



DIVISION OF
CORPORATION FINANCE

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

May 26, 2021

Mir Imran
President and Chief Executive Officer
Rani Therapeutics Holdings, Inc.
2051 Ringwood Avenue
San Jose, California 95131

Re: Rani Therapeutics Holdings, Inc.
Draft Registration Statement on Form S-1
Submitted April 27, 2021
CIK No. 0001856725

Dear Mr. Imran:

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 27, 2021

Cover Page

1. To facilitate an understanding of your corporate structure and the use of proceeds, please revise the prospectus cover page to explain that you will be implementing an "Up-C" structure in connection with this offering and clearly identify both the holding and the operating companies.
2. Please revise the disclosure of your controlled company status on the prospectus cover page to include the amount of the voting power the controlling shareholder will own following the completion of the offering and, if true, that you do not intend to comply with certain corporate governance requirements.

Prospectus Summary, page 1

3. We note your disclosure that RT-110 may be able to meet the need for a more effective treatment for hypoparathyroidism. As safety and efficacy determinations are solely within the authority of the FDA and comparable regulatory bodies, it is inappropriate to state or imply that your product candidates are safe or effective. Please revise this statement and similar statements throughout your prospectus that suggest the safety and efficacy of your candidates. Where you deem appropriate, you may present objective data without including your conclusions related to safety or efficacy. By way of example only, we note the following statements:
 - your trial results "validate the utility of the RaniPill capsule to deliver octreotide orally" and "validate the utility of the RaniPill capsule for other biologics"
 - administration of adalimumab via the RaniPill capsule is "an effective alternative to painful SC injections"
 - the RaniPill capsule "can be safely consumed on a daily basis for seven days" and "its remnants can be safely excreted without any complications"
4. We note your disclosure that your plan to create a Master File for the RaniPill capsule "will serve to significantly de-risk the regulatory pathway for biologic drugs delivered via the RaniPill capsule." Please remove this statement and any other statements that imply that you will be successful in mitigating risk associated with drug development.

Risks Associated with Our Business, page 10

5. Please revise your prospectus summary to discuss that your clinical trials to date have been conducted outside the U.S. Please also expand your disclosure in the sixth bullet point to highlight the risk that your clinical trials have been conducted outside the U.S. and that if the FDA or comparable regulators do not accept earlier preclinical and clinical data you may need to conduct additional clinical trials, as discussed on page 39.

Market, Industry and Other Data, page 94

6. Your statements that (i) you have not separately verified the data from third parties, (ii) your internal research has not been verified by any third party, and (iii) investors are cautioned not to give undue weight to any such information, projections and estimates, may imply an inappropriate disclaimer of responsibility with respect to such information. Please either delete these statements or specifically state that you are liable for the information related to the market and industry data and your internal research.

Use of Proceeds, page 95

7. Please revise your use of proceeds disclosure as follows:
- Revise to state the approximate amount of offering proceeds intended to be used for each of your intended uses of proceeds. In addition, provide an estimate of how far in the clinical development process for each of your product candidates the allocated proceeds of the offering will enable you to reach. Refer to Item 504 of Regulation S-K.
 - It appears from your disclosure that the proceeds from the offering will not be sufficient to fund development of your product candidates through regulatory approval and commercialization. Please disclose the amounts and the sources of other funds needed to reach regulatory approval and commercialization for each product candidate. Refer to Instruction 3 to Item 504 of Regulation S-K.
 - With respect to the repayment of your outstanding PPP Loan with Comerica Bank, revise to disclose the interest rate and maturity of such indebtedness. If the debt under the PPP Loan was incurred within one year, also describe the use of the proceeds of such indebtedness other than short-term borrowings used for working capital. Refer to Instruction 4 to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Research and Development Expenses, page 126

8. We note the discussion on page 123 that you do not track research and development costs on a project-by-project basis. Please revise the filing to disclose and discuss research and development costs by the nature of expense for each period presented.

Liquidity and Capital Resources, page 127

9. Please revise your liquidity disclosures to address the fact that you are a holding company with no operations of your own and that you depend on your subsidiaries for cash. Please also disclose any restrictions or other factors that could inhibit your subsidiaries' ability to pay dividends or make other distributions to the parent company. Please refer to Item 303(a)(1) of Regulation S-K.
10. Please revise your liquidity disclosures to address the Tax Receivable Agreement, disclosing your estimates of potential future payments. In this regard, we note your statements that you expect the future payments under the agreement could be significant. This information should also be disclosed in the Summary and in the relevant risk factors.

Business

Core Programs, page 155

11. We note your disclosure that you commissioned a market research study and your references to your survey conducted by Frost & Sullivan. With respect to the statements in your prospectus that are based on such data, please revise to clarify whether such

statements are statements of the third party or statements of the registrant. If your disclosure attributes a statement to the third party, or if you commissioned any other market or industry data cited in the prospectus, please revise your filing to identify such third party and file a consent from such third party. Please see Securities Act Rule 436 and Question 233.02 of the Securities Act Rules Compliance and Disclosure Interpretations.

Evaluation Agreements, page 160

12. For each of the Novartis Evaluation Agreement, Takeda Evaluation Agreement and CCHN Agreement, please revise to disclose the duration of the agreement, the aggregate potential future payments to be paid or received, and the termination provisions. In addition, please expand your disclosure to describe more clearly the nature and scope of the intellectual property transferred under these agreements and each party's rights and obligations. Please also file these agreements as exhibits or provide your analysis identifying how you determined that these agreements did not need to be filed as exhibits pursuant to Item 601(b)(10) of Regulation S-K.
13. We note your disclosure on page 201 regarding your Intellectual Property Agreement and Exclusive License Agreement with InCube Labs, LLC. Please disclose here the material terms and duration of each agreement, any aggregate amounts paid or received to date, and any aggregate future potential payments to be paid or received under each agreement. With respect to the Exclusive License Agreement, please also revise to clarify when the last-to-expire patent that is licensed to you is expected to expire.

Intellectual Property, page 162

14. Please revise your intellectual property disclosure to disclose for each material patent and patent application the specific products or technologies to which such patents or patent applications relate. Also clearly describe on an individual basis the type of patent protection granted for each product or technology (composition of matter, use, or process), whether the patents are owned or licensed, the expiration of each patent held, and the jurisdiction, including any foreign jurisdiction, of each pending or issued patent. In this regard, it may be useful to provide this disclosure in tabular form to support the narrative already included.

Executive Compensation

New Employment Agreements, page 190

15. Please file a form of the new employment agreement(s) to be entered into with each of the named executive officers, to be effective upon the closing of the offering.

Mir Imran
Rani Therapeutics Holdings, Inc.
May 26, 2021
Page 5

General

16. 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.
17. Please revise your pipeline table and other graphics throughout your filing to ensure that the text in all graphics, including footnotes, is legible.

You may contact Tracey McKoy at 202-551-3772 or Kevin Kuhar at 202-551-3662 if you have questions regarding comments on the financial statements and related matters. Please contact Kasey Robinson at 202-551-5880 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Josh Seidenfeld