

Oct 10, 2024

Healthcare

UNCY

NCM

Rating

Outperform

Unchanged

Current Price

\$0.36

Target Price

\$7.00

Market Capitalization

34.15m

Shares Outstanding

94.36m

Float

79.98m

Institutional Holdings

23.12%

12-Month Low/High

\$0.20/\$1.81

Average 90-Day Volume

2480000

Fiscal Year End

2024-12-31

Unicycive Therapeutics

Results From Phase 1 Trial Testing UNI-494 In Acute Kidney Injury Announced

Phase 1 Trial Tested Safety, Tolerability, and Pharmacokinetics At Multiple Doses.

Unicycive announced completion of the Phase 1 trial testing UNI-494, its product in development for protecting against acute kidney injury. The study was designed to determine tolerability, safety, and pharmacokinetic data for the design of Phase 2. Unicycive plans to present the study at an upcoming scientific meeting.

UNI-494 Is In Development For Preventing Acute Kidney Injury. UNI-494 is a proprietary formulation of nicorandil to protect against the mitochondrial dysfunction and prevent pathways that lead to cell death in acute kidney injury. The proprietary formulation increases the half-life and makes it practical for administration, while maintaining its properties as a nicotinamide ester derivative and selective activator of the ATP-sensitive mitochondrial potassium channel.

Design of The Phase 1 Trial. The Phase 1 study was a double-blind, placebo-controlled study with single ascending dose (SAD) and multiple ascending dose (MAD) portions. The study enrolled 40 healthy volunteers in the SAD portion. Of these, 30 participants were treated with a single dose at levels ranging from 10mg to 160mg. The MAD portion administered UNI-494 to a cohort of 9 participants at 40mg twice daily for five days then a second cohort of 10 participants at 80mg twice daily for five days.

Study Results Provide Dosing and Tolerability Limit Data. Most side effects in the SAD portion were mild. Headache was the most reported side effect, and all participants completed the study. In the MAD portion, the side effects in the 40mg cohort included headache, nausea, and vomiting. Only one participant dropped out of the study. In the 80mg cohort, four participants dropped out and it was not considered well-tolerated.

Conclusion. The Phase 1 trial provides data on the tolerability and pharmacokinetics of UNI-494. We expect the company to discuss the data with the FDA to determine the requirements for Phase 2. Our valuation is based on its phosphate binder, OLC, with its NDA currently under FDA review. We anticipate product approval and launch in mid-2025 and reiterate our Outperform rating and \$7 price target.

Equity Research

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Revenues (\$ MIL)

Period	2023A	2023E	2025E
Q1	0.7	0.0A	0.0E
Q2	0.0	0.0E	0.0E
Q3	0.0	0.0E	43.5E
Q4	0.7	0.0E	74.0E
	0.7	0.0E	117.5E

EPS (\$)

Period	2022A	2024E	2025E
Q1	(0.97)	(0.61)A	(0.30)E
Q2	(0.25)	0.08A	(0.31)E
Q3	(0.13)	(0.28)E	0.27E
Q4	(0.18)	(0.30)E	0.36E
	(1.24)	(1.11)E	0.65E

Valuation Summary

Our valuation of UNCY is based on successful introduction of OLC (oxylanthanum) with Medicare reimbursement under the TDAPA payment regulations. We anticipate introduction in mid-2025, followed by reimbursement approval about 6 months later. We base our valuation on revenues in 2027 discounted to allow for clinical and regulatory risk. These revenues are used to estimate 2027 EPS of \$0.91 per share, which we discount at 30% per year. We apply a multiple of 15X for a price target of \$6 per share.

Unicycive Therapeutics

Closing Price Oct 09, 2024 \$0.36



A - 09/04/2024	Outperform	Target \$6.00	Current \$0.34	B - 08/15/2024	Outperform	Target \$6.00	Current \$0.30
C - 07/11/2024	Outperform	Target \$6.00	Current \$0.48	D - 06/26/2024	Outperform	Target \$6.00	Current \$0.48
E - 05/29/2024	Outperform	Target \$6.00	Current \$0.84	F - 05/14/2024	Outperform	Target \$6.00	Current \$1.09
G - 03/11/2024	Outperform	Target \$6.00	Current \$1.49	H - 02/14/2024	Outperform	Target \$6.00	Current \$1.16

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Noble intends to seek compensation for investment banking services and non-investment banking services (securities and non-securities related) within the next 3 months.

Noble is not a market maker in the Company.

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The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or underserved needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclical, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

ANALYST CREDENTIALS, PROFESSIONAL DESIGNATIONS, AND EXPERIENCE

Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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NOBLE RATINGS DEFINITIONS	% OF SECURITIES COVERED	% IB CLIENTS
Outperform: potential return is >15% above the current price	90%	25%
Market Perform: potential return is -15% to 15% of the current price	10%	3%
Underperform: potential return is >15% below the current price	0%	0%

NOTE: On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

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