



# Outlook Therapeutics, Inc.

Q1 about inline. LYTENAVA development on track for Q1 2022 BLA FDA submission. Raising P/T to \$7.50.

## COMPANY UPDATE

**Rating: BUY**

Ticker: OTLK

Price: \$1.74  
(intraday)

Target: \$7.50  
(from \$7.25)

**Q1 about inline:** Outlook recently (on February 14) reported its Q1 FY22 (ending December) results. EPS of \$(0.08) compared with our estimates of \$(0.05). There was no Q1 guidance. Outlook is an early/clinical stage medical device development/commercialization company so it generates minimal revenue.

**Operating expense:** Operating expenses were \$13 million, flat with \$13 million in Q4. Management declined to provide FY22 guidance. However, we believe ~\$11 - 12 million is a reasonable near term quarterly burn rate.

**Adjusting estimates:** We are adjusting our FY22 EPS estimate to \$(0.24) from \$(0.20). We are maintaining our FY23 estimate for revenue of \$4 million and EPS of \$(0.21).

**Q1 2022 BLA submission on track:** Outlook is still on track to submit a new BLA (Biologics License Application) to the FDA for ONS-5010 for treatment of wet AMD in the first calendar quarter of 2022.

**Positive topline results:** In August, 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.

**Prior positive studies:** 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).

**ONS-5010 development on track:** 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.

**Top-Line data should be major positive catalysts:** Outlook continues to be on track in its development of ONS-5010. ONS-5010 has reported three positive trial results. The data from these studies will support its Biologics License Application (BLA) filing with the FDA in Q1 2022.

**Commercial launch in 2023:** Pending regulatory approvals, Outlook expects commercial launches shortly after FDA approval expected in Q1 2023.

**More studies planned:** Outlook has received agreements from the FDA on three Special Protocol Assessments (SPAs) for three additional clinical trials. These SPAs cover ONS-5010 to treat branch retinal vein occlusion (BRVO), and for the treatment of diabetic macular edema (DME). These studies are planned to initiate in 2023 (after FDA approval for wet AMD).

**Capital raise:** Outlook has \$71 million in cash and \$22 million in debt as of Q1 FY22. In Q1, it raised ~\$58 million selling stock (46 million shares at \$1.25/share). We believe it has enough cash into mid-FY23.

**Valuation attractive:** Maintaining our BUY rating, but raising our 12-month price target to \$7.50 from \$7.25. 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:	\$1.19 – 3.27
Shares Outstanding (million):	225
Market cap (\$million):	\$392
EV (\$million):	\$343
Debt (\$million):	\$22
Cash (\$million):	\$71
Avg. Daily Trading Vol. (\$million):	\$3
Float (million shares):	123
Short Interest (million shares):	5
Dividend, annual (yield):	\$0 (NA%)

### Revenues (US\$ million)

	<u>2022E</u> <u>(Cur.)</u>	<u>2022E</u> <u>(Old)</u>	<u>2023E</u> <u>(Cur.)</u>	<u>2023E</u> <u>(Old)</u>
Q1 Dec	0A	0E	0E	
Q2 Mar	0E		1E	
Q3 Jun	0E		1E	
Q4 Sep	<u>0E</u>		<u>3E</u>	
Total	0E		4E	
EV/Revs	N/A		86x	

### Earnings per Share (pro forma)

	<u>2022E</u> <u>(Cur.)</u>	<u>2022E</u> <u>(Old)</u>	<u>2023E</u> <u>(Cur.)</u>	<u>2023E</u> <u>(Old)</u>
Q1 Dec	(0.08)A	(0.05)E	(0.05)E	
Q2 Mar	(0.06)E	(0.04)E	(0.06)E	
Q3 Jun	(0.05)E		(0.05)E	
Q4 Sep	<u>(0.05)E</u>		<u>(0.05)E</u>	
Total	<u>(0.24)E</u>	<u>(0.20)E</u>	<u>(0.21)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 14.**

**Exhibit 1: Outlook’s Investment Highlights**

Company  
Summary

- Targeting \$13.1 billion global ophthalmic anti-VEGF market<sup>1</sup>
  - Initial U.S. target segment worth potentially billions in yearly revenue are served by compounding pharmacies which by law should give way to Outlook Therapeutics’ ONS 5010, if FDA approved

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- Potential for first FDA approved ophthalmic formulation of bevacizumab

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- U.S. FDA BLA submission targeted for calendar Q1 2022 with anticipated approval to follow 9-12 months later

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- Sufficient capital through the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023

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- Management team with proven ophthalmic commercial launch expertise

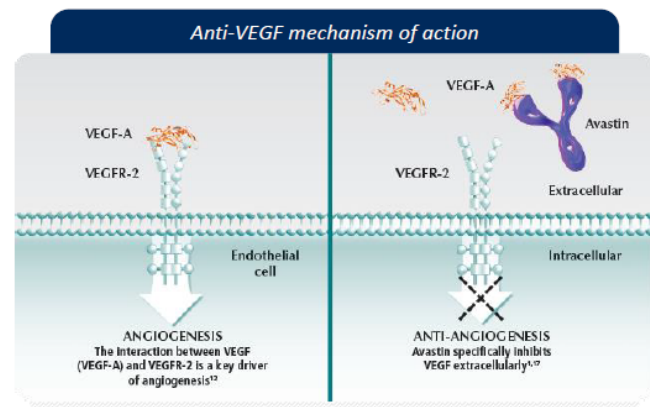
Source: Company reports.

**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

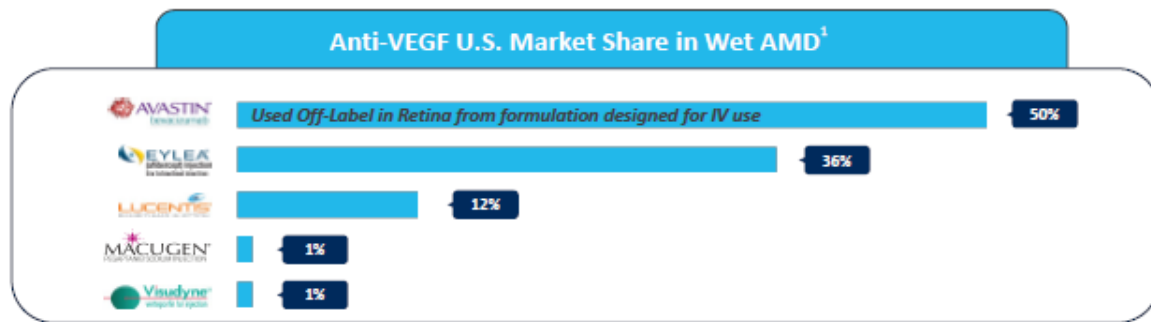
- ❑ Anti-VEGF drugs have been standard of care since 2006
  - Block growth of abnormal blood vessels and leakage of fluid from the vessels behind the retina
- ❑ Several new clinical-stage anti-VEGF drugs, including biosimilars, in development and/or recently approved
  - Require significant time and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

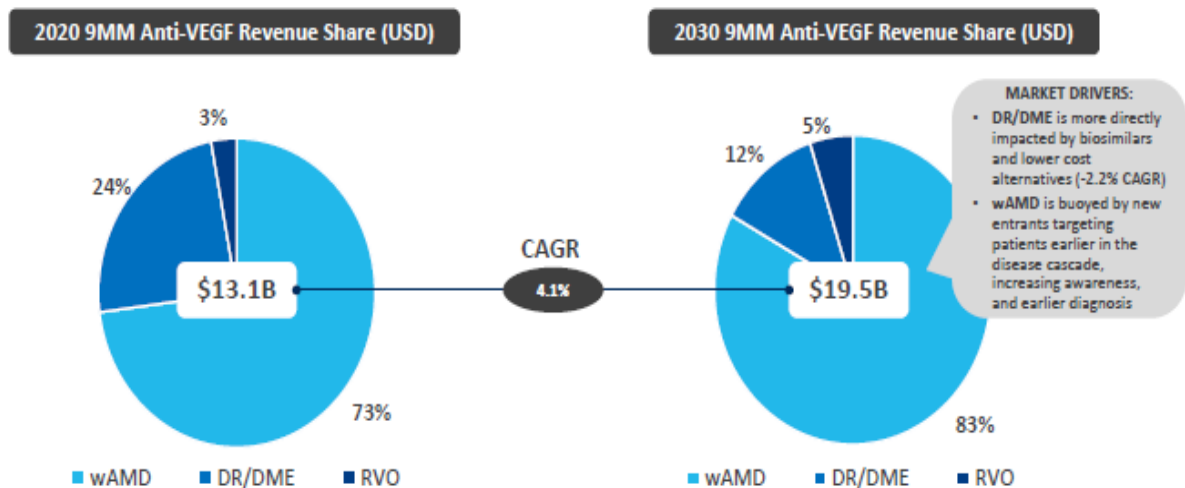


Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics, if Approved by FDA

- 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

## Pathway Towards Potential FDA Approval in Wet AMD – NORSE TWO Top-Line Results Recently Unveiled

### U.S. BLA Submission Targeted Calendar Q1 2022

✓ Positive Signals



Clinical Experience Trial  
1<sup>st</sup> Registration Trial

✓ Positive Top-Line Data



Pivotal Trial  
2<sup>nd</sup> Registration Trial

✓ Completed



Open-Label Safety Study  
Supports BLA Requirements

Source: Company reports.

Exhibit 5: ONS-5010 ((LYTENAVA) Commercial Strategy

## Commercial Strategy



Commercial launch will be led by Jeff Evanson, Chief Commercial Officer. Former V.P., Head, Global Pharmaceutical Franchise and Global Director, Alcon



#### Commercial Drivers

Provide safe and cost-effective approved bevacizumab

Responsible pricing (collaborative payor strategy)

Pre-filled syringes expected to provide convenience and safety

Market exclusivity (new BLA)  
12 years in United States  
8+2 years in EU



#### Step-Edit Therapy

Opportunity to become first line “step-edit” drug of choice, if approved



#### Expand Outside U.S.

Penetrate EU5, Japan and developing markets where unapproved bevacizumab use has been restricted

Source: Company reports.

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## Exhibit 6: Recent Highlights (as of Q1 FY22)

### Recent Corporate Highlights

- Expanded commercial team with appointment of SVP, Commercial Operations;
- Closed a \$57.5 million gross proceeds equity offering, including full exercise of underwriter's option to purchase additional shares;
- Presented data at scientific conferences including the Retina Subspecialty Day, American Academy of Ophthalmology (AAO) 2021 Annual Conference, the Eyecelerator@AAO 2021 Conference Retina Showcases, the 2021 American Society of Retina Specialists (ASRS) Annual Meeting, the Ophthalmology Innovation Summit (OIS) Retina Innovation Showcase, the EURETINA Virtual 2021 Medical Conference, the Asia-Pacific Vitreo-Retina Society (APVRS) Congress and the International Congress on OCT and OCT Angiography in Rome (ICOOR/ FLORetina) Symposia; and
- Reported positive 12-month safety data from pivotal Phase 3 NORSE TWO trial, which reinforce strong safety profile consistent with previous trials of ONS-5010 ophthalmic bevacizumab and with prior published data on ophthalmic use of bevacizumab.

### ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Development Updates

Outlook Therapeutics' wet AMD clinical program for ONS-5010 for the planned BLA submission consists of three clinical trials, NORSE ONE, NORSE TWO, and NORSE THREE, all of which have been completed. In early August, Outlook Therapeutics reported positive top-line data from its NORSE TWO pivotal Phase 3 clinical trial. In NORSE TWO, ONS-5010 achieved statistically significant and clinically relevant primary endpoint results with 41.7% of subjects gaining at least 15 letters of best corrected visual acuity (BCVA). Additionally, key secondary endpoint results were achieved including an average gain of 11.2 letters of BCVA from baseline to month 11. In November 2021, these positive results were also reported at the Retina Subspecialty Day at the AAO 2021 Annual Conference, together with the remaining secondary endpoints, with 56.5% of ONS-5010 subjects gaining  $\geq 10$  letters of vision and 68.5% of ONS-5010 subjects gaining  $\geq 5$  letters of vision. ONS-5010 was also found to be safe and well tolerated in the NORSE TWO trial.

With the registration clinical trials completed, Outlook Therapeutics plans to submit a new BLA under the Public Health Service Act (PHSA) 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved as planned in the first quarter of calendar 2023, it is expected to result in 12 years of marketing exclusivity for ONS-5010 as the first and only ophthalmic formulation of bevacizumab approved by the FDA to treat wet AMD.

Source: Company reports.

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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

### 2<sup>nd</sup> Registration Trial



**Trial Highlights:**

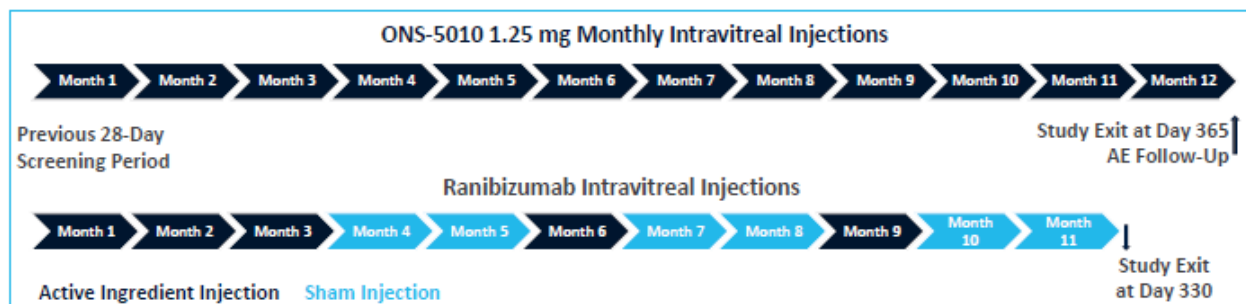
- Randomized masked controlled trial
- ONS-5010 (bevacizumab-vikg) vs LUCENTIS® (ranibizumab)
- 228 patients enrolled
- Trial conducted in the United States
- Trial arms included >95% treatment-naïve patients
- Safety & efficacy data support planned U.S. BLA submission in calendar Q1 2022

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

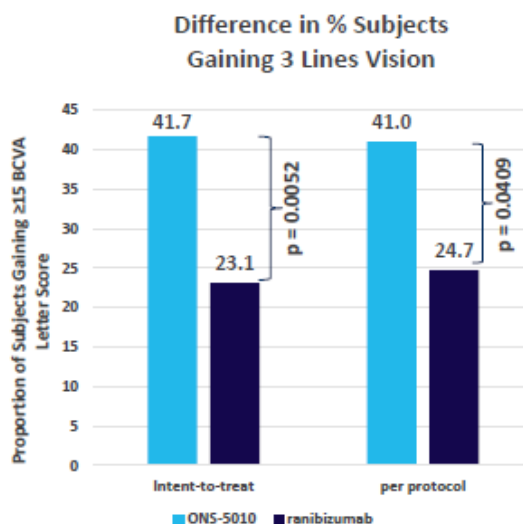
- Active, primary CNV due to wet AMD
- Treatment-naïve
- BCVA: 20/50 – 20/320

#### Key Study Outcomes

- Proportion of subjects who gain  $\geq 15$  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<sup>1</sup>

Characteristic	Statistic	ONS-5010 (n=113)	Ranibizumab (n=115)
<b>Intent-to-Treat Pop.</b>			
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	
<b>Per Protocol Pop.</b>			
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



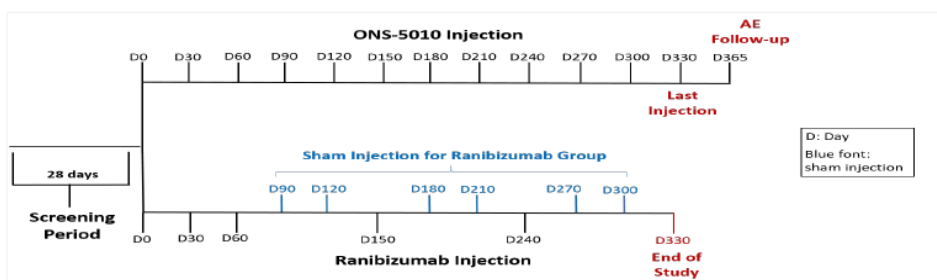
ONS-5010 (bevacizumab-vikg) administered monthly X 12



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 pre-filled syringe
- Enrolling ~120 subjects with visual impairment due to retinal disorders
  - Wet AMD
  - BRVO
  - DME

Source: Company reports.

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

 Source: <https://bigcharts.marketwatch.com/>
**Exhibit 15: Consensus Expectations (as of February 15, 2022)**

	Revenue (mil)			EPS	
	2022E	2023E		2022E	2023E
Q1 Dec	\$0A		Q1 Dec	\$(0.08)A	
Q2 Mar	\$0E		Q2 Mar	\$(0.06)E	
Q3 Jun	\$0E		Q3 Jun	\$(0.07)E	
Q4 Sep			Q4 Sep		
Total	\$0E	\$55E	Total	\$(0.27)E	\$(0.16)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-19	Mar-20	Jun-20	Sep-20	2020	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
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
<b>Total Revenue</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.5</b>	<b>1.0</b>	<b>2.5</b>	<b>4.0</b>
<u>Cost of Revenues</u>					<u>0.0</u>					<u>0.0</u>					<u>0.0</u>					<u>0.0</u>
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	0.5	1.0	2.5	4.0
Research and development	5.8	4.4	8.5	7.6	26.3	11.9	8.5	8.5	9.9	39.0	9.9	8.5	6.0	5.0	29.4	4.0	5.0	5.0	5.0	19.0
General and administrative	2.3	2.0	3.3	2.4	10.0	2.2	4.1	2.9	3.5	12.8	3.3	3.5	4.5	6.0	17.3	7.0	7.0	7.0	7.0	28.0
Restructuring and other	0.4	0.1	0.0	0.0	0.5					0.0					0.0					0.0
Total operating expenses	8.2	6.8	11.9	10.0	36.8	14.2	12.6	11.5	13.4	51.7	13.1	12.0	10.5	11.0	46.6	11.0	12.0	12.0	12.0	47.0
<b>Operating income (loss)</b>	<b>(8.2)</b>	<b>(6.8)</b>	<b>(11.9)</b>	<b>(10.0)</b>	<b>(36.8)</b>	<b>(14.2)</b>	<b>(12.6)</b>	<b>(11.5)</b>	<b>(13.4)</b>	<b>(51.7)</b>	<b>(13.1)</b>	<b>(12.0)</b>	<b>(10.5)</b>	<b>(11.0)</b>	<b>(46.6)</b>	<b>(11.0)</b>	<b>(11.5)</b>	<b>(11.0)</b>	<b>(9.5)</b>	<b>(43.0)</b>
Interest income (expense)	(0.6)	(0.7)	(0.4)	(0.0)	(1.8)	(0.2)	(0.3)	(0.3)	(0.3)	(0.9)	(0.4)	(1.0)	(1.0)	(1.0)	(3.4)	(1.0)	(1.0)	(1.0)	(1.0)	(4.0)
Other income (expense)	(9.7)	(10.0)	6.0	9.1	(13.5)	(0.1)	(0.2)	(0.5)	0.3	(0.5)	(1.0)				(1.0)					0.0
Income before income taxes	(18.5)	(17.5)	(6.3)	(9.9)	(52.1)	(14.5)	(13.1)	(12.2)	(13.4)	(53.2)	(14.5)	(13.0)	(11.5)	(12.0)	(51.0)	(12.0)	(12.5)	(12.0)	(10.5)	(47.0)
Income taxes			(3.3)	(0.0)	(3.3)		0.0		0.2	0.2		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss)	(18.5)	(17.5)	(3.0)	(9.9)	(48.9)	(14.5)	(13.1)	(12.2)	(13.6)	(53.4)	(14.5)	(13.0)	(11.5)	(12.0)	(51.0)	(12.0)	(12.5)	(12.0)	(10.5)	(47.0)
Nonrecurring/noncash adjustments	10.2	11.0	(6.9)	0.8	15.1					0.0					0.0					0.0
<b>Net income (pro forma)</b>	<b>(8.2)</b>	<b>(6.4)</b>	<b>(10.0)</b>	<b>(9.2)</b>	<b>(33.8)</b>	<b>(14.5)</b>	<b>(13.1)</b>	<b>(12.2)</b>	<b>(13.6)</b>	<b>(53.4)</b>	<b>(14.5)</b>	<b>(13.0)</b>	<b>(11.5)</b>	<b>(12.0)</b>	<b>(51.0)</b>	<b>(12.0)</b>	<b>(12.5)</b>	<b>(12.0)</b>	<b>(10.5)</b>	<b>(47.0)</b>
EBITDA																				
Shares, Basic	29.9	47.9	90.8	124.0	72.6	121.7	150.7	168.4	175.3	152.7	188.2	225.0	225.1	225.2	215.9	225.2	225.3	225.4	225.5	225.4
Shares, Diluted	29.9	47.9	90.8	124.0	72.6	121.7	150.7	168.4	175.3	152.7	188.2	225.0	225.1	225.2	215.9	225.2	225.3	225.4	225.5	225.4
EPS Basic (Pro forma)	(\$0.28)	(\$0.13)	(\$0.11)	(\$0.07)	(\$0.47)	(\$0.12)	(\$0.09)	(\$0.07)	(\$0.08)	(\$0.35)	(\$0.08)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.24)	(\$0.05)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.21)
EPS Diluted (Pro forma)	(\$0.28)	(\$0.13)	(\$0.11)	(\$0.07)	(\$0.47)	(\$0.12)	(\$0.09)	(\$0.07)	(\$0.08)	(\$0.35)	(\$0.08)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.24)	(\$0.05)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.21)
<b>Margins</b>																				
Gross margin	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	100%	100%	100%	#DIV/0!	100%	100%	100%	100%	100%
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!	1000%	500%	200%	475%
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!	1400%	700%	280%	700%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-2300%	-1100%	-380%	-1075%
Tax rate, GAAP	0%	0%	52%	0%	6%	0%	0%	0%	-1%	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	-2500%	-1200%	-420%	-1175%
<b>Y/Y % change</b>																				
Total Revenue	-100%	-100%	-100%	-100%	-100%	#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	-100%	-100%	-100%	-100%	-100%	#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	-31%	-33%	93%	70%	11%	104%	95%	1%	30%	48%	-17%	0%	-30%	-50%	-25%	-59%	-41%	-17%	0%	-35%
General and administrative	-20%	6%	79%	-14%	6%	-4%	109%	-11%	47%	28%	46%	-15%	54%	71%	35%	114%	100%	56%	17%	62%
Operating income (loss)	-20%	-12%	110%	-21%	1%	73%	87%	-3%	34%	40%	-7%	-5%	-8%	-18%	-10%	-16%	-4%	5%	-14%	-8%
Net income (loss)	87%	55%	-34%	-3%	36%	-22%	-25%	305%	37%	9%	0%	-1%	-6%	-12%	-4%	-17%	-4%	4%	-13%	-8%
EPS Diluted (Pro forma)	-61%	-77%	-54%	-40%	-62%	-57%	-35%	-34%	5%	-25%	-35%	-34%	-29%	-31%	-32%	-31%	-4%	4%	-13%	-12%

Source: Company reports and Ascendant Capital Markets estimates.

**Outlook Therapeutics, Inc.**

Balance Sheet (\$ mils)	Dec-19	Mar-20	Jun-20	Sep-20	Dec-20	Mar-21	Jun-21	Sep-21	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23
Fiscal Year End: September 30	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
<b>Assets</b>																
Cash and cash equivalents	1.3	4.7	24.0	12.5	5.6	37.2	19.7	14.5	70.2	58.4	48.2	37.7	26.9	15.7	4.9	(4.3)
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	5.2	4.8	4.3	5.4	5.5	6.6	12.2	7.0	7.3	7.3	7.3	7.3	7.3	7.3	7.3	7.3
Total current assets	6.5	9.5	28.2	17.9	11.0	43.8	31.9	21.5	77.5	65.7	55.5	45.0	34.2	23.0	12.3	3.0
Long term securities/investments								0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
Property and equipment, net	0.6	0.5	0.4	0.3	0.3	0.2	0.2	0.2	0.1	0.1	0.0	(0.0)	(0.1)	(0.1)	(0.2)	(0.2)
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	3.3	3.2	1.6	1.5	1.2	1.1	0.8	0.3	0.3	0.3	0.3	0.0	0.0	0.0	0.0	0.0
<b>Total assets</b>	<b>10.4</b>	<b>13.2</b>	<b>30.2</b>	<b>19.7</b>	<b>12.5</b>	<b>45.1</b>	<b>32.9</b>	<b>22.8</b>	<b>78.7</b>	<b>66.9</b>	<b>56.6</b>	<b>45.8</b>	<b>35.0</b>	<b>23.7</b>	<b>12.9</b>	<b>3.6</b>
<b>Liabilities and stockholders' equity</b>																
Accounts payable	2.6	3.3	5.0	2.4	3.3	6.3	2.7	2.2	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Accrued expenses	4.6	7.5	7.3	7.8	6.3	4.5	3.5	1.7	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
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	0.3	0.2	0.2	0.2	0.1	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Short term debt	10.7	11.1	4.1	3.7	0.5	11.2	11.5	0.9	12.7	12.7	12.7	12.7	12.7	12.7	12.7	12.7
<b>Total current liabilities</b>	<b>20.1</b>	<b>23.7</b>	<b>18.5</b>	<b>15.9</b>	<b>12.1</b>	<b>23.9</b>	<b>19.6</b>	<b>6.8</b>	<b>19.9</b>	<b>19.9</b>	<b>19.9</b>	<b>19.9</b>	<b>19.9</b>	<b>19.9</b>	<b>19.9</b>	<b>19.9</b>
Deferred income taxes										0.0	0.0	0.0	0.0	0.0	0.0	0.0
Warrant liabilities	8.3	6.5	0.2	0.1	0.2	0.4	0.4	0.5	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Deferred revenue										0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other long term liabilities	7.4	3.4	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Long term debt	0.0	0.0	0.5	0.9	10.7	0.1		10.9	9.6	9.6	9.6	9.6	9.6	9.6	9.6	9.6
<b>Total other liabilities</b>	<b>15.7</b>	<b>10.0</b>	<b>0.8</b>	<b>1.0</b>	<b>10.9</b>	<b>0.6</b>	<b>0.5</b>	<b>11.5</b>	<b>9.9</b>	<b>9.9</b>	<b>9.9</b>	<b>9.9</b>	<b>9.9</b>	<b>9.9</b>	<b>9.9</b>	<b>9.9</b>
Preferred stock	5.5									0.0	0.0	0.0	0.0	0.0	0.0	0.0
Common stock	0.4	0.9	1.3	1.3	1.3	1.7	1.7	1.8	2.2	3.4	4.7	5.9	7.1	8.3	9.5	10.7
Additional paid-in capital	239.8	255.4	289.5	291.3	292.4	336.2	340.5	345.7	403.9	403.9	403.9	403.9	403.9	403.9	403.9	403.9
Retained earnings	(271.1)	(276.8)	(279.8)	(289.7)	(304.2)	(317.3)	(329.5)	(342.9)	(357.3)	(370.3)	(381.8)	(393.8)	(405.8)	(418.3)	(430.3)	(440.8)
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									0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total stockholders' equity</b>	<b>(25.4)</b>	<b>(20.5)</b>	<b>11.0</b>	<b>2.8</b>	<b>(10.5)</b>	<b>20.7</b>	<b>12.7</b>	<b>4.6</b>	<b>48.8</b>	<b>37.0</b>	<b>26.7</b>	<b>15.9</b>	<b>5.1</b>	<b>(6.2)</b>	<b>(17.0)</b>	<b>(26.2)</b>
<b>Total stockholders' equity and liabil</b>	<b>10.4</b>	<b>13.2</b>	<b>30.2</b>	<b>19.7</b>	<b>12.5</b>	<b>45.1</b>	<b>32.9</b>	<b>22.8</b>	<b>78.7</b>	<b>66.9</b>	<b>56.6</b>	<b>45.8</b>	<b>35.0</b>	<b>23.7</b>	<b>12.9</b>	<b>3.6</b>

**Balance Sheet Drivers**

	Dec-19	Mar-20	Jun-20	Sep-20	Dec-20	Mar-21	Jun-21	Sep-21	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23
	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
<b>Book &amp; Cash Value (per share)</b>																
Book Value per Share (diluted)	-\$0.85	-\$0.43	\$0.12	\$0.02	-\$0.09	\$0.14	\$0.08	\$0.03	\$0.26	\$0.16	\$0.12	\$0.07	\$0.02	-\$0.03	-\$0.08	-\$0.12
Cash per Share (diluted)	\$0.04	\$0.10	\$0.26	\$0.10	\$0.05	\$0.25	\$0.12	\$0.09	\$0.38	\$0.26	\$0.22	\$0.17	\$0.12	\$0.07	\$0.03	-\$0.02
Net cash per Share (diluted)	-\$0.32	-\$0.13	\$0.21	\$0.06	-\$0.05	\$0.17	\$0.05	\$0.02	\$0.26	\$0.16	\$0.12	\$0.07	\$0.02	-\$0.03	-\$0.07	-\$0.11

Source: Company reports and Ascendant Capital Markets estimates

**Outlook Therapeutics, Inc.**

Cash Flow Statement (\$ mils)	Dec-19	Mar-20	Jun-20	Sep-20	2020	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
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
<b>Cash flow from operating activities</b>																				
Net income	(16.6)	(5.7)	(3.0)	(9.9)	(35.2)	(14.5)	(13.1)	(12.2)	(13.4)	(53.2)	(14.5)	(13.0)	(11.5)	(12.0)	(51.0)	(12.0)	(12.5)	(12.0)	(10.5)	(47.0)
Depreciation	0.2	0.2	0.1	0.1	0.6	0.1	0.1	0.0	0.1	0.3	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.2
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	0.0	0.1	0.1	0.0	0.2	0.1	0.2	0.2	0.3	0.9	0.3	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0
Stock comp	0.4	0.3	1.4	0.8	2.8	1.2	1.1	1.2	1.4	4.9	1.2	1.2	1.2	1.2	4.8	1.2	1.2	1.2	1.2	4.8
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	(0.2)	(1.8)	0.1	(0.1)	(2.0)	0.1	0.2	0.0	0.1	0.5	(0.1)	0.0	0.0	0.0	(0.1)	0.0	0.0	0.0	0.0	0.0
Writedowns and impairments	8.1	0.4	(7.3)	0.0	1.2	(0.7)	0.2	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 gains/losses	0.0	0.0	1.9	0.0	1.9	0.0	0.0	0.4	(0.4)	0.0	1.0	0.0	0.0	0.0	1.0	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	(0.1)	0.4	(1.0)	(0.3)	0.0	(1.4)	(5.6)	5.2	(1.7)	(0.3)	0.0	0.0	0.0	(0.3)	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	(0.2)	(0.0)	(0.0)	(0.0)	(0.2)	0.1	0.0	0.0	(0.0)	0.1	(0.0)	0.0	0.0	0.3	0.2	0.0	0.0	0.0	0.0	0.0
Accounts payable	0.3	0.7	(0.1)	(2.4)	(1.5)	0.9	2.7	(3.5)	(0.4)	(0.2)	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0
Accrued expenses	1.1	(1.3)	0.4	0.5	0.7	(0.7)	(1.9)	(1.0)	(1.8)	(5.3)	1.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
Deferred revenue	0.0	0.0	0.0	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	0.0	0.0	0.0
Other liabilities	0.0	0.0	0.0	(0.0)	0.0	(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
<b>Net cash (used in) provided by</b>	<b>(6.7)</b>	<b>(7.1)</b>	<b>(6.0)</b>	<b>(12.1)</b>	<b>(31.8)</b>	<b>(13.3)</b>	<b>(11.7)</b>	<b>(20.2)</b>	<b>(9.0)</b>	<b>(54.3)</b>	<b>(11.0)</b>	<b>(11.7)</b>	<b>(10.2)</b>	<b>(10.5)</b>	<b>(43.5)</b>	<b>(10.7)</b>	<b>(11.2)</b>	<b>(10.7)</b>	<b>(9.2)</b>	<b>(42.0)</b>
<b>Cash flow from investing activities</b>																				
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	(0.9)	0.0	(0.9)	0.0	0.0	0.0	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
<b>Net cash used in investing activi</b>	<b>0.0</b>	<b>0.0</b>	<b>(0.9)</b>	<b>0.0</b>	<b>(0.9)</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Cash flow from financing activities</b>																				
Issuance of debt	0.0	0.0	0.9	0.0	0.9	10.0	0.0	0.0	0.0	10.0	10.0	0.0	0.0	0.0	10.0	0.0	0.0	0.0	0.0	0.0
Repayment of debt	(0.1)	(0.1)	(0.0)	(0.0)	(0.3)	(3.6)	(0.0)	(0.0)	(0.0)	(3.7)	(1.0)	0.0	0.0	0.0	(1.0)	0.0	0.0	0.0	0.0	0.0
Issuance of stock	0.0	9.5	25.3	0.7	35.4	0.0	39.8	2.7	3.8	46.3	57.7	0.0	0.0	0.0	57.7	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	0.1	1.1	0.0	0.0	1.1	0.0	3.6	0.0	0.0	3.6	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
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
<b>Cash provided by (used in) fina</b>	<b>(0.0)</b>	<b>10.4</b>	<b>26.2</b>	<b>0.7</b>	<b>37.2</b>	<b>6.4</b>	<b>43.3</b>	<b>2.7</b>	<b>3.8</b>	<b>56.2</b>	<b>66.7</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>66.7</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
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
<b>Net increase (decrease) in cash</b>	<b>(6.7)</b>	<b>3.3</b>	<b>19.3</b>	<b>(11.4)</b>	<b>4.5</b>	<b>(7.0)</b>	<b>31.6</b>	<b>(17.5)</b>	<b>(5.2)</b>	<b>1.9</b>	<b>55.7</b>	<b>(11.7)</b>	<b>(10.2)</b>	<b>(10.5)</b>	<b>23.2</b>	<b>(10.7)</b>	<b>(11.2)</b>	<b>(10.7)</b>	<b>(9.2)</b>	<b>(42.0)</b>
<b>Beginning cash and equivalents</b>	<b>8.0</b>	<b>1.3</b>	<b>4.7</b>	<b>24.0</b>	<b>8.0</b>	<b>12.5</b>	<b>5.6</b>	<b>37.2</b>	<b>19.7</b>	<b>12.5</b>	<b>14.5</b>	<b>70.2</b>	<b>58.4</b>	<b>48.2</b>	<b>14.5</b>	<b>37.7</b>	<b>26.9</b>	<b>15.7</b>	<b>4.9</b>	<b>37.7</b>
<b>Ending cash and equivalents</b>	<b>1.3</b>	<b>4.7</b>	<b>24.0</b>	<b>12.5</b>	<b>12.5</b>	<b>5.6</b>	<b>37.2</b>	<b>19.7</b>	<b>14.5</b>	<b>14.5</b>	<b>70.2</b>	<b>58.4</b>	<b>48.2</b>	<b>37.7</b>	<b>37.7</b>	<b>26.9</b>	<b>15.7</b>	<b>4.9</b>	<b>(4.3)</b>	<b>(4.3)</b>

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	Rating	Price 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

- 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 Rating System

*Prior to January 31, 2014, ASCM used the following rating system:*

**Strong Buy:** We expect the stock to provide a total return of 30% or more within a 12-month period.

**Buy:** We expect the stock to provide a total return of between 10% and 30% within a 12-month period.

**Neutral:** We expect the stock to provide a total return of between minus 10% and plus 10% within a 12-month period.

**Sell:** We expect the stock to provide a total return of minus 10% or worse within a 12-month period.

**Speculative Buy:** This rating is reserved for companies we believe have tremendous potential, but whose stocks are illiquid or whose equity market capitalizations are very small, often in the definition of a nano cap (below \$50 million in market cap). In general, for stocks ranked in this category, we expect the stock to provide a total return of 50% or more within a 12-month period. However, because of the illiquid nature of the stock's trading and/or the nano cap nature of the investment, we caution that these investments may not be suitable for all parties.

Total return is defined as price appreciation plus dividend yield.

### Ascendant Capital Markets, LLC Distribution of Investment Ratings (as of January 15, 2022)

Rating	Count	Percent	Investment Banking Services Past 12 months	
			Count	Percent
Buy	40	98%	16	40%
Hold	0	0%	0	0%
Sell	1	2%	0	0%
Total	41	100%	16	39%

### **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.

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