.7	2.7	0.3	1.6	62.3	24.6	(0.3)	3.3	2.4	30.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Repurchase of common stock	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	
Proceeds from stock option exe	0.0	0.2	0.0	0.0	0.2	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	
Other	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	
Dividends and distributions	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 provided by (used in) fina	66.7	2.6	(11.3)	1.6	59.6	43.8	(0.6)	3.3	2.4	49.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Effect of exchange rate on cash	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	
Net increase (decrease) in cash	55.7	(11.7)	(32.4)	(8.6)	2.9	34.9	(8.7)	(9.9)	(10.3)	6.0	(14.1)	(14.1)	(15.1)	(14.6)	(57.9)	(15.1)	(15.1)	(15.1)	(15.1)	(60.4)	
Beginning cash and equivalents:	14.5	70.2	58.4	26.0	14.5	17.4	52.3	43.6	33.7	17.4	23.4	9.3	(4.8)	(19.9)	23.4	(34.5)	(49.6)	(64.7)	(79.8)	(34.5)	
Ending cash and equivalents	70.2	58.4	26.0	17.4	17.4	52.3	43.6	33.7	23.4	23.4	9.3	(4.8)	(19.9)	(34.5)	(34.5)	(49.6)	(64.7)	(79.8)	(94.9)	(94.9)	

Source: Company reports and Ascendant Capital Markets estimates

ANALYST CERTIFICATION

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Outlook Therapeutics, Inc.



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

Report	Report Date		Price	
	Date	Rating	Target	
1	4/22/2019	B	4.00	
2	5/16/2019	B	3.00	
3	8/20/2019	B	4.00	
4	12/22/2019	B	3.50	
5	1/29/2020	B	3.75	
6	2/20/2020	B	3.50	
7	5/21/2020	B	3.25	
8	8/21/2020	B	4.00	
9	8/31/2020	B	3.25	
10	1/6/2021	B	3.50	
11	2/17/2021	B	5.00	
12	5/22/2021	B	6.00	
13	9/6/2021	B	7.00	
14	12/23/2021	B	7.25	
15	3/2/2022	B	7.50	
16	5/27/2022	B	7.75	
17	8/17/2022	B	7.00	
18	3/29/2023	B	7.25	
19	5/30/2023	B	7.50	
20	9/9/2023	B	1.50	

- Ascendant Capital Markets, LLC has received compensation for advisory or investment banking services from the company in the past 12 months.

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Risks & Considerations

Risks to attainment of our share price target include balance sheet/liquidity risks, failure of product candidates to demonstrate safety and efficacy in clinical trials, failure to gain regulatory approvals, ability to commercialize product, failure to obtain suitable reimbursement, competition, changing macroeconomic factors, investor sentiment for investing in biotech stocks, and changes in consumer or government priorities for healthcare.

Ascendant 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.

Ascendant Capital Markets, LLC Distribution of Investment Ratings (as of October 13, 2023)

Rating	Count	Percent	Investment Banking Services Past 12 months	
			Count	Percent
Buy	51	98%	19	37%
Hold	0	0%	0	0%
Sell	1	2%	0	0%
Total	52	100%	19	37%

Other Important Disclosures

Our analysts use various valuation methodologies including discounted cash flow, price/earnings (P/E), enterprise value/EBITDAS, and P/E to growth rate, among others. Risks to our price targets include failure to achieve financial results, product risk, regulatory risk, general market conditions, and the risk of a change in economic conditions.

Dissemination of Research

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