

Cadrenal Therapeutics Provides First Quarter 2024 Corporate Update

PONTE VEDRA, Fla., May 9, 2024 /PRNewswire/ — Cadrenal Therapeutics, Inc., (Nasdaq: CVKD), a biopharmaceutical company developing tecarfarin, a late-stage novel oral and reversible anticoagulant (blood thinner) designed to prevent heart attacks, strokes and deaths due to blood clots in patients with rare cardiovascular conditions, today provided a corporate update in connection with the filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024.



Recent Highlights

- In April 2024, received FDA Orphan Drug Designation for tecarfarin for the prevention of thromboembolism and thrombosis in patients with an implanted mechanical circulatory support device, including (left ventricular assist devices (LVADs), right ventricular assist devices (RVADs), collectively known as ventricular assist devices (VADs), biventricular assist device, and total artificial heart.
- Engaged pharmaceutical contract development and manufacturing organizations (CDMOs) to supply active pharmaceutical ingredients (API) and clinical trial materials.
- Appointed Jeff Cole to the newly created position of Chief Operating Officer, responsible for the Company's manufacturing and supply chain operations, intellectual property, commercialization strategies, and supporting partnering activities for tecarfarin.
- Engaged The Sage Group to assist the company in exploring strategic partnerships, co-development, and licensing agreements for tecarfarin.
- Extensive peer-reviewed articles and industry presentations continue to document the need for improved VKA-based anticoagulant therapy. Tecarfarin is the only New Chemical Entity (NCE) that has been developed specifically to address this need.
- Q1 2024 operating expenses (excluding non-cash items) totaled \$1.6 million.
- Cash used in operating activities totaled \$1.8 million during Q1 2024.
- As of March 31, 2024, cash balances were \$6.6 million.

Recent Reports and Presentations

- Quang Pham, Chief Executive Officer, and Douglas Losordo, M.D., Chief Medical Officer of Cadrenal, participated in a company presentation and fireside chat at the Noble Capital Markets Emerging Growth Virtual Healthcare Equity Conference. The webcast can be accessed [HERE](#).

- Douglas Losordo, M.D., Chief Medical Officer of Cadrenal, participated in a fireside chat at the Lytham Partners 2024 Investor Select Conference. The webcast can be accessed [HERE](#).
- Company presented at Biotech Showcase™ 2024, alongside the J.P. Morgan 42nd Annual Healthcare Conference.
- Participated in the Technology and Heart Failure Therapeutics Conference (THT 2024), which is produced by the Cardiovascular Research Foundation (CRF).
- Filed updated corporate slide presentation in April 2024 highlighting the opportunity for tecarfarin.

“The past few months was highlighted by the receipt of the orphan drug designation for tecarfarin by the FDA for the prevention of thromboembolism and thrombosis in patients with an implanted mechanical circulatory support device, including LVADs,” commented Quang Pham, Founder, Chairman and Chief Executive Officer of Cadrenal Therapeutics. “This latest regulatory development significantly enhances optionality regarding the pathways to approval and the marketing exclusivity for tecarfarin. Further, over the last few months, we have seen an increasing number of industry articles and data presentations concurring with our belief that there is a desperate need for a new solution to prevent heart attacks, strokes and deaths due to blood clots in patients with rare cardiovascular conditions who require chronic anticoagulation.”

Pham concluded, “Given the absence of FDA-approved drugs for our targeted indications and our accelerated regulatory pathway with orphan and fast-track designations, tecarfarin is just one pivotal study away from NDA submission and possible approval. We are committed to swiftly advancing tecarfarin through clinical development options to provide these patients with the much-needed solution they deserve.”

ABOUT CADRENAL THERAPEUTICS, INC.

Cadrenal Therapeutics is developing tecarfarin for unmet needs in anticoagulation therapy. Tecarfarin is a late-stage novel oral and reversible anticoagulant (blood thinner) to prevent heart attacks, strokes, and deaths due to blood clots in patients with rare cardiovascular conditions. Tecarfarin has orphan drug and fast-track designations from the FDA for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with end-stage kidney disease (ESKD) and atrial fibrillation (AFib). Tecarfarin also has orphan drug designation for the prevention of thrombosis and thromboembolism in patients with ventricular assist devices (VADs). Cadrenal is also pursuing additional regulatory strategies for unmet needs in anticoagulation therapy for patients with thrombotic antiphospholipid syndrome (APS). Tecarfarin is specifically designed to leverage a different metabolism pathway than the oldest and most commonly prescribed Vitamin K Antagonist (warfarin). Tecarfarin has been evaluated in eleven (11) human clinical trials and more than 1,000 individuals. In Phase 1, Phase 2, and Phase 2/3 clinical trials, tecarfarin has generally been

well-tolerated in both healthy adult subjects and patients with chronic kidney disease. For more information, please visit: www.cadrenal.com.

Safe Harbor Statement

Any statements contained 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.” These statements include statements regarding the receipt of the orphan drug designation for tecarfarin by the FDA, significantly enhancing optionality regarding the pathways to approval and the marketing exclusivity for tecarfarin, there being a desperate need for a new solution to prevent heart attacks, strokes and deaths due to blood clots in patients with rare cardiovascular conditions who require chronic anticoagulation, tecarfarin being just one pivotal study away from NDA submission and possible approval and swiftly advancing tecarfarin through clinical development options to provide patients with the much-needed solution they deserve. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, the Company’s ability to derive the anticipated benefits from the orphan drug designation for tecarfarin, the Company’s ability to advance tecarfarin through clinical development and the other risk factors described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, and the Company’s subsequent filings with the SEC, 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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