

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

October 5, 2018

Milton Werner President and Chief Executive Officer Inhibikase Therapeutics, Inc. 3350 Riverwood Parkway SE, Suite 1900 Atlanta, GA 30339

Re: Inhibikase Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted August 31, 2018
CIK No. 0001750149

Dear Dr. Werner:

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.

<u>Draft Registration Statement on Form S-1</u>

Our Programs, page 1

- 1. Please delete the statement that IkT-001Pro is a "near-term commercial opportunity." The statement inappropriately assumes the successful result of your clinical trials and FDA approval. Additionally, clarify whether the FDA has made a final determination that a single 12-24 patient trial is sufficient to support the submission of an NDA.
- 2. Please describe the significance of three columns under the Biomarker column. For example, please tell us how you are "Validating" clinical target engagement prior to initiating clinical development and the meaning of "Can be used for patient selection."

Overview, page 1

3. Please balance your disclosure in the Prospectus Summary regarding the near-term commercial opportunity you have with IkT-001Pro by indicating your current stage of development, rather than indicating when you anticipate you will complete the clinical development, and whether you have filed an IND for IkT-001Pr. Please also clarify that validating the pharmacology advantage will require a post-approval study to demonstrate comparative efficacy and safety results to Imatinib.

<u>Implications of Being an Emerging Growth Company and a Smaller Reporting Company</u>, page 6

4. 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.

Some intellectual property may have been discovered through governemt funded programs, page 48

5. Please identify your product candidates that are dependent on patent rights subject to "march in" rights.

Use of Proceeds, page 67

- 6. If any of the net proceeds of the offering, together with existing resources, will be used to develop IkT-001Pro, please disclose the amount you will allocate to its development and the development stage you expect to reach.
- 7. Please revise this section to clarify whether you will be able to complete the Phase 2 clinical trials in early-stage PD patients and treatment-naive PD patients with your existing cash and the net proceeds of this offering. To the extent you will need to raise additional capital to complete such stage of development, please disclose the amount and sources of such other funds needed to complete such trials. Refer to Instruction 3 to Item 504 of Regulation S-K.

Results of Operations

Research and Development, page 79

8. You disclose on page 78 that external costs are tracked by therapeutic indication. Please revise your disclosures here to include the external costs incurred during each period presented for each program or therapeutic area separately to provide more transparency as to the type of expenses incurred.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates

Stock-Based Compensation, page 84

9. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

<u>Critical Accounting Policies and Significant Judgments and Estimates</u> <u>Stock-Based Compensation, page 85</u>

10. On this page, you disclose you estimate the fair value of stock options using the reduced Net Product Value, or rNPV, option pricing model as performed by an independent third party consultant. On page F-10, you disclose you use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. Please clarify which model you use and revise your disclosures for consistency.

Business

Overview, page 88

11. We note your statement on page 88 that you believe you 'pre-determine' the human safety margin of your novel chemical entities using the RAMP drug discovery program. Statements regarding safety are determinations that only the FDA has the authority to make. Please revise your disclosure here to eliminate any suggestion that your product candidates have been or will ultimately be determined safe, reduced/eliminated risks related to safety or to have demonstrated safety for purposes of granting marketing approval by the FDA or comparable agency.

Clinical Development Strategy for IkT-001Pro in Stable Phase CML, page 97

12. We note that your pipeline table and the discussion of the toxicity and tolerability discussion on page 96 appear to indicate that you have completed the Ikt-001Pro preclinical trial in monkeys. However, your discussion on page 97 indicates the trial is still ongoing. Please revise your disclosure to address the apparent inconsistency. If you have completed the preclinical study, please describe the observable data resulting from the trial. In addition, please explain your statement that you "believe the FDA is requiring a single dose comparison study."

Material Agreements, page 101

13. We note that you have funded your operations primarily through private, state and federal contracts and grants, including from the National Institutes of Health, Department of Defense and State of Georgia. Please expand your disclosure to describe the terms of the

research grants you received from these institutions. For instance, clarify whether the government has any rights to the products developed with the funds received, whether there are any circumstances under which you may have to pay back the funds received, etc. Alternatively, provide an analysis as to why you believe such disclosure is not required.

Duke University, page 102

14. Please disclose when the agreement expires.

Sphaera Pharma Pte. Ltd., page 103

15. We note your disclosure indicates that Sphaera is entitled to milestone payments upon the achievement of certain preclinical, clinical and regulatory milestones. You have disclosed the payments related to dosing of the first patient in a Phase 1 clinical trial and FDA approval. Please revise your disclosure regarding the milestone payments to also disclose payments related to your preclinical milestones and indicate whether the milestone has been met or you anticipate achieving it in the near future. Additionally, confirm that the payments disclosed constitute all milestone payments. Alternatively, quantify the milestone payments made to date and all remaining potential milestone payments.

Sponsored Research Agreements, page 103

16. We note that you have entered into sponsored research agreements with academic and research institutions to perform certain testing and research for you and that you currently do not have a research and development facility of your own. To the extent any of the sponsored research agreements identified are material to your business, please describe their material terms, and file them as exhibits to your registration statement. Alternatively, please explain why you believe these agreements are not material.

Government Regulation, page 106

17. We note your belief that approval of IkT-001Pro can be achieved through the 505(b)(2) regulation. Please expand your disclosure in this section to explain the 505(b)(2) regulatory pathway and how the requirements differ from the traditional pathway.

Management, page 120

18. Please revise the biographies of each of the key non-executive officers and non-employee directors to state the period(s) during which each individual served in such capacity. Please also disclose the principal occupations and employment of Surendra Singh and Lisa Evrén during the past five years. Refer to Item 401(a), (c) and (e) of Regulation S-K.

Notes to Financial Statements

10. Commitments and Contingencies

License Agreements, page F-18

19. Please revise your disclosure of the Sphaera Pharma Pte. Ltd. collaboration agreement to include the total aggregate amount of potential milestone payments Sphaera may be entitled to receive under the agreement.

General

20. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus.

You may contact Rolf Sundwall at 202-551-3105 or Sharon Blume at 202-551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Irene Paik at 202-551-6553 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance Office of Healthcare & Insurance

cc: Merrill M Kraines