United States securities and exchange commission logo

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.

Mir Imran

Rani Therapeutics Holdings, Inc.

May 26, 2021

Page 2

Prospectus Summary, page 1

1. 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"

1. 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

1. 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

1. 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,

FirstName LastNameMir Imran

may imply an inappropriate disclaimer of responsibility with respect to such information.

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PleaseTherapeutics

either delete Holdings,

these statements Inc.

or specifically state that you are

liable for the

May 26,information

2021 Pagerelated

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to the market and industry data and your internal

research.

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Rani Therapeutics Holdings, Inc.

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May NameRani Therapeutics Holdings, Inc.

26, 2021

May 26,

Page 3 2021 Page 3

FirstName LastName

Use of Proceeds, page 95

1. 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

1. 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

1. 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.

1. 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

1. 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

Mir Imran

Rani Therapeutics Holdings, Inc. May 26, 2021

Page 4

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

1. 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

FirstName Agreements,

LastNameMir Imran page 190

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15. NameRani

Please Therapeutics

file a form of the new Holdings,

employmentInc.agreement(s) to be entered

into with each of the

named

May 26, 2021 executive

Page 4 officers, to be effective upon the closing of the offering. FirstName LastName

Mir Imran

FirstName LastNameMir Imran

Rani Therapeutics Holdings, Inc.

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May NameRani Therapeutics Holdings, Inc.

26, 2021

May 26,

Page 5 2021 Page 5

FirstName LastName

General

1. 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.

1. 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