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Cadrenal Therapeutics, Inc. (CVKD-NASDAQ)

CVKD: Designing Phase 3 Trial for CAD-1005 in HIT

Based on our probability adjusted DCF model that takes into account potential future revenues for CAD-1005 in HIT, CVKD is valued at $25.00/share. This model is highly dependent upon continued clinical success of tecarfarin and will be adjusted accordingly based upon future clinical results.

Current Price (05/08/26)	$6.02
Valuation	**$25.00**

OUTLOOK

On May 7, 2026, Cadrenal Therapeutics, Inc. (CVKD) announced financial results for the first quarter of 2026 and provided a business update. The company recently received the official meeting minutes from its 'End-of-Phase 2' meeting with the U.S. Food and Drug Administration (FDA) that included guidance on key aspects of the planned pivotal Phase 3 trial of CAD-1005, the company's 12-lipoxygenase (12-LOX) inhibitor, for the treatment of heparin-induced thrombocytopenia (HIT). The trial will enroll approximately 120 patients in clinical centers worldwide with a primary endpoint, which will be centrally adjudicated, of incidence of new or worsening thrombotic events in patients with Serotonin Release Assay (SRA)-confirmed HIT. There will be one planned interim analysis and, if positive, an NDA filing would be likely in 2029.

SUMMARY DATA

52-Week High	**$16.27**
52-Week Low	**$4.25**
One-Year Return (%)	**-61.16**
Beta	**1.81**
Average Daily Volume (sh)	**65,332**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2026 Estimate	**N/A**
P/E using 2027 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2026	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2027					0.0 E
2028					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	-$2.13 A	-$1.87 A	-$1.31 A	-$1.43 A	-$6.64 A
2026	-$1.04 A	-$1.36 E	-$1.12 E	-$1.30 E	-$4.82 E
2027					-$2.93 E
2028					$2.89 E

WHAT'S NEW

Business Update

Planning for Phase 3 Registration Trial of CAD-1005 in HIT

On April 30, 2026, Cadrenal Therapeutics, Inc. (CVKD) announced an 'End-of-Phase 2' meeting with the U.S. Food and Drug Administration (FDA) in which the agency provided critical guidance on the company's upcoming Phase 3 pivotal trial for CAD-1005 for the treatment of heparin-induced thrombocytopenia (HIT).

The planned Phase 3 trial, which will be the first randomized, double blind, placebo controlled registration trial for HIT, will enroll approximately 120 patients from up to 50 clinical centers worldwide. Patients will be randomized to CAD-1005 or placebo while receiving standard-of-care anticoagulant therapy and treated for up to 14 days during hospitalization. The centrally adjudicated primary endpoint will be the incidence of new or worsening thrombotic events in patients with Serotonin Release Assay (SRA)-confirmed HIT. The trial will also have at least one planned interim analysis. If the trial is positive, we believe this would set up the company for a potential NDA filing in 2029.

Background on HIT

HIT is a severe, immune-mediated prothrombotic disorder triggered by exposure to heparin, an anticoagulant used widely in clinical practice (e.g., surgery, dialysis). It is estimated to occur in approximately 1 in 1500 hospital admissions (Dhakal *et al*., 2018). Data shows that certain variables can increase the risk of developing HIT, including cardiac surgery (Pishko *et al*., 2017) and exposure to unfractionated heparin vs. low molecular weight heparin (Warkentin *et al*., 1995), while a shorter exposure to heparin appears to decrease the risk of developing HIT (Smythe *et al*., 2007).

Diagnosis of HIT uses the "4Ts Score", which is a pre-test scoring system that assesses the probability of HIT (Lo *et al*., 2006). It is calculated as a sum of points from four components: **T**hrombocytopenia, **T**iming of platelet count fall, **T**hrombosis or other sequelae, and o**T**her causes of thrombocytopenia. Laboratory diagnosis of HIT is divided into two steps: an immunoassay and a functional assay. The immunoassay examines for the presence of anti-platelet factor 4 (PF4)/heparin antibodies. If anti-PF4/heparin antibodies are identified, a functional assay is performed to determine if those antibodies are pathogenic. The 14C-serotonin release assay (SRA) is the "gold standard" functional assay and has both high sensitivity (~0.95) and specificity (~0.95) (Warkentin *et al*., 2015).

Management for patients suspected of suffering from HIT includes 1) the avoidance of heparin, indefinitely if possible, and 2) use of non-heparin anticoagulation. The duration of non-heparin anticoagulation will be dictated by the presence of absence of thrombosis. Preferred agents for non-heparin anticoagulation therapy include argatroban and bivalirudin, which can be administered IV, or danaparoid, which can be administered subcutaneously.

For patients who develop HIT, there are a number of potential negative outcomes, including thrombosis, bleeding, amputation, increased risk of hospital stay, and even death. Despite decades of research, no approved therapy directly targets the core immune and platelet activation mechanisms in HIT. Current anticoagulants decrease the risk of coagulation but do not modulate immune-mediated platelet activation, which leaves patients at persistent risk of thrombosis.

CAD-1005 for HIT

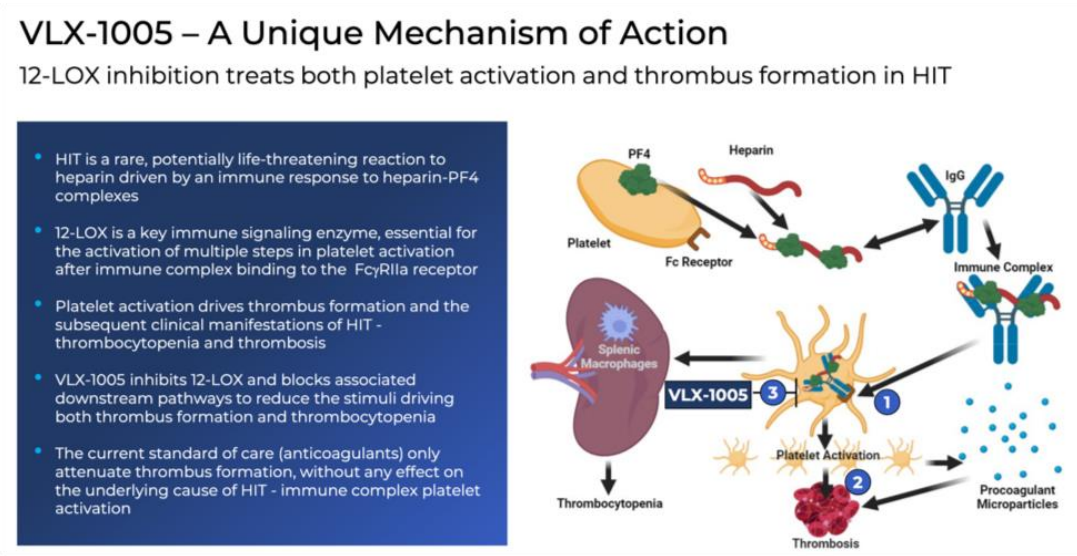
CAD-1005 is a highly selective inhibitor of human 12-LOX and is designed to reduce or prevent platelet activation and the downstream pro-thrombotic cascade in HIT. By inhibiting 12-LOX activity, CAD-1005 reduces the production of proinflammatory and procoagulant 12-LOX metabolites that feed into platelet activation loops. The drug also addresses the immune-driven aspect of HIT pathogenesis, which is the pathway that links immune complexes and platelet hyperactivity, a mechanism wholly distinct from direct

anticoagulation. Lastly, preclinical and Phase 1 clinical trial results indicate there is no increased bleeding signal, which distinguishes CAD-1005 from traditional anticoagulants that reduce the risk of clotting at the cost of an increased risk of bleeding.

12-LOX Biology

12-LOX (encoded by the *ALOX12* gene) catalyzes the oxidation of arachidonic acid to proinflammatory lipid mediators such as 12-hydroxyeicosatetraenoic acid (12-HETE) (Dobrian *et al*., 2011). 12-LOX is expressed in platelets (Contursi *et al*., 2022), however unlike cycolooxygenase-1 (COX-1), which drives thromboxane A2 (TXA2) production and classical platelet aggregation, 12-LOX does not primarily initiate aggregation but instead acts as a potentiator and amplifier of platelet activation. The main bioactive product of 12-LOX, 12-HETE, is a lipid molecule that easily transits cell membranes and can induce its effects both intracellularly, where it promotes oxidative stress, and extracellularly, where it impacts a variety of signaling pathways to modulate inflammatory activity. Importantly, 12-HETE does not cause strong platelet activation alone, it just lowers the activation threshold thus making platelets hyper-responsive (Tamang *et al*., 2024).

In HIT, platelets are activated via FcγRIIa binding of anti-PF4/heparin antibody complexes (Yeung *et al*., 2024). 12-LOX acts downstream of FcγRIIa signaling: FcγRIIa activation leads to phospholipase A2 activation that leads to arachidonic acid release. The arachidonic acid is then converted to 12-HETE, and it is the 12-HETE that feeds back to sustain and amplify the activation signal. By inhibiting 12-LOX, pathologic amplification is selectively inhibited by reducing 12-HETE generation. This targets the disease itself and as opposed to current HIT therapies does not result in a residual thrombotic risk. The high selectivity of CAD-1005 helps to preserve baseline platelet function and allows it to be used with standard anticoagulants while being short-lived and controllable in an in-patient setting.



Source: Cadrenal Therapeutics, Inc.

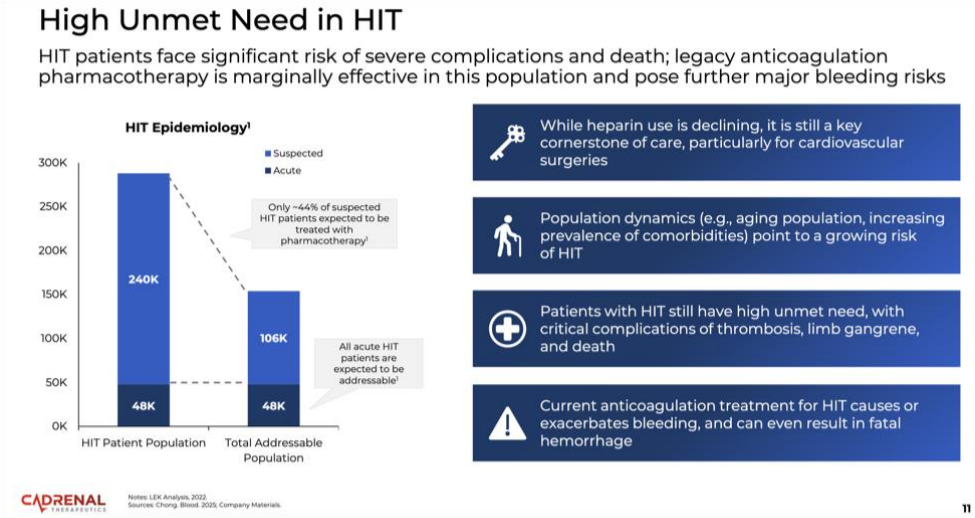
Phase 1 Results

Veralox previously completed a Phase 1a study in healthy volunteers that consisted of a single ascending dose (SAD) and multiple ascending dose (MAD) portion to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of CAD-1005. In that study, CAD-1005 was found to be well tolerated with no reports of serious adverse events (SAEs), dose-limiting toxicities (DLTs) or discontinuations. The data showed a dose linear increase in key PK metrics with no upper limits on tolerability to the maximum dose tested.

Veralox also completed a Phase 1b drug-drug interaction (DDI) study of CAD-1005 in combination with argatroban, an anticoagulant drug approved for the treatment of HIT. The results showed that co-administration of CAD-1005 with argatroban was well tolerated with no SAEs. Analysis of the PK and PD data showed no evidence for DDI.

Market Opportunity

Currently approved HIT treatments focus on non-heparin anticoagulation, which mitigate clot propagation but do not directly modulate immune platelet activation, which is the core driver of HIT pathology. Thus, there is a high residual risk of thrombosis that persists in HIT patients despite anticoagulant therapy. In addition, there are no approved agents that target the immune-mediated platelet activation pathway, thus positioning CAD-1005 as a first-in-class drug. There are approximately 240,000 suspected cases and approximately 48,000 confirmed cases of HIT in the U.S. each year, thus offering a large patient population that could potentially benefit from a safe and effective HIT therapy.



Source: Cadrenal Therapeutics, Inc.

Financial Update

On May 7, 2026, Cadrenal announced financial results for the first quarter of 2026. As expected, the company did not record any revenues for the three months ending March 31, 2026. R&D expenses in the first quarter of 2026 were $0.8 million compared to $1.7 million in the first quarter of 2025. The decrease was primarily due to lower expenses associated with chemistry, manufacturing, and controls (CMC), lower personnel expenses, and decreased stock-based compensation. G&A expenses were $1.7 million in the first quarter of 2026 compared to $2.3 million in the first quarter of 2025. The decrease was primarily due to lower expenses related to being a public company along with decreased personnel, stock-based, and consulting expenses.

As of March 31, 2026, Cadrenal had approximately $2.3 million in cash and cash equivalents. Subsequent to the end of the quarter, the company completed a $2.5 million financing to support near-term development activities. We estimate the company has sufficient capital to fund operations into the fourth quarter of 2026, however it will need to raise additional capital to conduct the planned Phase 3 CAD-1005 trial. The company currently has approximately 2.9 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 4.3 million.

Conclusion

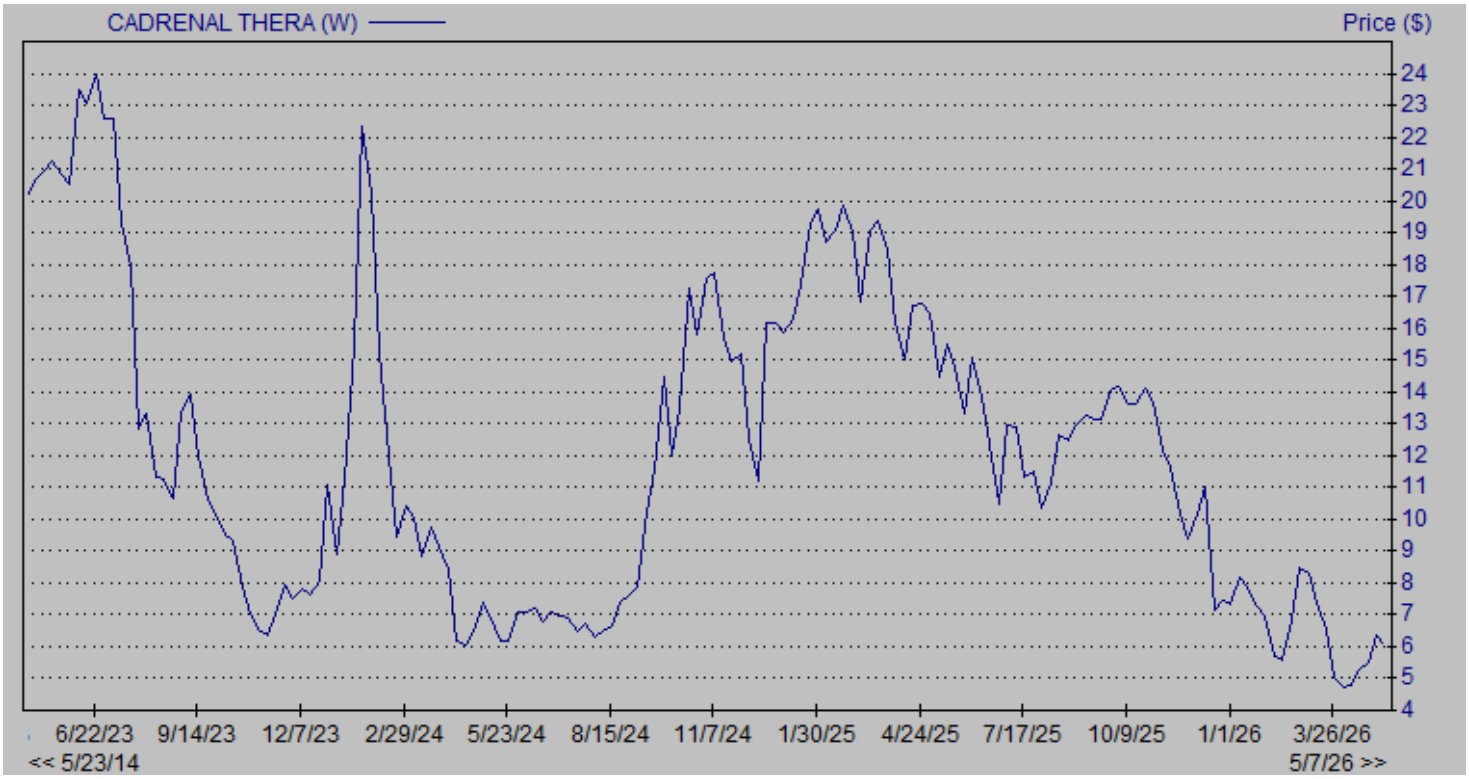
We are glad to see the FDA provided the company with clear guidance as it prepares for the Phase 3 trial of CAD-1005 in HIT. Cadrenal is continuing to evaluate various financing and strategic alternatives to advance the trial, and we anticipate an update once there is a clear plan in place. With no changes to our model, our valuation remains at $25 per share.

PROJECTED FINANCIALS

Cadrenal Therapeutics, Inc.	2025 A	Q1 A	Q2 E	Q3 E	Q4 E	2026 E	2027 E	2028 E
CAD-1005	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
License and other revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$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	$0.0	$0.0	$0.0	$0.0
Research & development	$4.1	$0.8	$1.1	$2.0	$3.0	$6.8	$10.0	$15.0
General & administrative	$9.4	$1.7	$2.5	$2.5	$2.5	$9.2	$10.5	$11.0
Depreciation Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($13.5)	($2.5)	($3.6)	($4.5)	($5.5)	($16.1)	($20.5)	($26.0)
Non-Operating Expenses (Net)	$0.2	$0.0	$0.1	$0.1	$0.1	$0.2	$0.0	$1.0
Pre-Tax Income	($13.2)	($2.5)	($3.5)	($4.5)	($5.5)	($15.9)	($20.5)	($25.0)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Net Income	**($13.2)**	**($2.5)**	**($3.5)**	**($4.5)**	**($5.5)**	**($15.9)**	**($20.5)**	**($26.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($6.64)**	**($1.04)**	**($1.36)**	**($1.12)**	**($1.30)**	**($4.82)**	**($2.93)**	**($2.89)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.0	2.4	2.6	4.0	4.2	3.3	7.0	9.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



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