

## Cadrenal Therapeutics

Jun 05, 2024

Healthcare

**CVKD**

NCM

Rating

**Outperform**

Unchanged

Current Price

**\$0.48**

Target Price

**\$4.00**

Market Capitalization

**7.68M**

Shares Outstanding

**16.01M**

Float

**8.02M**

Institutional Holdings

**3.63%**

12-Month Low/High

**\$0.36/\$3.14**

Average 90-Day Volume

**219820**

Fiscal Year End

**12/31/2024**

### Data Presentation From LVAD Study Points Out The Need For Tecarfarin

**Patients With LVADs Need A New Anticoagulant.** A new analysis of anticoagulant regimens from a study in cardiovascular devices patients was presented at the International Society of Heart and Lung Transplantation Annual Meeting. The presentation included data from the ARIES-HM3 study testing anticoagulation with warfarin and aspirin against warfarin alone. We believe the data highlights the need for tecarfarin in left ventricular assist device (LVAD) patients.

**Abbott Has An Interest In LVAD Patient Outcomes.** The ARIES-HM3 study was sponsored by Abbott (ABT, Not Rated), maker of the HeartMate3 LVAD. Patients with these devices cannot take DOAC anticoagulant drugs, leaving them with only warfarin. The study tested warfarin (a vitamin K antagonist, VKA) with and without aspirin. The findings showed lower time in the therapeutic range (TTR) is a predictor of excessive bleeding events, and warfarin patients are typically below target values.

**Tecarfarin Was Cited As A Potential Replacement For Warfarin.** The ARIES-HM3 study chairman pointed out that TTR increases of 10% over the average level of 56% reduces the risk of bleeding events. He also stated that tecarfarin could become an important therapy for LVAD patients and mentioned its “lack of drug-drug interactions or changes in kidney function.” Clinical trials with tecarfarin have shown TTR levels that exceed warfarin and have reached 71.5% TTR.

**Cadrenal Has Orphan Drug Designation For Tecarfarin In VLAD Patients.** Cadrenal has been developing tecarfarin as a replacement for warfarin in several Orphan indications, and has Orphan drug designation for LVAD. It acts through a similar mechanism to warfarin but has shown higher TTR in clinical studies. It also does not need to be titrated for each patient or require routine monitoring, and its route of metabolism prevents drug-drug interactions.

**Conclusion.** Although conducted by Abbott, the ARIES-HM3 data presentation highlighted the need for an effective, reliable anticoagulant and mentioned tecarfarin as a potential replacement for warfarin. We believe this validates Cadrenal's business plan, the market need, and potential for partnership agreements. We reiterate our Outperform and \$4 price target.

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**Refer to the last two pages for Analyst Certification & Disclosures**

#### Revenues (\$ MIL)

Period	2022A	2023A	2024E
Q1	0.0A	0.0A	0.0E
Q2	0.0A	0.0A	0.0E
Q3	0.0A	0.0A	0.0E
Q4	0.0A	0.0A	0.0E
	0.0A	0.0A	0.0E

#### EPS (\$)

Period	2022A	2023E	2024E
Q1	(0.02)A	(0.48)A	(0.05)E
Q2	(0.07)A	(0.09)A	(0.05)E
Q3	(0.13)A	(0.07)A	(0.06)E
Q4	(0.77)A	(0.07)A	(0.07)E
	(0.85)A	(0.62)A	(0.22)E

## Company Profile

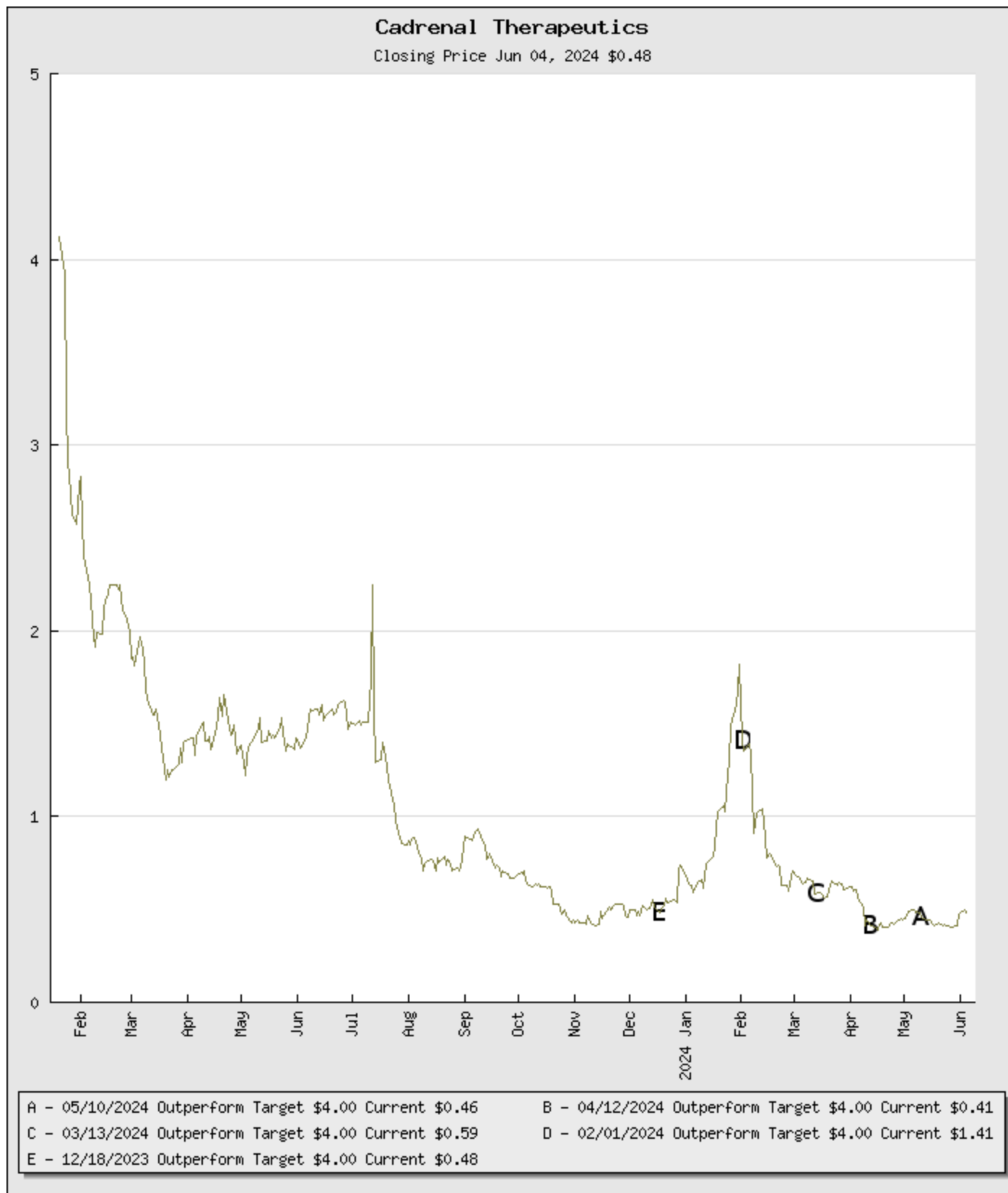
Cadrenal is a biopharmaceutical company developing tecarfarin, an oral anticoagulant for prevention of systemic thromboembolism (blood clots) in patients with rare medical conditions. The lead indication is for patients with end-stage kidney disease (ESKD) with atrial fibrillation (irregular heartbeat, AFib), an orphan indication currently in the Phase 3 design stage. Additional potential pipeline orphan indications include patients with left ventricular assist devices (LVAD) and antiphospholipid syndrome (APS).

## Fundamental Analysis

In our analysis, we give Cadrenal Therapeutics a rating of 4.0 checks out of 5 checks. This falls in the upper half of our "above average" range. Our positive fundamental rating is based on the company's position to introduce a new drug for an unserved orphan market. For further explanation of our fundamental analysis, please refer to the disclosures at the end of this report.

## Valuation Summary

Our models assume the Phase 3 ACTOR-AF trial begins in 2H24. Patient enrollment is expected to take about 12 to 18 months, with the last results in 2H27. We allow additional time for data analysis, filing an application with the FDA, with product launch in 2028. Based on our estimates of the target patient populations, we estimate FY2029 EPS of \$1.31 per share. We discount these earnings at 35% per year and assign a multiple of 15X for a price target of \$4 per share.



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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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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.

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Report ID: 26799