Cadrenal Therapeutics Reports First Quarter 2026 Financial Results and Provides Phase 3 Development Update on CAD-1005 Following End-of-Phase 2 Meeting with FDA

Official FDA meeting minutes and Phase 2 data provide guidance on the pivotal Phase 3 registration path for CAD-1005 in heparin-induced thrombocytopenia (HIT)

PONTE VEDRA, Fla., May 07, 2026 (GLOBE NEWSWIRE) — Cadrenal Therapeutics, Inc. (Nasdaq: CVKD), a late-stage biopharmaceutical company advancing novel therapies for life-threatening immune and thrombotic conditions, today reported its financial results for the first quarter ended March 31, 2026, and provided a corporate update highlighting continued progress in its CAD-1005 program for HIT. The Company has now received the official minutes from its End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA), which provided guidance on key elements of the planned pivotal Phase 3 registration trial for CAD-1005, Cadrenal's investigational first-in-class 12-lipoxygenase (12-LOX) inhibitor being developed to treat suspected heparin-induced thrombocytopenia (HIT). Based on this feedback and Phase 2 data, Cadrenal plans to advance directly to a randomized, blinded, placebo-controlled Phase 3 study evaluating CAD-1005 added to standard-of-care anticoagulation in patients with HIT.

Recent Highlights

- Received official FDA EOP2 meeting minutes providing guidance on protocol design, study population, dosing, background therapy, exposure, safety database, and the primary endpoint of new or worsening thrombotic events.
- After considering FDA feedback on a pivotal registration study, Cadrenal plans to advance directly to a randomized, blinded, placebo-controlled Phase 3 study evaluating CAD-1005 added to the current standard of care for patients with HIT.
- Planned pivotal Phase 3 study, the first randomized, blinded, placebo-controlled registration trial in HIT, will evaluate CAD-1005 in approximately 120 patients across clinical centers worldwide and is intended to support a projected NDA submission in 2029.
- Primary endpoint, centrally adjudicated, is expected to be the incidence of new or worsening thrombotic events in patients with Serotonin Release Assay (SRA)-confirmed HIT, with at least one planned interim analysis.
- Phase 2 data showed an absolute reduction of more than 25% in thrombotic events when CAD-1005 was added to standard anticoagulant therapy, supporting the continued advancement of CAD-1005 as Cadrenal's near-term development priority.
- Continues to position CAD-1005 as a first-in-class, selective 12-LOX inhibitor and the only treatment in clinical development that targets the underlying immune drivers of HIT, supported by Orphan Drug and Fast Track designations from the FDA and by orphan drug status from the European Medicines Agency.

“With the official EOP2 meeting minutes now in hand, we believe the registration path for CAD-1005 in HIT is clearly defined,” commented Quang X. Pham, Chairman & CEO. “The FDA’s guidance on trial design and the primary endpoint of new or worsening thrombotic events reinforces our confidence in advancing directly to a pivotal Phase 3 study. We believe CAD-1005 has the potential to be the first new therapy for HIT in more than two decades.”

First Quarter 2026 Financial Highlights

Research and development expenses for the quarter ended March 31, 2026, were $0.8 million compared to $1.7 million for the same period in 2025. General and administrative expenses were $1.7 million compared to $2.3 million for the same period in 2025. Total operating expenses were $2.5 million compared to $3.9 million for the same period in 2025. Cadrenal reported a net loss of $2.5 million for the quarter ended March 31, 2026, compared to $3.8 million for the same period in 2025.

As of March 31, 2026, Cadrenal had cash and cash equivalents of $2.3 million. Subsequent to quarter end, on April 1, 2026, the Company completed a $2.5 million financing, providing additional capital to support near-term development activities. The Company continues to evaluate financing and strategic alternatives to support its planned clinical development activities, including the anticipated pivotal Phase 3 trial of CAD-1005 in HIT.

The Company is advancing Phase 3 readiness activities, including protocol finalization, and expects to provide further updates in the coming quarters.

About Cadrenal Therapeutics, Inc.

Cadrenal Therapeutics, Inc. is a late-stage biopharmaceutical company advancing novel therapies for life-threatening immune and thrombotic conditions. Its lead program, CAD-1005, is a first-in-class 12-LOX inhibitor being developed to treat heparin-induced thrombocytopenia (HIT), a deadly immune-mediated thrombotic disorder. CAD-1005 has received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration and orphan drug status from the European Medicines Agency. Second-generation 12-LOX oral therapeutics are also in development for chronic indications.

The Company’s broader pipeline includes tecarfarin, a late-stage oral vitamin K antagonist designed to prevent heart attacks, strokes, and deaths from blood clots in patients requiring chronic anticoagulation, including those with end-stage kidney disease and those with left ventricular assist devices, and frunexian, a parenteral Factor XIa inhibitor intended for use in acute hospital settings.

For more information, visit https://www.cadrenal.com/ and connect with the Company on LinkedIn.

Safe Harbor

Any statements in this press release about future expectations, plans, and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements.” The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements include, without limitation, statements regarding continued progress in its CAD-1005 program for HIT ; plans to advance directly to a randomized, blinded, placebo-controlled Phase 3 study evaluating CAD-1005 added to standard-of-care anticoagulation in patients with HIT; the planned pivotal Phase 3 study being the first randomized, blinded, placebo-controlled registration trial in HIT; the Phase 3 study evaluating CAD-1005 in approximately 120 patients across clinical centers worldwide; the trial supporting a projected NDA submission in 2029; the incidence of new or worsening thrombotic events in patients with Serotonin Release Assay (SRA)-confirmed HIT being the primary endpoint of the trial; the trial having at least one planned interim analysis; continuing to position CAD-1005 as a first-in-class, selective 12-LOX inhibitor and the only treatment in clinical development that targets the underlying immune drivers of HIT; the registration path for CAD-1005 in HIT being clearly defined; and CAD-1005 having the potential to be the first new therapy for HIT in more than two decades. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the ability to raise sufficient capital to continue progress of CAD-1005; the ability to advance directly to a randomized, blinded, placebo-controlled Phase 3 study evaluating CAD-1005 added to standard-of-care anticoagulation in patients with HIT; the ability to successfully design and complete the Phase 3 study and derive the results needed for an NDA submission: and the other risk factors described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025, and the Company’s subsequent filings with the Securities and Exchange Commission, including subsequent periodic reports on Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Any forward-looking statements contained in this press release speak only as of the date hereof and, except as required by federal securities laws, the Company specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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CADRENAL THERAPEUTICS, INC.
BALANCE SHEETS

	March 31, 2026 (unaudited)	December 31, 2025
Assets:		
Current assets:		
Cash and cash equivalents	$ 2,308,137	$ 4,007,789
Interest receivable	5,466	5,096
Prepaid expenses and other current assets	428,071	200,140
Deferred offering costs	113,607	106,342
Total current assets	2,855,281	4,319,367
Property, plant and equipment, net	4,619	5,174
Other assets	2,167	2,167
Total assets	$ 2,862,067	$ 4,326,708
Liabilities and Stockholders' Equity:		
Current liabilities:		
Accounts payable	$ 824,809	$ 650,663
Accrued liabilities	240,143	937,319
Total current liabilities	1,064,952	1,587,982
Total liabilities	1,064,952	1,587,982
Stockholders' equity:		
Preferred stock, $0.001 par value, 7,500,000 shares authorized, no shares issued and outstanding as of March 31, 2026 and December 31, 2025	–	–
Common stock, $0.001 par value; 75,000,000 shares authorized, 2,506,817 shares issued and outstanding as of March 31, 2026; 2,338,127 shares issued and outstanding as of December 31, 2025	2,507	2,338
Additional paid-in capital	43,251,293	41,696,533
Accumulated deficit	(41,456,685)	(38,960,145)
Total stockholders' equity	1,797,115	2,738,726
Total liabilities and stockholders' equity	$ 2,862,067	$ 4,326,708

CADRENAL THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
General and administrative expenses	$ 1,742,315	$ 2,254,577
Research and development expenses	771,508	1,667,882
Depreciation expense	555	5,517
Total operating expenses	2,514,378	3,927,976
Loss from operations	(2,514,378)	(3,927,976)
Other income		

Interest and dividend income	17,838	82,596
Total other income	17,838	82,596
Net loss and comprehensive loss	$ (2,496,540)	$ (3,845,380)
Net loss per common share, basic and diluted	$ (1.04)	$ (2.09)
Weighted average number of common shares used in computing net loss per common share, basic and diluted	2,407,665	1,844,072