



DIVISION OF  
CORPORATION FINANCE

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

May 2, 2021

Shaun Bagai  
Chief Executive Officer  
RenovoRx, Inc.  
4546 El Camino Real, Suite 223  
Los Altos, CA 94022

**Re: RenovoRx, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted April 2, 2021**  
**CIK No. 0001574094**

Dear Mr. Bagai:

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 April 2, 2021

Overview, page 3

1. Please revise the Summary to clarify the meaning of scientific or technical terms the first time they are used in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by cholangiocarcinoma, hilar CCA and TIGeR-PaC. Also revise the Business section to explain the terms RECIST criteria and Cmax.
2. Please revise the opening paragraph to provide context and balance to your disclosure that you are a "late-stage" clinical biopharmaceutical company. In this regard we refer to your statement on page 46 that you do not expect to generate any revenue from the sale of products for several years.

3. We refer to your disclosure that your therapy platform, RenovoRx Trans-Arterial Micro-Perfusion, or RenovoTAMP™ utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles. Based on your disclosures, it appears that your clinical work has focused on a single generic drug, namely gemcitabine. Accordingly please revise to clarify, if true, that your clinical work has focused on gemcitabine and clarify that it is a generic drug.
4. We refer to your statements here and elsewhere in your prospectus that your Phase 1/2 and observational registry studies of RenovoGem have demonstrated “safety.” You also state on page 74 that your RR2 observational registry study “further validate[d] the safety and clinical efficacy of the RenovoTAMP procedure” and conclude on page 78 that RenovoTAMP in patients with LAPC “is sufficiently safe” to permit a large Phase 3 study. Determinations of safety and efficacy are within the sole authority of the FDA. Although we note your disclosure that FDA has cleared your RenovoCath delivery system, it is premature for you to suggest that the RenovoTAMP platform or RenovoGem will be determined to be safe and effective. Please revise your prospectus disclosure accordingly.
5. We note your disclosure on page 3 comparing the median overall survival rate of 27.9 months in patients treated with RenovoGem and radiation versus the expected survival rate of 12-15 months in patients receiving IV chemotherapy. Given that you have not conducted head-to-head trials, please expand your disclosure to discuss any known differences in trial protocols, conditions and patient populations that could materially impact the comparability of the trial data presented.
6. We note your disclosure on page 4 that your Phase 1/2 safety study (RR1) enrolled 20 patients with a diagnosis of Stage 3 pancreatic cancer. Please include the number of patients enrolled (or expected to be enrolled) in each of your trials and studies the first time they are referenced on page 3 as well. Please also expand your disclosure of your RR2 observational study to include key inclusion criteria of the 25 patients enrolled in your study, such as their cancer diagnosis.
7. We note your disclosure on page 3 that you “anticipate launching a Phase 2/3 trial to evaluate RenovoGem in your second indication” or HCCA in the first half of 2022. Please revise your disclosure in the Summary to clarify that you have not yet submitted your proposed Phase 2/3 clinical trial for your second indication to the FDA. While we note your reference to the Phase 2/3 trial for the treatment of HCCA throughout the prospectus, we also note disclosure on page 59 of your plans to launch a Phase 2 trial in the first half of 2022. Please revise to reference the Phase 2 trial for your second indication or expand your disclosure on the scope of the combined Phase 2/3 trial in the Summary and elsewhere in the prospectus.
8. Please revise the Summary to provide clear descriptions of the primary endpoints for each of the programs discussed, and where applicable, whether the product candidate met such primary endpoints. Please also disclose any reported serious adverse events.

Cautionary Statements Concerning Forward-Looking Statements, page 37

9. We note that Section 21E of the Securities Exchange Act of 1934 and Section 27A of the Securities Act of 1933 do not apply to initial public offerings. Accordingly, please revise to remove these references.

Use of Proceeds, page 39

10. Please revise your disclosure to include each of the programs listed in your Summary pipeline table and also indicate how far the proceeds from the offering will allow you to proceed with continued development of each program listed.

Business, page 56

11. We note your disclosure on page 57 and your website that your Scientific Advisors make up your Advisory Board. If material, please include disclosure that describes the role or function of your Scientific Advisors, whether there are any rules of procedures governing this board, as well as how the Scientific Advisors are compensated.

Research and Development Pipeline, page 58

12. We refer to the second row in your pipeline table under the heading “Cholangiocarcinoma.” In light of your disclosure that you are not intending to launch the Phase 2 trial until the first half of 2022, please shorten the arrow in the second row to show that you have not yet initiated the Phase 2 trial.

Our Platform: RenovoTAMP, page 60

13. Please revise to discuss briefly your development of RenovoCath. In this regard, please revise to explain when you commenced work designing the delivery system, when you conducted the studies referenced in this section and when the product received 510(k) clearance.

Observational Registry Study RR2, page 74

14. We note your disclosure on page 76 that Figure 16 measures the median survival rate starting from when patients were given their first IA gemcitabine therapy, while Figure 17 measures the overall survival rate of the patients. Please revise the description of Figure 17 to identify the starting point from when the survival rate was measured from (such as from the date of diagnosis or the start of treatment).

Clinical Development of RenovoGem in HCCA, page 81

15. Please revise the statement that you plan to perform a definitive Phase 2/3 trial with early discussion with the FDA for approval of your indication based on this study. This statement is not appropriate given that safety determinations and approvals are in the purview of the FDA.

Intellectual Property, page 83

16. We refer to the second through fifth rows in Table 3 on page 84. Please revise to identify the type of patent protection for the specified patents. With respect to the four pending patents, please expand your disclosure to include the date that each of these patent applications were submitted, whether the patents are owned or licensed, the technology or product group each patent relates to, the type of patent protection and their expected expiration date.

Manufacturing and Supply, page 85

17. We note your disclosure of the material terms of your agreement with Medical Murray, your single-source contract manufacturer for RenovoCath. Please also file the agreement as an exhibit to the registration statement or explain to us why you believe you are not required to do so under Item 101(h)(4) of Regulation S-K.

Directors and Executive Officers, page 91

18. We note that your disclosure on page 101 identifies Kamran Najmabadi as your founder and as a technical engineering advisor, and further indicates that he holds a 44.6% beneficial ownership stake in the company. Accordingly, please revise the prospectus, where appropriate, to discuss Mr. Najmabadi's role in founding the company and describe his current advisory role, including any compensation derived from his services.

Exclusive Forum, page 104

19. We note that your forum selection provision identifies the State of Delaware as the exclusive forum for certain litigation, including any "derivative action." Please disclose whether this provision applies to actions arising under the Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. If this provision does not apply to actions arising under the Exchange Act, please also ensure that the exclusive forum provision in the governing documents states this clearly, or tell us how you will inform investors in future filings that the provision does not apply to any actions arising under the Exchange Act.

Related Party Transactions, page F-27

20. We note your disclosure of the consulting agreement you have entered into with your Chief Medical Officer. Please revise to disclose your consulting agreement with your Chief Financial Officer as well. We refer to your disclosure on page 96.

Shaun Bagai  
RenovoRx, Inc.  
May 2, 2021  
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General

21. Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

You may contact Kristin Lochhead at (202) 551-3664 or Al Pavot at (202) 551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at (202) 551-7439 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Jeffrey Fessler, Esq.