

The New York Times Building  
37th Floor  
620 Eighth Avenue  
New York, NY 10018-1405  
212.808.2700  
Fax 212.286.9806

October 16, 2018

**VIA EDGAR AND OVERNIGHT DELIVERY**

Securities and Exchange Commission  
Division of Corporation Finance  
Office of Healthcare & Insurance  
100 F Street, N.E.  
Washington, D.C. 20549-3720

Attention: Rolf Sundwall  
Sharon Blume  
Irene Paik  
Suzanne Hayes

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

Ladies and Gentlemen:

On behalf of our client, Inhibikase Therapeutics, Inc. ("**Inhibikase**" or the "**Company**"), we submit this letter in response to comments from the staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") contained in its letter dated October 5, 2018 (the "**Comment Letter**"), relating to the above referenced Draft Registration Statement on Form S-1 (the "**Registration Statement**"). We are concurrently submitting via EDGAR this letter and a revised draft of the Registration Statement. For the Staff's reference, we have included with this letter via overnight delivery both a clean copy of the Registration Statement and a copy marked to show all changes from the version confidentially submitted on August 31, 2018.

In this letter, we have recited the comments from the Staff in italicized, bold type and have followed each comment with the Company's response. Except for the page references contained in the comments of the Staff, or as otherwise specifically indicated, page references herein correspond to the page of the revised draft of the Registration Statement.

Philadelphia	Boston	Washington, D.C.	Los Angeles	New York	Pittsburgh	
Detroit	Berwyn	Harrisburg	Orange County	Princeton	Silicon Valley	Wilmington

[www.pepperlaw.com](http://www.pepperlaw.com)

Draft Registration Statement on Form S-1

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.***

The Company respectfully advises the Staff that it has deleted the statement that IKT-001Pro is a “near-term commercial opportunity,” on pages 1, 2, 3, 89 and 96, and has removed the statement that IKT-001Pro requires “a single 12-24 patient trial” on page 2 of the Registration Statement to address the Staff’s comment. The FDA’s statement to the Company was not a final determination, rather the statement was a suggestion that a single dose comparative clinical study to Imatinib with 96 hour pharmacokinetics measurement in healthy volunteers may be sufficient to calibrate the dose of IKT-001Pro to 400 mg Imatinib.

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.”***

The Company respectfully advises the Staff that it has revised the disclosure on page 2 of the Registration Statement to address the Staff’s comment. The Company has included the explanation that ‘Validating’ indicates ongoing efforts to prove target engagement (meaning if and to what extent a drug occupies its target) using proprietary sources and methods under development from human tissues and fluids and that ‘Can be used for patient selection’ refers to the Company’s ability to use one or more markers that the Company is currently ‘Validating’ to screen patients for the presence of that marker as a means of defining the patients most likely to benefit from the proposed treatment.

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.***

The Company respectfully advises the Staff that it has revised the disclosure on pages 1, 2 and 3 of the Registration Statement to address the Staff’s comment. The Company is currently in the process of completing its remaining pre-clinical study for IKT-001. Once this study is completed, the Company intends to file an Investigational New Drug Application (“IND”). In addition, the Company respectfully advises the staff that the Company has stated on pages 4 and 12 that the Company is a preclinical drug development company.

The Company respectfully advises the Staff that it is the Company’s understanding, based on meetings and post-meeting FDA notes, that it will not be required by the Federal Drug Administration (“FDA”) to undertake a post-approval study to demonstrate comparative efficacy and safety results to Imatinib, and the FDA has not raised such a study as a requirement for approval. The Company may choose, at its discretion, to undertake additional post-approval studies to demonstrate comparative efficacy and safety results to Imatinib in order to further differentiate the Company’s product from Imatinib.

---

**Implications of Being an Emerging Growth Company and a Smaller Reporting Company, 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.***

The Company respectfully acknowledges the Staff's comment. To the extent that the Company relies upon Section 5(d) of the Securities Act of 1933, as amended (the "Securities Act"), the Company will supplementally provide the Staff with copies of all written communications, as defined in Rule 405 under the Securities Act, that the Company, or anyone authorized to do so on the Company's behalf, presents to potential investors in reliance on Section 5(d), whether or not they retain copies of the communications.

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

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

The Company respectfully advises the Staff that it has revised the disclosure on pages 50, 102 and 108 of the Registration Statement to address the Staff's comment.

**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.***

The Company respectfully advises the Staff that it has revised the disclosure on page 68 of the Registration Statement to address the Staff's comment. The Company has not yet determined the amount of money that it will allocate to complete dose-calibration studies for IkT-001Pro relative to the Imatinib standard of care and to prepare the new drug application ("NDA") for IkT-001Pro.

---

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-naïve 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.*

The Company respectfully advises the Staff that it has revised the disclosure on page 68 of the Registration Statement to address the Staff's comment. The Company intends to undertake two Phase 2 clinical trials in treatment-naïve PD patients: one using traditional measures of function in the central nervous system, and a second in treatment-naïve PD patients who have GI complications using a unique set of primary endpoints. The Company believes it will be able to complete these Phase 2 clinical trials with its existing cash and the net proceeds of this offering, but has not yet determined the amount of money that it will allocate to these clinical trials. The Company may elect to expand the clinical development by conducting a separate Phase 2 clinical trial in early-stage PD patients, but does not need to do so at this time. The Company believes it will not need to raise additional capital to complete the necessary Phase 2 clinical trials.

**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.*

The Company respectfully advises the Staff that it has revised the disclosure on pages 80 and 81 of the Registration Statement to address the Staff's comment and has presented the external costs incurred during each period for each program or therapeutic area separately in the narrative descriptions of Research and Development for the fiscal year ended December 31, 2017 and the nine-month period ended September 30, 2018.

**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.*

The Company respectfully acknowledges the Staff's comment. At this time, the Company and the lead underwriter have not yet determined the initial public offering price range. When the initial public offering price range is determined, the Company intends to supplementally provide the requested information to the Staff.

---

**Critical Accounting Policies and Significant Judgments and Estimates**  
**Stock-Based Compensation, page 85**

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.***

The Company respectfully advises the Staff that it has revised the disclosure on page 86 of the Registration Statement to address the Staff's comment. The Company estimates the fair value of stock options granted to its employees and directors on the grant date, and the resulting stock-based compensation expense, using the Black-Scholes-Merton option pricing model. The Black-Scholes-Merton option pricing model requires management to determine the fair market value of the common stock at the date of the award. The fair market value of the common stock at the date of the award is determined utilizing the reduced Net Product Value, or rNPV, option-pricing model as performed by an independent third party consultant. For options or warrants granted to non-employee consultants, the fair value of these options is also remeasured using the rNPV Black-Scholes-Merton option-pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option.

**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.***

The Company respectfully advises the Staff that it has revised the disclosure on page 89 of the Registration Statement to eliminate the statement regarding safety and to address the Staff's comment.

**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."***

The Company respectfully advises the Staff that it has revised the disclosure on pages 97 and 98 of the Registration Statement to address the Staff's comment. The reference to "monkeys" on page 97 refers to a separate dose range finding study that is a predecessor study to the single species comparative toxicology study requested by the FDA for Ikt-001Pro's IND, which we are currently completing in monkeys. The Company has added this disclosure and revised the paragraph to address the Staff's comment.

In addition, on page 98, the Company has removed the statement that the Company "believe[s] the FDA is requiring a single dose comparison study." The FDA's statement to the Company was not a final determination, rather the statement was a suggestion that a single dose comparative clinical study to Imatinib with 96 hour pharmacokinetics measurement in healthy volunteers may be sufficient to calibrate the dose of Ikt-001Pro to 400 mg Imatinib. In addition, Company has clarified that the FDA agreed to a truncated IND program for Ikt-001Pro involving only a single species comparative toxicology experiment in a non-human primate. As recommended by the FDA, the Company is currently completing a pre-clinical single species comparative toxicology study wherein the Company is comparing Ikt-001Pro to Imatinib in non-human primates. The Company expects that this pre-clinical trial will be completed in the first quarter of 2019.

---

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.*

The Company respectfully advises the Staff that it has provided additional disclosure on page 102 of the Registration Statement regarding its federal contracts and grants to address the Staff's comment. This disclosure describes the terms of the research grants the Company has received from these institutions.

Duke University, page 102

14. *Please disclose when the agreement expires.*

The Company respectfully advises the Staff that it has revised the disclosure on page 104 of the Registration Statement to address the Staff's comment.

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.*

The Company respectfully advises the Staff that it has revised the disclosure on page 104 and 105 of the Registration Statement to address the Staff's comment. The Company confirms that the payments disclosed in the chart of milestone payments on page 105 of the Registration Statement constitute all milestone payments to Sphaera Pharma Pte. Ltd. ("Sphaera"). To date, the Company has not made any milestone payments to Sphaera and does not anticipate making any milestone payments to Sphaera within the next six months.

---

**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.***

The Company acknowledges the Staff's comment, and respectfully advises the Staff that it does not believe that it is substantially dependent on its sponsored research agreements with various academic and research institutions. The sponsored research agreements are terminable by the Company on short notice without penalty. In addition, the Company believes that there are many academic and research institutions that can perform the services identified in the sponsored research agreements and that the Company could replace any of the current institutions with which it has sponsored research agreements with alternative academic and research institutions without significant delay, expense or other disruption.

Further, the Company retains exclusively all right, title and interest in and to any Company property provided as part of any sponsored research agreement. The sponsored university does not acquire rights in Company compounds as a result of sponsored research, and the Company is not required to license any rights related to the Company compounds as a result of sponsored research. The Company has revised the disclosure on page 106 of the Registration Statement to clarify this.

Finally, the Company believes that the sponsored research agreements are the type of agreement that ordinarily accompanies the kind of business conducted by the Company and are made in the ordinary course of business. Accordingly, the Company respectfully submits that the sponsored research agreements are neither required to be described in the Business section of the prospectus nor filed as exhibits to the Registration Statement.

**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.***

The Company respectfully advises the Staff that it has revised the disclosure on pages 112 and 113 of the Registration Statement to explain the 505(b)(2) regulatory pathway and to address the Staff's comment.

**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.***

The Company respectfully advises the Staff that it has revised the disclosure on pages 124, 125 and 126 of the Registration Statement to address the Staff's comment.

---

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.*

The Company respectfully advises the Staff that it has revised the disclosure on page F-20 of the Registration Statement to address the Staff's comment.

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.*

The Company respectfully acknowledges the Staff's comment and advises the Staff that, once available, it will supplementally provide the Staff with copies of additional graphics and artwork it intends to use, if any.

\* \* \* \*

---



We hope that the foregoing has been responsive to the Staff's comments. Please direct any questions with respect to this confidential submission to me at (212) 808-2711 or [krainesm@pepperlaw.com](mailto:krainesm@pepperlaw.com).

Sincerely,

/s/ Merrill M. Kraines, Esq.

Merrill M. Kraines, Esq.

cc: Milton H. Werner, Ph.D., Inhibikase Therapeutics, Inc.  
Ivan K. Blumenthal, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

---