# Unicycive Therapeutics

Jun 26, 2024

## The Moment We've Been Waiting For: OLC Pivotal Trial Meets Endpoints For Phosphate Control

Healthcare

**UNCY**

NCM

Rating

**Outperform**

Unchanged

Current Price

**$0.50**

Target Price

**$6.00**

Market Capitalization
**18.80M**

Shares Outstanding
**37.61M**

Float
**14.78M**

Institutional Holdings
**60.54%**

12-Month Low/High
**$0.47/$1.82**

Average 90-Day Volume
**447420**

Fiscal Year End
**12/31/2024**

**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 | (0.32)E |
| Q2 | (0.25) | (0.28)E | (0.33)E |
| Q3 | (0.13) | (0.30)E | 0.28E |
| Q4 | (0.18) | (0.33)E | 0.37E |
| | (1.24) | (1.52)E | 0.68E |

**Side Effect Rates Were Low.** Unicycive announced top-line results from its pivotal study to determine OLC (oxylanthanum carbonate) tolerability, safety, and dosing. The trial met its tolerability and safety endpoints with data that compares favorably with Fosrenol (lanthanum carbonate). Over 90% of the patients were able to lower their serum phosphate to target levels, with 70% reaching target at the lowest dose tested. An NDA filing is expected in 3Q24.

**Low Discontinuation Rate Met The Primary Endpoint.** Tolerability, the rate of discontinuations due to treatment related adverse events (TRAEs), was the primary endpoint. The Evaluable Population of 71 patients had only 1 TRAE discontinuation, a rate of 1.4%. In the Safety Population, a total of 3 patients out of 86 discontinued due to TRAEs, a rate of 3.5%. In total, 5 patients discontinued due to AEs in the Safety Population, 3 were related to OLC and 2 were deemed unrelated to OLC.

**Low TRAEs Met The Secondary Endpoint.** The Secondary Endpoint was safety, defined as TRAEs occurring in greater than 5% of the patients. All 86 patients were included in the Safety Population. The events reported were diarrhea (9%) and vomiting (6%), which compares with Fosrenol of diarrhea (11%), vomiting (9%), and abdominal pain (5%). Most treatment-related AEs were mild to moderate in severity with only 2 AEs reported as severe.

**Potency Was Greater Than Expected.** The study included a 3-week washout period, followed by titration with a starting dose of 1500 mg/day, then increasing dosages every two weeks until phosphate control was achieved. Over 90% of the patients were able to reach the target range, with 70% reaching the range at doses lower than 1500mg/day. The number of patients achieving phosphate control (serum phosphate less than 5.5mg/dl) improved from 59% at the start of the study to 90% at the end of the titration period.

**Moving Forward With An NDA Filing.** These top-line data on the primary and secondary endpoints are being finalized for inclusion in an NDA submission. Several components of the NDA have been prepared, and NDA filing is expected to be ready for filing during 3Q24. We are reiterating our Outperform rating and $6 price target.

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**Summary: Pivotal Trial Achieved Its Safety and Tolerability Endpoints.** Unicycive announced top-line results from its pivotal study for OLC (oxylanthanum carbonate) tolerability, safety, and dosing. Side effects leading to discontinuation, its tolerability endpoint, was met with low discontinuation rate. Side effect rates, its safety endpoint, are lower than Fosrenol (lanthanum carbonate). Over 90% of the patients were able to lower their serum phosphate to target levels, with 70% reaching target at the lowest dose tested. An NDA filing is expected in 3Q24.

**Trial Design**. The trial enrolled 81 patients with chronic kidney disease (CKD) with high phosphate levels (greater than 4.0 mg/dL and less than 7.0 mg/dL for greater than 8 weeks) that were previously controlled with phosphate binders. The objective was to determine the tolerability and safety of clinically effective OLC doses, defined as the dose needed to lower serum phosphate to 5.5 mg/dl or less.

The study began with an initial 3-week washout period to eliminate previous phosphate binders from the body and allow serum phosphate to rise to levels between 5.5 mg/dL and 10.0 mg/dL. Next, patients went through a titration period. For the first two weeks, they received 1500 mg/day OLC (500 mg three times a day with meals or snacks). Dose was increased every two weeks until their serum phosphate was lowered below 5.5 mg/dL or until they reached a maximum dose of 3000 mg/day. Once achieving the target level or maximum dose, patients were maintained at that dose for 4 weeks.

The study enrolled a total of 106 patients, with 86 reaching titration and followed as the Safety Population. Out of these patients, 78 entered the Maintenance period. In this group, 7 patients did not have phosphate control, leaving 71 in the Evaluable Population. This exceeded the planned 60 Evaluable patients.

**Primary Endpoint.** The primary endpoint was tolerability, defined as the discontinuation rate due to treatment related adverse events (TRAEs) during the maintenance period. In the Safety Population, a total of 3 patients out of 86 discontinued due to TRAEs, or 3.5%. The Evaluable Population of 71 patients had only 1 TRAE discontinuation, or 1.4%. In total, 5 patients discontinued due to AEs in the Safety Population, 3 were related to OLC and 2 were deemed unrelated to OLC.

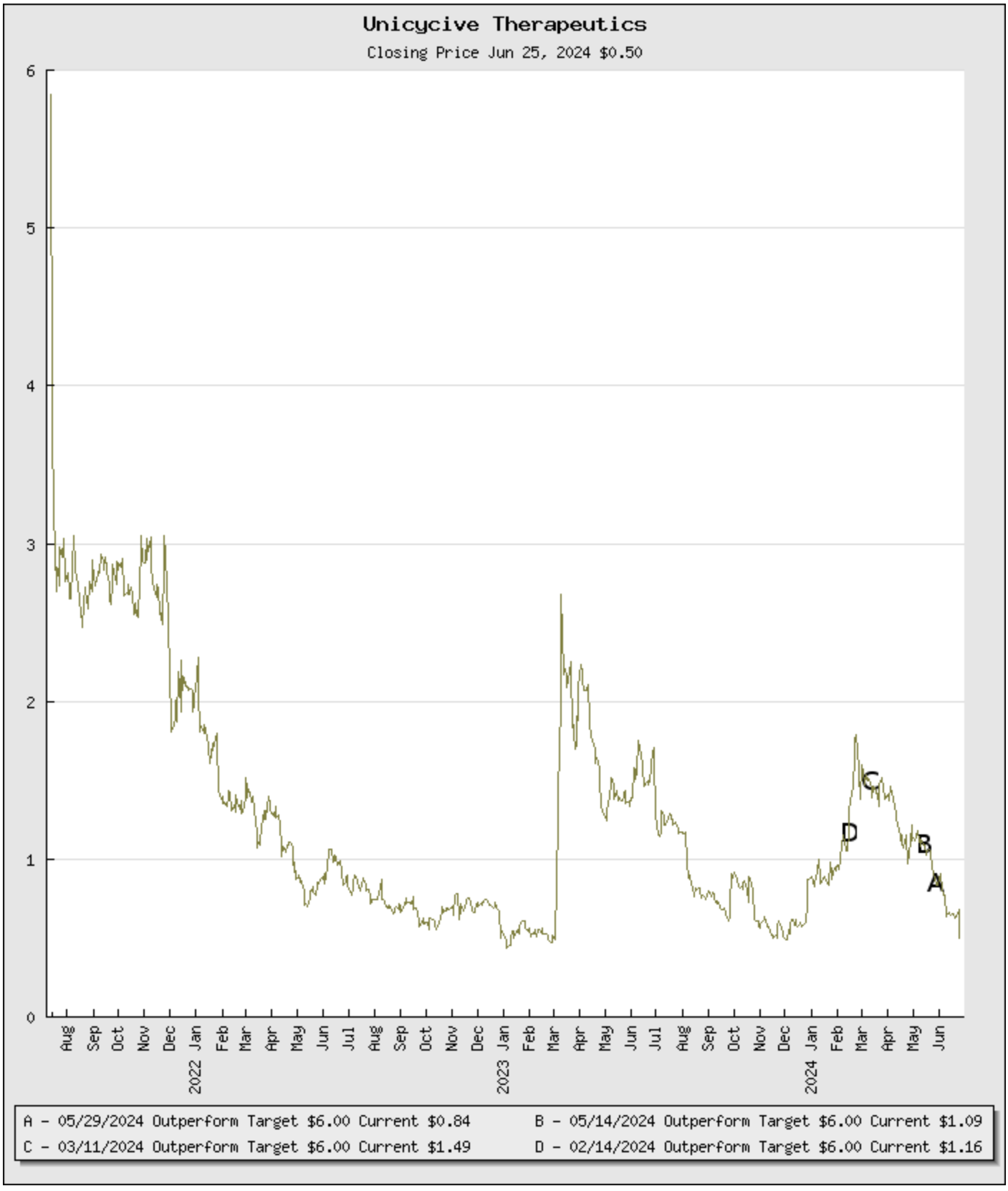
**Secondary Endpoint.** The Secondary Endpoint was safety, defined as TRAEs occurring in greater than 5% of the patients. All 86 patients were included in the Safety Population. The events reported were diarrhea (9%) and vomiting (6%), which compares favorably with the Fosrenol (lanthanum carbonate) product label, showing rates of diarrhea (11%), vomiting (9%), and abdominal pain (5%). Most treatment-related AEs were mild to moderate in severity with only 2 AEs reported as severe.

**Potency Was Greater Than Expected.** The study included a 3-week washout period, followed by titration with a starting dose of 1500 mg/day, then increasing dosages every two weeks until phosphate control was achieved. Overall, 90% of the patients were able to reach the target range, including 70% that received maintenance doses lower than 1500mg/day. The patients achieving phosphate control (serum phosphate less than 5.5mg/dl) improved from 59% at the start of the study to 90% at the end of the titration period.

**Moving Forward With An NDA Filing.** These pivotal trial is the top-line data necessary to file the NDA, and the risk of clinical disappointment has now passed. The final analysis of the primary and secondary endpoints are being prepared for inclusion in an NDA submission. Several components of the NDA have been prepared, and NDA filing is expected to be ready for filing during 3Q24. We had expected the low bill burden to have become a strong marketing advantage, and see that low side effect data as an additional patient benefit for OLC over Fosrenol. We are reiterating our Outperform rating and $6 price target.

**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 Jun 25, 2024 $0.50
6
5
4
3
2
1
0
Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun
2022
2023
2024
A
B
C
D
A - 05/29/2024 Outperform Target $6.00 Current $0.84
B - 05/14/2024 Outperform Target $6.00 Current $1.09
C - 03/11/2024 Outperform Target $6.00 Current $1.49
D - 02/14/2024 Outperform Target $6.00 Current $1.16

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| 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 under-served 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 cyclicality, 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 | 86% | 21% |
| Market Perform: potential return is -15% to 15% of the current price | 14% | 4% |
| 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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