United States
Healthcare

September 9, 2023

Edward Woo, CFA
(561) 327-9435
ewoo@ascendiant.com

Outlook Therapeutics, Inc.

Reports Q3 about inline. FDA issues CRL for ONS-5010 BLA. Lowering P/T to $1.50.

COMPANY UPDATE

Rating: BUY

Ticker: OTLK

Price: $0.20

Target: $1.50 (from $7.50)

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.

PDUFA date of August 29, 2023: Outlook submitted its new BLA (Biologics License Application) to the FDA for ONS-5010 for treatment of wet AMD in August 2022. In October, the FDA accepted its BLA and had set a Prescription Drug User Fee Act (PDUFA) goal (decision) date of August 29, 2023.

Waiting for FDA meeting: The company will be setting up a meeting (likely in the next month or two) with the FDA to go over the issues in the CRL and will provide more details and the path forward after that.

Q3 about inline: Outlook recently (on August 14) reported its Q3 FY23 (ending June) results. EPS of $(0.08) compared with our and consensus estimates of $(0.05) - (0.06). There was no Q3 guidance. Outlook is a clinical stage medical device development/commercialization company so it generates minimal revenue.

Adjusting estimates: We are adjusting our FY23 EPS estimate to $(0.26) from $(0.23).

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).

FDA and EU approvals now uncertain: Potential FDA marketing approval was expected in August 2023 and for EU in early 2024, but now this timeline is now delayed and uncertain.

Balance sheet: Outlook has $35 million in cash and $35 million in debt as of Q3 FY23. We believe it has enough cash through Q1 FY24.

Disappointing, but priced in now: Outlook's shares closed at $1.41 on 8/29, and $0.27 on 8/30 (-81%) reflecting the disappointing news. Although it will now take much 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.

Lowering P/T: Maintaining our BUY rating, but lowering our 12-month price target to $1.50 from $7.50. 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 very 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):	$52
EV ($million):	$52
Debt ($million):	$35
Cash ($million):	$35
Avg. Daily Trading Vol. ($million):	$1
Float (million shares):	128
Short Interest (million shares):	18
Dividend, annual (yield):	$0 (NA%)

Revenues (US$ million)

	2023E (Cur.)	2023E (Old)	2024E (Cur.)	2024E (Old)
Q1 Dec	0A		0E	0E
Q2 Mar	0A		0E	1E
Q3 Jun	0A	0E	0E	3E
Q4 Sep	0E		0E	4E
Total	**0E**		**0E**	**8E**
EV/Revs	N/A		N/A	

Earnings per Share (pro forma)

	2023E (Cur.)	2023E (Old)	2024E (Cur.)	2024E (Old)
Q1 Dec	(0.08)A		(0.06)E	
Q2 Mar	(0.03)A		(0.06)E	
Q3 Jun	(0.08)A	(0.06)E	(0.06)E	
Q4 Sep	(0.07)E	(0.06)E	(0.06)E	
Total	**(0.26)E**	**(0.23)E**	**(0.25)E**	**(0.23)E**
P/E	N/A		N/A	

Exhibit 1: Outlook's Investment Highlights (as of August 14, 2023)

Investment Highlights

FDA Market Approval of ONS-5010 (bevacizumab-vikg)[1], an Investigational Therapy for the Treatment of Wet AMD, Targeted for August 29, 2023 PDUFA Date

Targeting $13.1 Billion Global Ophthalmic Anti-VEGF Market[2]

Differentiated Drug Product

- Designed to meet robust standards required for FDA 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 FDA Approved Ophthalmic Bevacizumab

- U.S. FDA BLA accepted with target PDUFA action date of August 29, 2023
- Potential U.S. launch in Q4 2023
- Received validation of Marketing Authorization Application by European Medical Agency
- Provides an economically elegant anti-VEGF solution for patients, payers and doctors

Attractive Market Opportunity

- Strategic commercialization agreement with AmerisourceBergen
- Over 50% of the U.S. market estimated to be available for conversion to ONS-5010, representing up to billions in potential yearly sales
- 12-years US regulatory exclusivity expected upon approval
- Label expansion opportunity into DME and BRVO

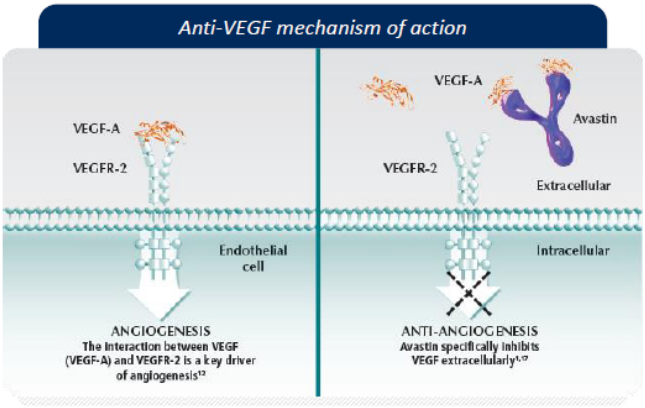
Source: Company reports.

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

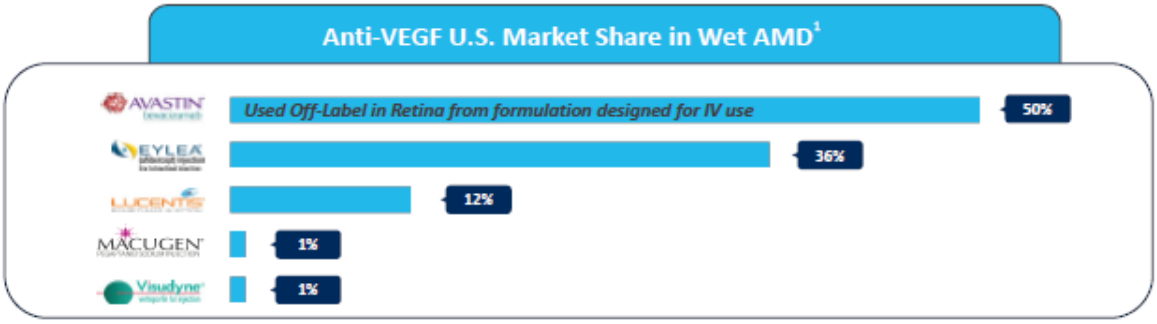
- Anti-VEGF drugs have been standard of care since 2006
  - Block growth of abnormal blood vessels and leakage of fluid from the vessels behind the retina
- Several new clinical-stage anti-VEGF drugs, including biosimilars, in development and/or recently approved
  - Require significant time and capital 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

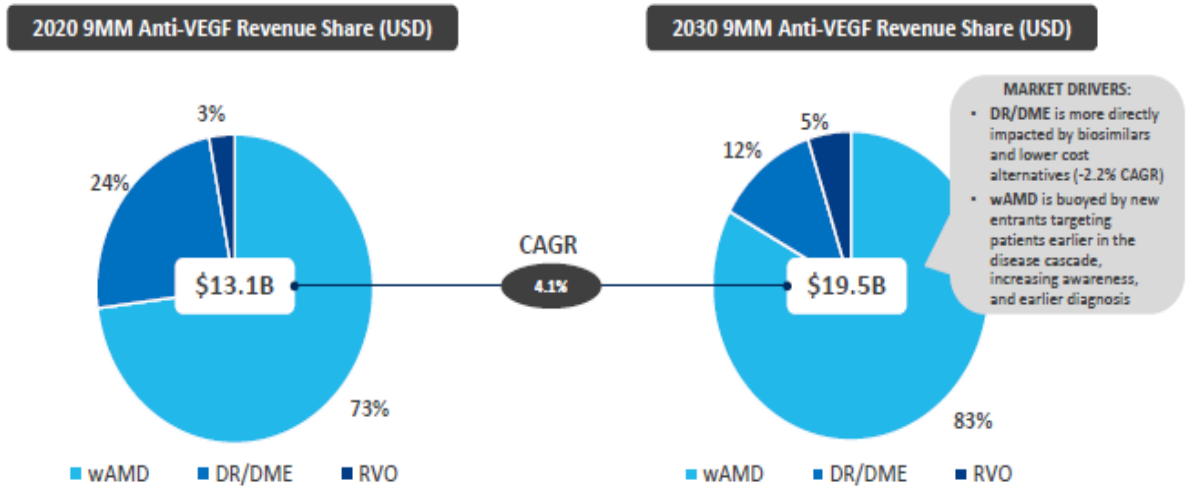


Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics, if Approved by FDA

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

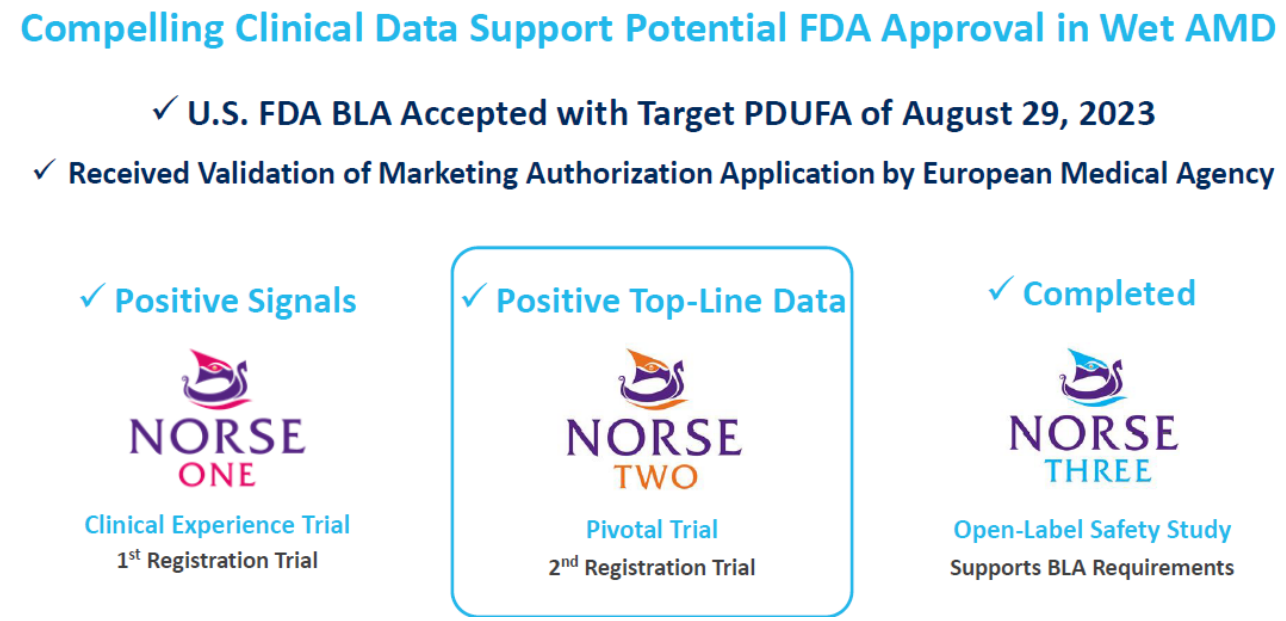
Targeting Large and Growing Ophthalmic Markets

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



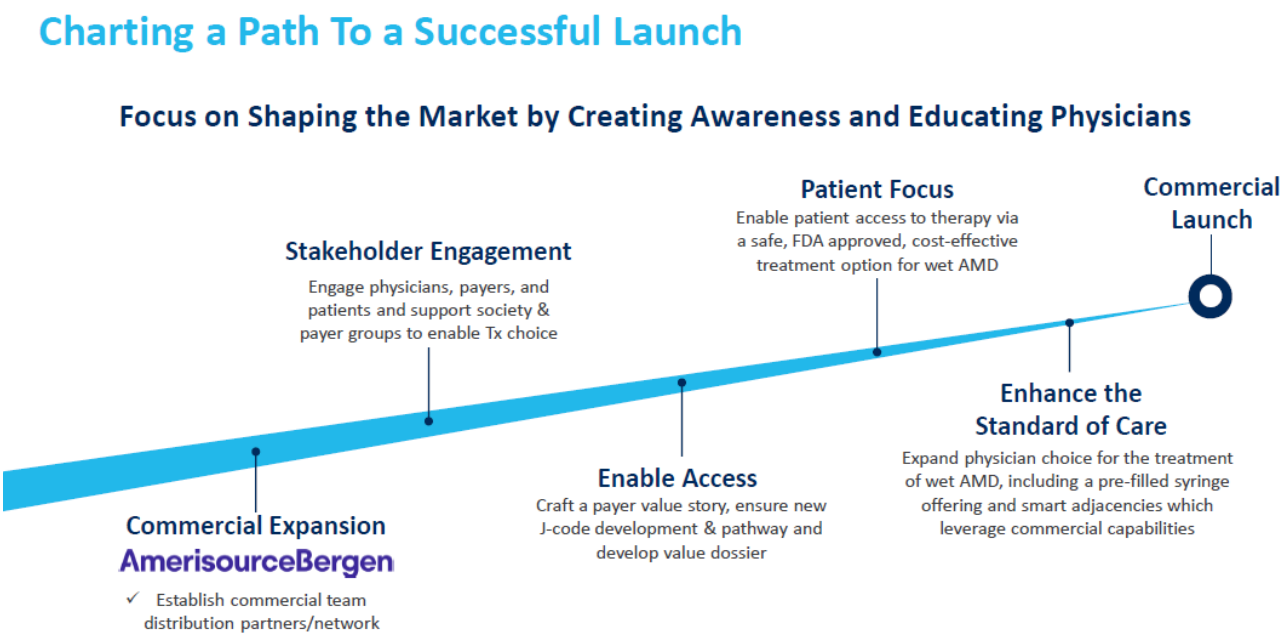
Source: Company reports.

Exhibit 4: ONS-5010 ((LYTENAVA) Planned Milestones (as of August 14, 2023)



Source: Company reports.

Exhibit 5: ONS-5010 (LYTENAVA) Commercial Strategy



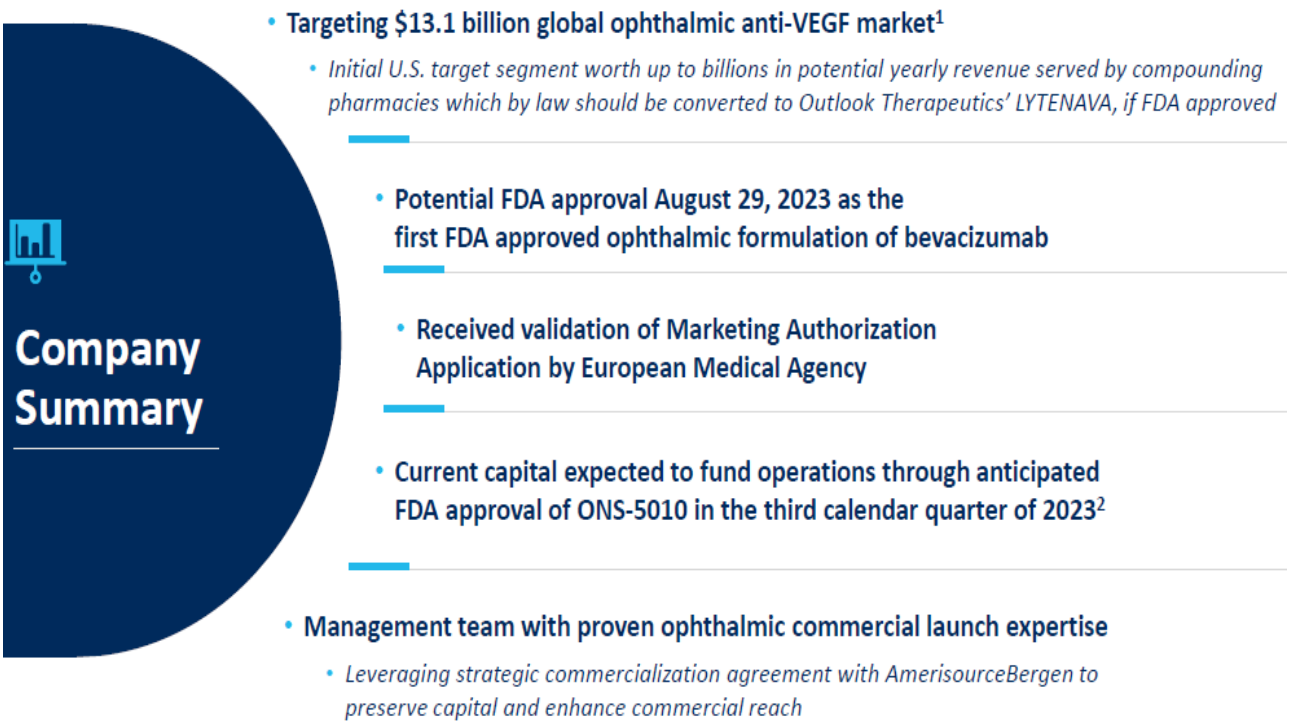
Source: Company reports.

Exhibit 6: Recent Highlights and Upcoming Milestones (as of Q3 FY23 – August 14, 2023)

- **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)**

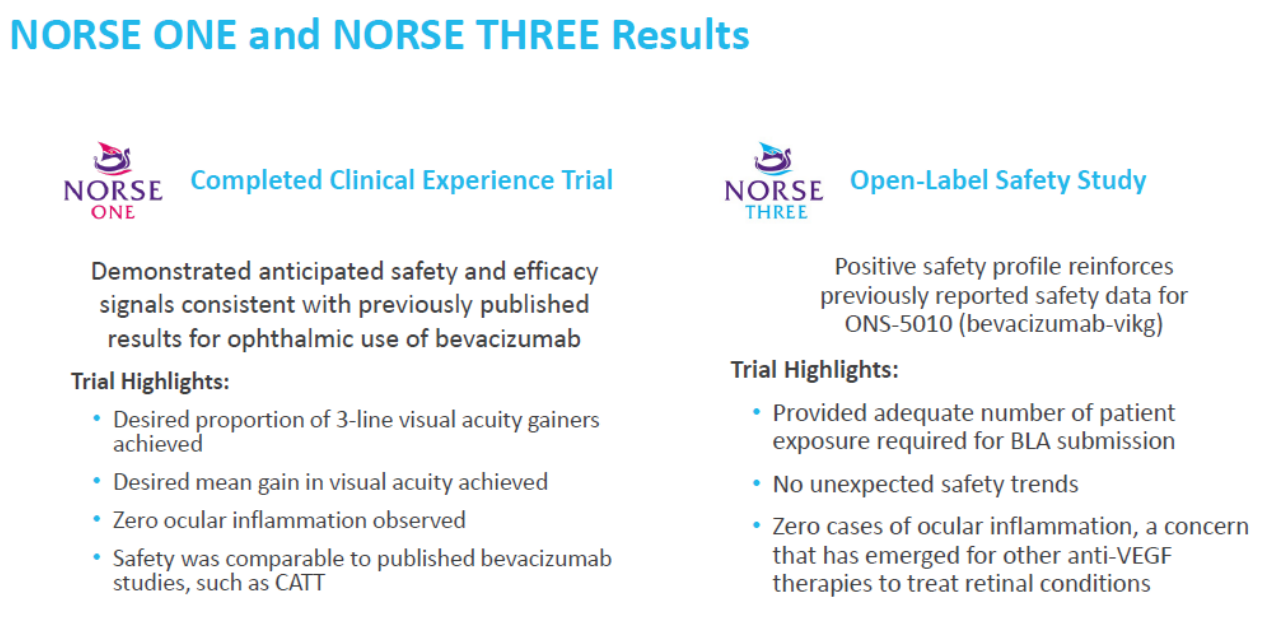
Upcoming Anticipated Milestones

- PDUFA goal date of August 29, 2023;
- Evaluation of ONS-5010 in a pre-filled syringe in the NORSE SEVEN clinical trial expected to be complete in 2024; and
- MAA decision date from the EMA's CHMP in the EU for ONS-5010 expected in first half of 2024.



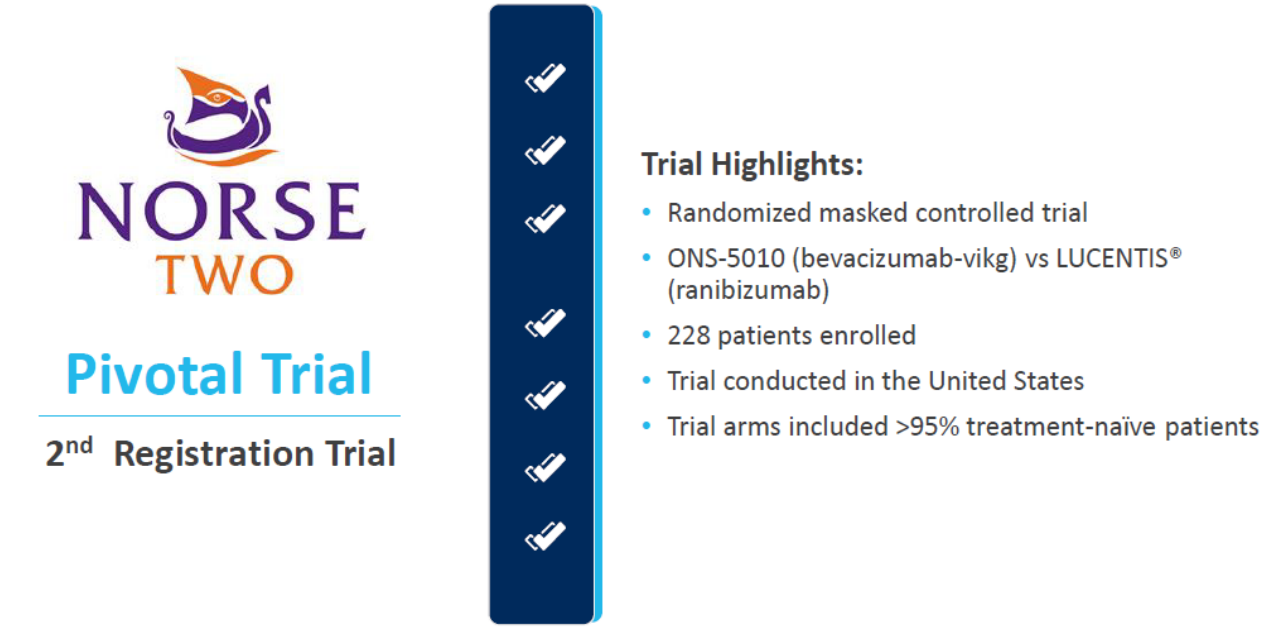
Source: Company reports.

Exhibit 7: NORSE ONE and THREE Studies Results



Source: Company reports.

Exhibit 8: NORSE TWO Pivotal Trial

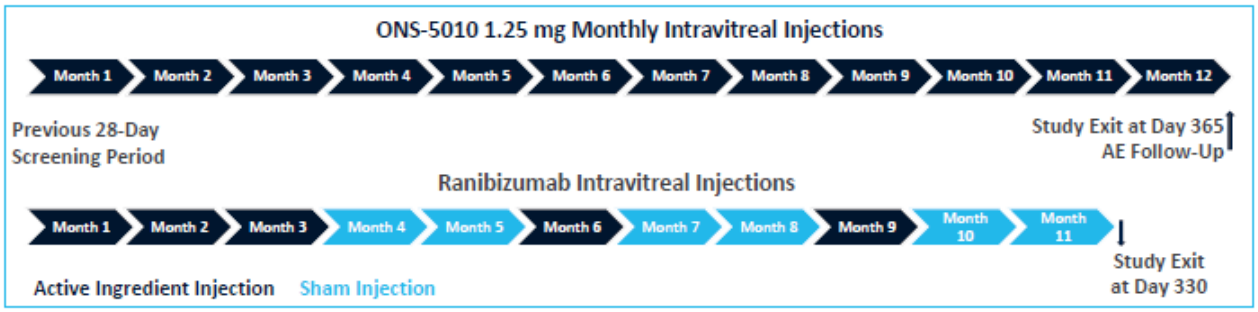


Source: Company reports.

Exhibit 9: NORSE TWO Study Conclusion

NORSE TWO 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

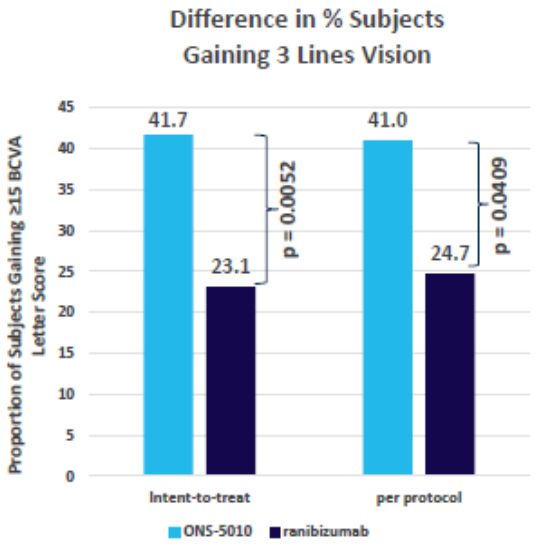


Study Eye Characteristics
- Active, primary CNV due to wet AMD
- Treatment-naïve
- BCVA: 20/50 – 20/320

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

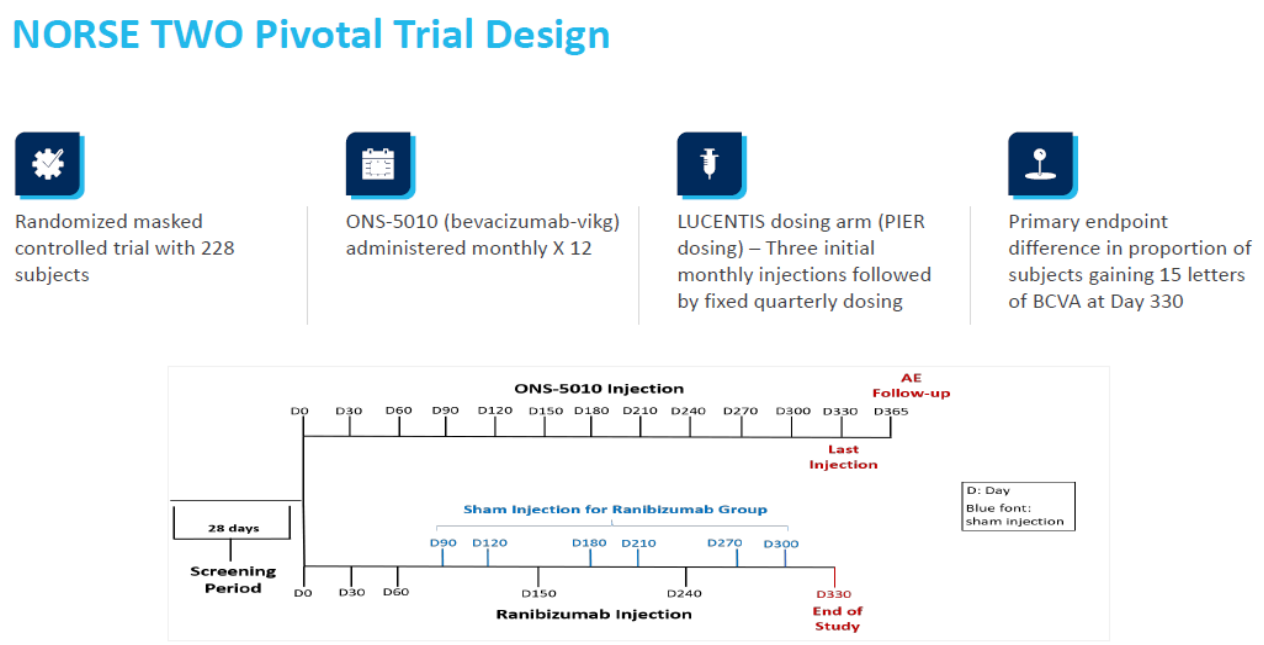
NORSE TWO Primary Endpoint Met with Statistically Significant, Clinically Relevant Results[1]

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	



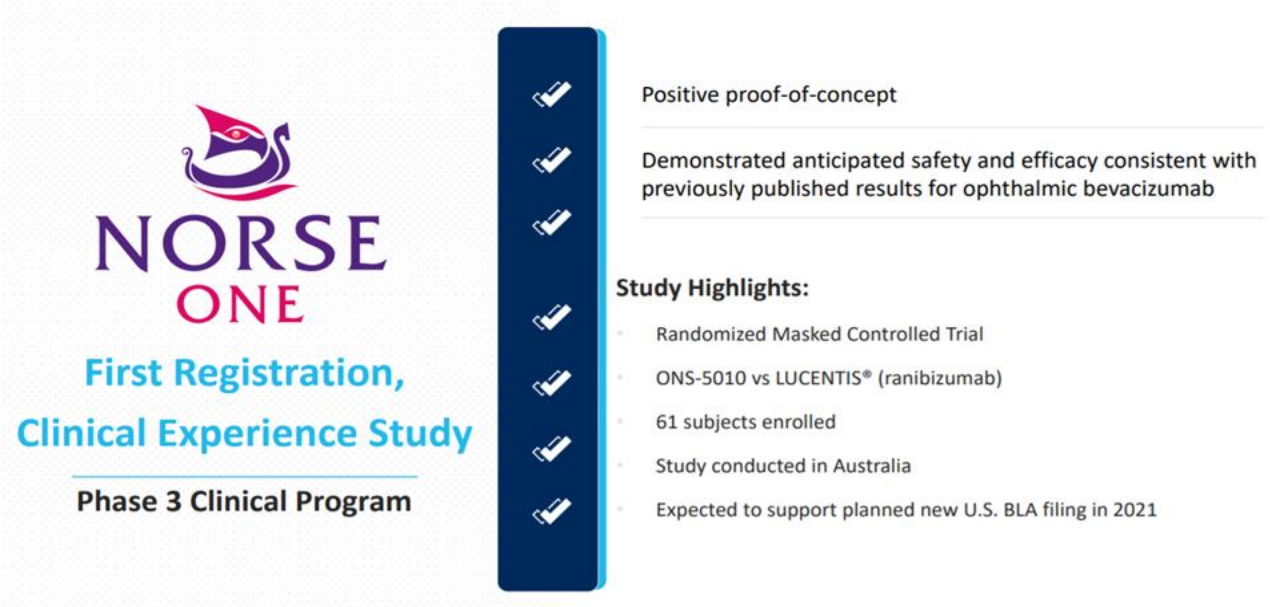
Source: Company reports.

Exhibit 10: NORSE TWO Study Design



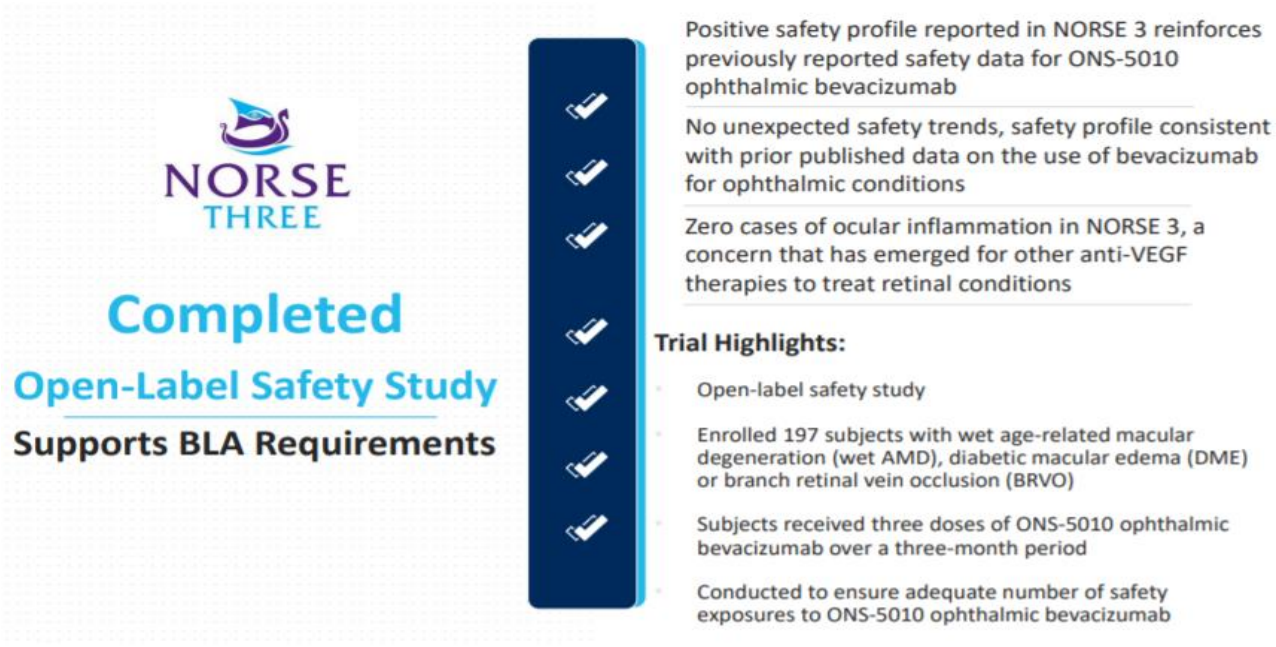
Source: Company reports.

Exhibit 11: NORSE ONE Study



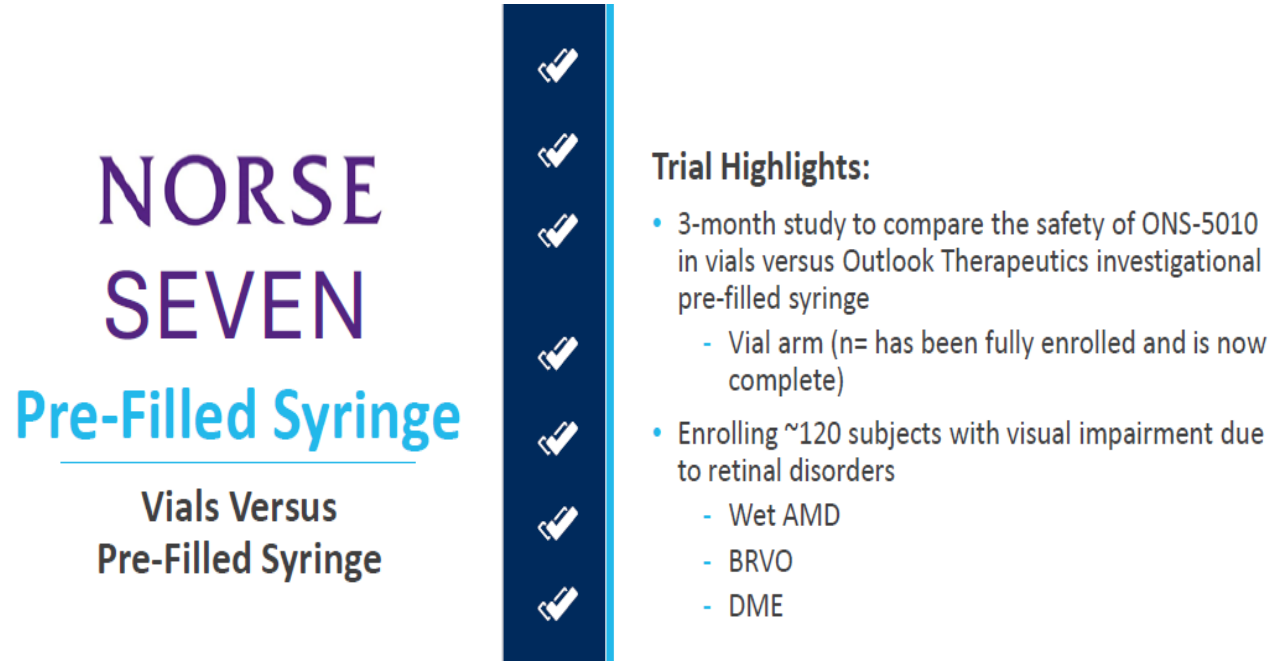
Source: Company reports.

Exhibit 12: NORSE THREE Safety Study



Source: Company reports.

Exhibit 13: NORSE SEVEN Study (ongoing currently)



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 August 14, 2023)

	Revenue (mil)			EPS	
	2023E	2024E		2023E	2024E
Q1 Dec	$0A		Q1 Dec	$(0.08)A	
Q2 Mar	$0A		Q2 Mar	$(0.03)A	
Q3 Jun	$0E		Q3 Jun	$(0.05)E	
Q4 Sep	$3.7E		Q4 Sep	$(0.05)E	
Total	$4.1E	$72.9E	Total	$(0.21)E	$(0.09)E

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

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

FINANCIAL MODEL

Outlook Therapeutics, Inc.

Income Statement ($ mils) Fiscal Year End: September 30	Dec-20 Q1A	Mar-21 Q2A	Jun-21 Q3A	Sep-21 Q4A	2021 FY-A	Dec-21 Q1A	Mar-22 Q2A	Jun-22 Q3A	Sep-22 Q4A	2022 FY-A	Dec-22 Q1A	Mar-23 Q2A	Jun-23 Q3A	Sep-23 Q4E	2023 FY-E	Dec-23 Q1E	Mar-24 Q2E	Jun-24 Q3E	Sep-24 Q4E	2024 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**
Cost of Revenues					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	11.9	8.5	8.5	9.9	39.0	9.9	12.2	11.2	9.0	42.3	9.9	0.5	11.1	9.0	30.5	6.0	6.0	6.0	6.0	24.0
General and administrative	2.2	4.1	2.9	3.5	12.8	3.3	6.7	5.8	5.0	20.7	5.8	6.3	7.0	8.0	27.2	8.0	8.0	8.0	8.0	32.0
Restructuring and other					0.0					0.0					0.0					0.0
Total operating expenses	14.2	12.6	11.5	13.4	51.7	13.1	18.9	17.0	14.0	63.1	15.7	6.8	18.1	17.0	57.7	14.0	14.0	14.0	14.0	56.0
Operating income (loss)	**(14.2)**	**(12.6)**	**(11.5)**	**(13.4)**	**(51.7)**	**(13.1)**	**(18.9)**	**(17.0)**	**(14.0)**	**(63.1)**	**(15.7)**	**(6.8)**	**(18.1)**	**(17.0)**	**(57.7)**	**(14.0)**	**(14.0)**	**(14.0)**	**(14.0)**	**(56.0)**
Interest income (expense)	(0.2)	(0.3)	(0.3)	(0.3)	(0.9)	(0.4)	(0.4)	(0.4)	(0.4)	(1.5)	(2.4)	0.2	0.4	(2.5)	(4.4)	(2.5)	(2.5)	(2.5)	(2.5)	(10.0)
Other income (expense)	(0.1)	(0.2)	(0.5)	0.3	(0.5)	(1.0)	(0.4)	(0.2)	0.0	(1.5)	(0.5)	(0.0)	(2.9)		(3.5)					0.0
Income before income taxes	(14.5)	(13.1)	(12.2)	(13.4)	(53.2)	(14.5)	(19.7)	(17.5)	(14.3)	(66.0)	(18.7)	(6.7)	(20.7)	(19.5)	(65.5)	(16.5)	(16.5)	(16.5)	(16.5)	(66.0)
Income taxes		0.0		0.2	0.2		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)	(13.1)	(12.2)	(13.6)	(53.4)	(14.5)	(19.7)	(17.5)	(14.3)	(66.1)	(18.7)	(6.7)	(20.7)	(19.5)	(65.5)	(16.5)	(16.5)	(16.5)	(16.5)	(66.0)
Nonrecurring/noncash adjustments					0.0					0.0					0.0					0.0
Net income (pro forma)	**(14.5)**	**(13.1)**	**(12.2)**	**(13.6)**	**(53.4)**	**(14.5)**	**(19.7)**	**(17.5)**	**(14.3)**	**(66.1)**	**(18.7)**	**(6.7)**	**(20.7)**	**(19.5)**	**(65.5)**	**(16.5)**	**(16.5)**	**(16.5)**	**(16.5)**	**(66.0)**
EBITDA																				
Shares, Basic	121.7	150.7	168.4	175.3	152.7	188.2	219.1	220.5	220.8	212.1	227.4	256.7	256.9	260.2	250.3	260.2	260.3	260.4	260.5	260.4
Shares, Diluted	121.7	150.7	168.4	175.3	152.7	188.2	219.1	220.5	220.8	212.1	227.4	256.7	256.9	260.2	250.3	260.2	260.3	260.4	260.5	260.4
EPS Basic (Pro forma)	**($0.12)**	**($0.09)**	**($0.07)**	**($0.08)**	**($0.35)**	**($0.08)**	**($0.09)**	**($0.08)**	**($0.06)**	**($0.31)**	**($0.08)**	**($0.03)**	**($0.08)**	**($0.07)**	**($0.26)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.25)**
EPS Diluted (Pro forma)	($0.12)	($0.09)	($0.07)	($0.08)	($0.35)	($0.08)	($0.09)	($0.08)	($0.06)	($0.31)	($0.08)	($0.03)	($0.08)	($0.07)	($0.26)	($0.06)	($0.06)	($0.06)	($0.06)	($0.25)
Margins																				
Gross margin	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	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!	#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!	#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%	-1%	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
Y/Y % change																				
Total Revenue	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#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!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Research and development	104%	95%	1%	30%	48%	-17%	43%	32%	-10%	9%	0%	-96%	-1%	0%	-28%	-39%	1001%	-46%	-33%	-21%
General and administrative	-4%	109%	-11%	47%	28%	46%	63%	97%	43%	62%	78%	-6%	22%	60%	31%	37%	27%	14%	0%	18%
Operating income (loss)	73%	87%	-3%	34%	40%	-7%	50%	48%	4%	22%	19%	-64%	7%	22%	-9%	-11%	105%	-23%	-18%	-3%
Net income (loss)	-22%	-25%	305%	37%	9%	0%	50%	44%	5%	24%	29%	-66%	18%	36%	-1%	-12%	148%	-20%	-15%	1%
EPS Diluted (Pro forma)	-57%	-35%	-34%	5%	-25%	-35%	3%	10%	-16%	-11%	7%	-71%	1%	15%	-16%	-23%	144%	-21%	-15%	-3%

Source: Company reports and Ascendiant Capital Markets estimates.

Outlook Therapeutics, Inc.

Balance Sheet ($ mils)	Dec-20	Mar-21	Jun-21	Sep-21	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4E	Q1E	Q2E	Q3E	Q4E
Assets																
Cash and cash equivalents	5.6	37.2	19.7	14.5	70.2	58.4	26.0	17.4	52.3	43.6	33.7	16.2	1.1	(14.0)	(29.1)	(44.2)
Short term investments												0.0	0.0	0.0	0.0	0.0
Accounts receivable, net												0.0	0.0	0.0	0.0	0.0
Deferred income taxes												0.0	0.0	0.0	0.0	0.0
Prepaid expenses and other	5.5	6.6	12.2	7.0	7.3	8.1	11.5	10.1	9.3	9.4	9.3	9.3	9.3	9.3	9.3	9.3
Total current assets	11.0	43.8	31.9	21.5	77.5	66.5	37.5	27.5	61.7	53.1	43.0	25.5	10.4	(4.7)	(19.8)	(34.9)
Long term securities/investments				0.9	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	0.3	0.2	0.2	0.2	0.1	0.1	0.0					(0.0)	(0.0)	(0.0)	(0.0)	(0.1)
Intangibles, net												0.0	0.0	0.0	0.0	0.0
Deferred income tax												0.0	0.0	0.0	0.0	0.0
Other	1.2	1.1	0.8	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.6	0.0	0.0	0.0	0.0	0.0
Total assets	**12.5**	**45.1**	**32.9**	**22.8**	**78.7**	**67.7**	**38.6**	**28.5**	**62.7**	**54.0**	**44.4**	**26.3**	**11.2**	**(3.9)**	**(19.0)**	**(34.1)**
Liabilities and stockholders' equity																
Accounts payable	3.3	6.3	2.7	2.2	2.5	4.2	2.5	3.5	4.2	3.6	5.1	5.1	5.1	5.1	5.1	5.1
Accrued expenses	6.3	4.5	3.5	1.7	2.8	2.5	3.6	3.4	9.0	6.2	8.3	8.3	8.3	8.3	8.3	8.3
Deferred revenue												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	0.0	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Short term debt	0.5	11.2	11.5	0.9	12.7	22.8	10.5	10.9		31.8	34.7	34.7	34.7	34.7	34.7	34.7
Total current liabilities	**12.1**	**23.9**	**19.6**	**6.8**	**19.9**	**31.4**	**18.4**	**19.7**	**15.1**	**43.5**	**49.9**	**49.9**	**49.9**	**49.9**	**49.9**	**49.9**
Deferred income taxes												0.0	0.0	0.0	0.0	0.0
Warrant liabilities	0.2	0.4	0.4	0.5	0.3	0.3	0.1	0.1	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
Other long term liabilities	0.0	0.0	0.1	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	10.7	0.1		10.9	9.6				31.8			0.0	0.0	0.0	0.0	0.0
Total other liabilities	**10.9**	**0.6**	**0.5**	**11.5**	**9.9**	**0.3**	**0.1**	**0.1**	**31.8**	**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
Common stock	1.3	1.7	1.7	1.8	2.2	2.3	2.3	2.3	2.6	2.6	2.6	4.0	5.4	6.7	8.1	9.5
Additional paid-in capital	292.4	336.2	340.5	345.7	403.9	410.8	412.4	415.4	440.8	442.2	446.8	446.8	446.8	446.8	446.8	446.8
Retained earnings	(304.2)	(317.3)	(329.5)	(342.9)	(357.3)	(377.1)	(394.6)	(408.9)	(427.6)	(434.3)	(454.9)	(474.4)	(490.9)	(507.4)	(523.9)	(540.4)
Treasury stock												0.0	0.0	0.0	0.0	0.0
Accumulated other comprehensive income												0.0	0.0	0.0	0.0	0.0
Other												0.0	0.0	0.0	0.0	0.0
Total stockholders' equity	**(10.5)**	**20.7**	**12.7**	**4.6**	**48.8**	**36.0**	**20.1**	**8.7**	**15.8**	**10.5**	**(5.5)**	**(23.6)**	**(38.7)**	**(53.9)**	**(69.0)**	**(84.1)**
Total stockholders' equity and liabil	**12.5**	**45.1**	**32.9**	**22.8**	**78.7**	**67.7**	**38.6**	**28.5**	**62.7**	**54.0**	**44.4**	**26.3**	**11.2**	**(3.9)**	**(19.0)**	**(34.1)**

Balance Sheet Drivers

	Dec-20	Mar-21	Jun-21	Sep-21	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24
	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4E	Q1E	Q2E	Q3E	Q4E
Book & Cash Value (per share)																
Book Value per Share (diluted)	-$0.09	$0.14	$0.08	$0.03	$0.26	$0.16	$0.09	$0.04	$0.07	$0.04	-$0.02	-$0.09	-$0.15	-$0.21	-$0.26	-$0.32
Cash per Share (diluted)	$0.05	$0.25	$0.12	$0.09	$0.38	$0.27	$0.12	$0.08	$0.23	$0.17	$0.13	$0.07	$0.01	-$0.05	-$0.11	-$0.17
Net cash per Share (diluted)	-$0.05	$0.17	$0.05	$0.02	$0.26	$0.17	$0.07	$0.03	$0.09	$0.05	$0.00	-$0.07	-$0.13	-$0.18	-$0.24	-$0.30

Source: Company reports and Ascendiant Capital Markets estimates

Outlook Therapeutics, Inc.

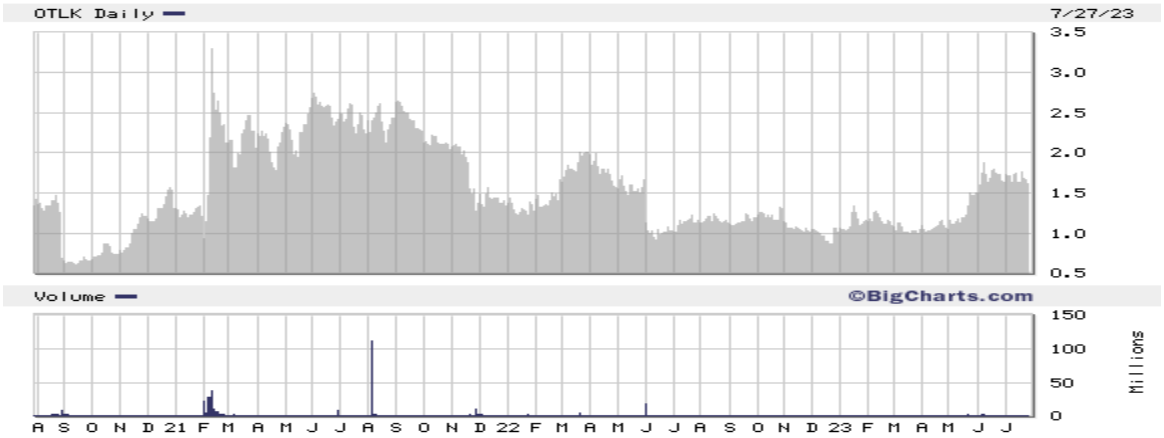
Cash Flow Statement ($ mils)	Dec-20	Mar-21	Jun-21	Sep-21	2021	Dec-21	Mar-22	Jun-22	Sep-22	2022	Dec-22	Mar-23	Jun-23	Sep-23	2023	Dec-23	Mar-24	Jun-24	Sep-24	2024
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Cash flow from operating activities																				
Net income	(14.5)	(13.1)	(12.2)	(13.4)	(53.2)	(14.5)	(19.7)	(17.5)	(14.3)	(66.1)	(18.7)	(6.7)	(20.7)	(19.5)	(65.5)	(16.5)	(16.5)	(16.5)	(16.5)	(66.0)
Depreciation	0.1	0.1	0.0	0.1	0.3	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
Amortization					0.0					0.0					0.0					0.0
Debt related amortization expen	0.1	0.2	0.2	0.3	0.9	0.3	0.4	0.4	0.5	1.7	1.4	0.0	0.0		1.4					0.0
Stock comp	1.2	1.1	1.2	1.4	4.9	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	5.5
Deferred income taxes					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	0.1	0.2	0.0	0.1	0.5	(0.1)	0.4	0.1	(0.9)	(0.5)	(0.0)	(0.0)	0.0		(0.0)					0.0
Writedowns and impairments	(0.7)	0.2			(0.6)			1.0	(0.1)	0.9			2.9		2.9					0.0
Other gains/losses			0.4	(0.4)	0.0	1.0	0.0	(1.0)	1.0	1.1	0.6	0.0	0.0		0.6					0.0
Other	(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
Prepaid expenses & other curre	0.0	(1.4)	(5.6)	5.2	(1.7)	(0.3)	(0.8)	(3.4)	1.4	(3.1)	0.8	(0.1)	0.1	0.0	0.8	0.0	0.0	0.0	0.0	0.0
Income tax					0.0					0.0					0.0					0.0
Other assets	0.1		0.0	(0.0)	0.1	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.2)	0.6	0.4	0.0	0.0	0.0	0.0	0.0
Accounts payable	0.9	2.7	(3.5)	(0.4)	(0.2)	0.2	1.8	(1.7)	1.0	1.3	0.7	(0.6)	1.2	0.0	1.3	0.0	0.0	0.0	0.0	0.0
Accrued expenses	(0.7)	(1.9)	(1.0)	(1.8)	(5.3)	1.0	(0.2)	(0.5)	(0.2)	0.2	5.0	(2.2)	2.1	0.0	4.8	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
Other liabilities		(0.1)	0.1		0.0					0.0				0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash (used in) provided by	**(13.3)**	**(11.7)**	**(20.2)**	**(9.0)**	**(54.3)**	**(11.0)**	**(14.3)**	**(21.1)**	**(10.3)**	**(56.7)**	**(8.9)**	**(8.1)**	**(13.2)**	**(17.5)**	**(47.7)**	**(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
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 acti	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**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				10.0	10.0				10.0	30.0			0.0	30.0	0.0	0.0	0.0	0.0	0.0
Repayment of debt	(3.6)	(0.0)	(0.0)	(0.0)	(3.7)	(1.0)	(0.3)	(11.6)	(0.0)	(12.9)	(10.8)	(0.3)	(0.0)		(11.1)					0.0
Issuance of stock		39.8	2.7	3.8	46.3	57.7	2.7	0.3	1.6	62.3	24.6	(0.3)	3.3	0.0	27.6	0.0	0.0	0.0	0.0	0.0
Repurchase of common stock				0.0	0.0					0.0					0.0					0.0
Proceeds from stock option exercises		3.6		0.0	3.6	0.0	0.2	0.0	0.0	0.2					0.0					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	**6.4**	**43.3**	**2.7**	**3.8**	**56.2**	**66.7**	**2.6**	**(11.3)**	**1.6**	**59.6**	**43.8**	**(0.6)**	**3.3**	**0.0**	**46.5**	**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	**(7.0)**	**31.6**	**(17.5)**	**(5.2)**	**1.9**	**55.7**	**(11.7)**	**(32.4)**	**(8.6)**	**2.9**	**34.9**	**(8.7)**	**(9.9)**	**(17.5)**	**(1.2)**	**(15.1)**	**(15.1)**	**(15.1)**	**(15.1)**	**(60.4)**
Beginning cash and equivalents	**12.5**	**5.6**	**37.2**	**19.7**	**12.5**	**14.5**	**70.2**	**58.4**	**26.0**	**14.5**	**17.4**	**52.3**	**43.6**	**33.7**	**17.4**	**16.2**	**1.1**	**(14.0)**	**(29.1)**	**16.2**
Ending cash and equivalents	**5.6**	**37.2**	**19.7**	**14.5**	**14.5**	**70.2**	**58.4**	**26.0**	**17.4**	**17.4**	**52.3**	**43.6**	**33.7**	**16.2**	**16.2**	**1.1**	**(14.0)**	**(29.1)**	**(44.2)**	**(44.2)**

Source: Company reports and Ascendiant Capital Markets estimates

ANALYST CERTIFICATION

Each analyst hereby certifies that the views expressed in this report reflect the analyst's personal views about the subject securities or issuers. Each analyst also certifies that no part of the analyst's compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this report. The analyst who prepared this report is compensated based upon the overall profitability of Ascendiant Capital Markets, LLC, which may, from time to time, include the provision of investment banking, financial advisory and consulting services. Compensation for research is based on effectiveness in generating new ideas for clients, performance of recommendations, accuracy of earnings estimates, and service to clients.

Outlook Therapeutics, Inc.



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

	Report Date		Price
Report	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

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

IMPORTANT DISCLOSURES

This report has been distributed by Ascendiant Capital Markets, LLC and is for the sole use of our clients. This report is based on current public information that we consider reliable, but we do not represent it is accurate or complete, and it should not be relied on as such. This report contains information from various sources, including United States government publications, The Wall Street Journal and other periodicals, Yahoo! Finance and other sources, and is for informational purposes only and is not a recommendation to trade in the securities of the companies mentioned within the report. We seek to update our research and recommendations as appropriate, but the large majority of reports are published at irregular intervals as we consider appropriate and, in some cases, as constrained by industry regulations.

We may have a business relationship with companies covered in this report. Ascendiant Capital Markets, LLC may make a market in the securities of the subject company. We and our affiliates, officers, directors, and employees will from time to time have long or short positions in, act as principal in, and buy or sell, the securities or derivatives (including options and warrants) thereof of covered companies referred to in this report. This report is not an offer to sell or the solicitation of an offer to buy any security in any jurisdiction where such an offer or solicitation would be illegal. It does not constitute a personal recommendation or take into account the particular investment objectives, financial situations, or needs of individual clients. Clients should consider whether any information in this report is suitable for their particular circumstances and, if appropriate, seek professional advice, including tax advice. The price and value of the investments referred to in this report may fluctuate.

Following are some general risks that can adversely impact future operational and financial performance and share price valuation: (1) industry fundamentals with respect to legislation, mandates, incentives, customer demand, or product pricing; (2) issues relating to competing companies or products; (3) unforeseen developments with respect to management, financial condition or accounting policies or practices; or (4) external factors that affect the interest rates, currency, the economy or major segments of the economy. Past performance is not a guide to future performance, future returns are not guaranteed, and loss of original capital may occur. Certain transactions, including those involving futures, options, and other derivatives, give rise to substantial risk and are not suitable for all investors. Our report is disseminated primarily electronically, and, in some cases, in printed form. The information contained in this report is not incorporated into the contents of our website and should be read independently thereof.

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.

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 July 14, 2023)

			Investment Banking Services Past 12 months	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy	51	98%	16	31%
Hold	0	0%	0	0%
Sell	1	2%	0	0%
Total	52	100%	16	31%

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

Ascendiant Capital Markets, LLC research is distributed electronically via the Thomson Reuters platforms, Bloomberg, Capital IQ and FactSet. Please contact your investment advisor or institutional salesperson for more information.

General Disclaimer

The information and opinions in this report were prepared by Ascendiant Capital Markets, LLC. This information is not intended to be used as the primary basis of investment decisions and because of individual client objectives it should not be construed as advice designed to meet the particular investment needs of any investor. This material is for information purposes only and is not an offer or solicitation with respect to the purchase or sale of any security. The reader should assume that Ascendiant Capital Markets, LLC may have a conflict of interest and should not rely solely on this report in evaluating whether or not to buy or sell securities of issuers discussed herein. The opinions, estimates, and projections contained in this report are those of Ascendiant Capital Markets, LLC as of the date of this report and are subject to change without notice. Ascendiant Capital Markets, LLC endeavors to ensure that the contents have been compiled or derived from sources that we believe are reliable and contain information and opinions that are accurate and complete. However, Ascendiant Capital Markets, LLC makes no representation or warranty, express or implied, in respect thereof, takes no responsibility for any errors and omissions contained herein, and accepts no liability whatsoever for any loss arising from any use of, or reliance on, this report or its contents. Information may be available to Ascendiant Capital Markets, LLC, or its affiliates that is not reflected in this report. This report is not to be construed as an offer or solicitation to buy or sell any security.

Additional Disclosures

Ascendiant Capital Markets, LLC is a broker-dealer registered with the United States Securities and Exchange Commission (SEC) and a member of the FINRA and SIPC. Ascendiant Capital Markets, LLC is not a Registered Investment Advisor nor is it an investment advisor registered with the Securities and Exchange Commission or with the securities regulators of any state, and at the present time is not eligible to file for federal registration.