



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

August 11, 2022

Quang Pham  
Chief Executive Officer  
Cadrenal Therapeutics, Inc.  
822 A1A North, Suite 320  
Ponte Vedra, FL 32082

**Re: Cadrenal Therapeutics, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted July 15, 2022**  
**CIK No. 0001937993**

Dear Mr. Pham:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 submitted July 15, 2022

Cover Page

1. Please revise the cover page to note that you will be a controlled company under Nasdaq rules and, as a result, may elect not to comply with certain corporate governance requirements.

Prospectus Summary

Our Business , page 1

2. Please revise your disclosure here and upfront in your business section to:
  - clarify how you acquired your product candidate, tecarfarin;
  - identify the "previous owner"; and
  - disclose that the eleven human clinical trials were conducted by third parties.
3. Please remove statements that tecarfarin is a "late-stage" therapy, as these statements imply that your product is farther into the development process than it really is. We note statements to this effect throughout the filing. Additionally, please revise to explain what tecarfarin being "Phase 3- ready" means.
4. Please revise your statement that, in 2019, the FDA "concurred with the recommended design of the remaining pivotal Phase 3 trial for tecarfarin, submitted by the previous owner of tecarfarin" to remove any implication that the FDA has approved your Phase 3 trial design. Specifically, disclose that you have not received FDA input on your current Phase 3 design and that there can be no assurance that the design will be accepted by the FDA. We note risk factor disclosure to this effect on pages 15 and 16. Additionally, disclose whether you are making any changes to the design of the Phase 3 trial for tecarfarin that was submitted by the "previous owner" of tecarfarin and disclose the name of this owner.
5. Please balance your statement that tecarfarin has generally been "well-tolerated in both healthy adult subjects and patients" with disclosure discussing whether any severe adverse events have been observed that have been deemed to be related to tecarfarin and the nature of any such events and the number of patients who experienced them. We note your risk factor disclosure on page 25 that major hemorrhages occurred in 1.6% of the blinded tecarfarin patients randomized in the EMBRACE-AC trial. In addition, we note your disclosure on page 74 that at least one patient died due to intracerebral hemorrhage that was considered to be possibly related to tecarfarin.
6. Please remove statements that: (1) tecarfarin may "potentially eliminate specific side effects while maintaining or improving effectiveness" when compared to the most commonly prescribed drugs for the treatment of thrombosis and AFib and; (2) that tecarfarin "was designed to have the same well-established and reversible VKA mechanism of action as warfarin, but to be free of certain potentially life-threatening clearance and drug-to-drug interaction problems associated with warfarin." These statements imply that your product candidate is safe and effective, which is a determination solely within the authority of the FDA and comparable foreign regulatory authorities. Remove similar statements from pages 58, 59, 64, and 71.

7. Please provide balancing disclosure in the Prospectus Summary concerning the following:
- your history of net losses and limited operating history;
  - the going concern opinion provided by your auditors;
  - that you do not believe that the proceeds from this offering will provide you with sufficient funds to complete the Phase 3 clinical trial for tecarfarin; and
  - that your patents directed to tecarfarin expire in 2024.

Clinical Trials, page 3

8. Please disclose when the Phase 2/3 CLN-505 trial occurred and who sponsored the trial. Additionally, balance your discussion of its results with disclosure that it did not achieve statistical significance on its primary endpoint and the results of the primary analysis showed that tecarfarin was not superior to warfarin as measured by TTR. Similarly revise the discussion of this trial on page 66.

Our Strategy, page 3

9. Please revise the statement that you plan to expand your existing pipeline of "investigational products" to clarify that you currently only have one investigational product or otherwise advise.

Recent Events, page 3

10. Please disclose that you intend to use \$1.8 million of this offering's proceeds to pay HESP LLC pursuant to the terms of the Asset Purchase Agreement and clarify whether this payment will impact the milestone payments that you owe to HESP LLC.

Summary of Risks Associated with Our Business, page 4

11. We note that your summary risk factors are four pages in length. Please revise to limit to two pages and disclose only the principal factors that make an investment in the registrant or offering speculative or risky, as required by Item 105(b) of Regulation S-K.

Risk Factors

Our amended and restated certificate of incorporation and amended and restated bylaws. . . . page 45

12. We note your disclosure that your amended and restated certificate of incorporation and amended and restated bylaws will be in effect upon consummation of this offering. When available, please file both documents as exhibits to the registration statement. Refer to Item 601(b)(3) of Regulation S-K.

Use of Proceeds, page 52

13. Please revise to state how far in the clinical development of tecarfarin you expect to proceed with the offering proceeds. We note your disclosure on page 14 that you will need additional funding to enroll patients and complete the Phase 3 trial.

Business, page 64

14. Your pipeline table on page 66 shows the clinical trial of tecarfarin for mechanical heart valves has completed its Phase 2 trial; however, your disclosure states that the Phase 2 trial has not yet begun to enroll patients. Please reconcile and, if necessary, revise to reduce the length of the arrow to accurately reflect the actual status of your pipeline candidate as of the latest practicable date.

Our Investigational Product Candidate, page 68

15. We note your disclosure on page 69 that warfarin was initially marketed as rat poison. Please explain why this is relevant to an investor's understanding of the current FDA approved uses for warfarin. Relatedly, please provide the basis for your statement that, "due to its side effects, the use of warfarin has decreased during the last decade."

Tecarfarin Clinical Program, page 71

16. We note that you do not disclose any narrative explanation for four of the 11 clinical trials listed in this table (CLN-501, CLN-502, CLN-503, and CLN-509). Please describe the results these trials or explain why you do not believe this information is material. In addition, please update your summary table to disclose who sponsored each study.

Lee's Pharmaceutical Holdings Limited, page 76

17. Please file the LPH License as an exhibit to the registration statement or, alternatively, provide your analysis supporting your belief that such filing is not required. See Item 601(b)(10) of Regulation S-K.

Market Opportunity, page 77

18. We note that you commissioned a 2019 study by Navigant/Guidehouse. Please analyze whether you are required to file a consent pursuant to Rule 436 of the Securities Act and, if necessary, file this consent or otherwise advise. Additionally, please balance your statement concerning your estimated annual U.S. market revenue potential for tecarfarin with disclosure that tecarfarin would first have to receive FDA approval to be sold in the United States.

Summary of Safety and Tolerability of Tecarfarin, page 77

19. This section, including its sub-heading, implies that your product candidates are safe, which is a determination solely within the authority of the FDA and comparable foreign regulatory authorities. For example, it is not appropriate to state that you believe "tecarfarin is at least as safe as warfarin and believe tecarfarin may show improved safety, as measured by bleeding events, as compared to warfarin." Please revise. In addition, we advise you that you may present the objective data from pre-clinical and clinical trials without drawing a conclusion from the results.

Intellectual Property, page 78

20. We note that both of your issued patents directed to tecarfarin expire in 2024 and that the corresponding foreign patents expire in 2025. Please revise your disclosure to explain the material impact, if any, of the patent expiration on your business. We note your risk factor disclosure on page 37 that your "success depends in large part on [y]our ability to obtain and maintain patent protection in the United States and other countries with respect to [y]our proprietary product candidate."
21. We note only footnotes (1) and (2) to your list of U.S. and foreign patents discuss the type of patent protection and which product candidates are covered by each patent. Please revise your disclosure regarding your patent portfolio to clarify the specific product candidate or technology to which each of these patents relate and identify the type of patent protection (e.g., composition of matter, use, or process).

Management, page 89

22. We note that Quang Pham previously served as Espero CEO from 2015 until Espero's "assets were assigned for the benefit of its creditors in July 2020." Please clarify the nature of this assignment. Please provide the disclosures required by Item 401(f) of Regulation S-K or otherwise advise.

Scientific Advisory Board (SAB), page 91

23. Please describe the role or function of the Scientific Advisory Board and whether there are any rules or procedures governing such board. Additionally, please file the Scientific Advisory Board and Consulting Agreement with Dr. Pokorney as an exhibit to the registration statement or, alternatively, provide an analysis supporting your belief that such filing is not required. Refer to Item 601(b)(10) of Regulation S-K.

Certain Relationships and Transactions , page 100

24. Please file the subscription agreements with Quang Pham dated January 25, 2022 and the convertible promissory note with John Murphy dated March 1, 2022 as exhibits to the registration statement or, alternatively, provide an analysis supporting your belief that such filing is not required. Refer to Item 601(b)(10) of Regulation S-K.
25. We note your disclosure that you entered into an agreement with Phamace, LLC, a consulting firm of which your chief executive officer is the sole member. Please update your disclosure to more specifically describe the "services rendered."

Quang Pham  
Cadrenal Therapeutics, Inc.  
August 11, 2022  
Page 6

Material U.S. Federal Income Tax Considerations for Non-U.S. Holders of Our Common Stock,  
page 110

26. Please remove the disclaimer on page 111 indicating that the discussion of material tax considerations are provided "for informational purposes only" and the disclaimer on page 113 that this discussion is "for general information only." These statements imply that investors are not entitled to rely on the disclosure in your registration statement

Exhibits

27. Please revise so that all agreements show the signatures or conformed signatures of all the parties to the agreements. It appears, for example only, that Exhibit 10.7 and 10.8 do not show signatures by all parties to the agreements.

General

28. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Ibolya Ignat at 202-551-3636 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Dillon Hagius at 202-551-7967 or Jason Drory at 202-551-8342 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Leslie Marlow