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

DIVISION OF
CORPORATION FINANCE

April 23, 2019

Asa Abeliovich
President and Chief Executive Officer
Prevail Therapeutics Inc.
430 East 29th Street, Suite 940
New York, NY 10016

Re: Prevail Therapeutics Inc.
Draft Registration Statement on Form S-1
Submitted March 27, 2019
CIK No. 0001714798

Dear Dr. Abeliovich:

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

Prospectus Summary
Overview, page 1

1. Your disclosure indicates that you intend to initiate two Phase 1/2 trials for PR001 in PD-GBA and neuronopathic Gaucher disease. Please revise to explain briefly why you plan to proceed to combined Phase 1/2 trials without having conducted any prior Phase 1 trials. Additionally, revise to state whether you have submitted an IND for PR001.

2. Please explain at first use the terms "precision medicine approach" and "capsid serotype."

3. On page 2 of the Summary, you highlight that AAV-based viral vectors have a "well-established" safety profile in humans, and that AAV9 enables "efficient" gene delivery in the CNS. Please balance your Summary presentation on pages 2 and 3 by addressing uncertainties and risks relating to viral vector-based gene therapies. In this regard, we refer to your risk factor disclosures on pages 14 and 20, which address the novelty of gene transduction technologies, the uncertainties surrounding mechanism of action and the ability to meet safety and efficacy levels necessary for therapeutic use in humans, as well as risks relating to immunogenicity.

4. With reference to Regulation S-K, Item 503(a), please tell us why you believe that the PR004 product candidate should be highlighted in your Summary pipeline table. We note that you include only a limited narrative discussion of the PR004 candidate in the Summary and it is unclear from your Business discussion on page 109 whether you have identified specific indications to target based on this broad preclincial program.

5. Please revise the final sentence on page 1 to differentiate the mouse model and the non-human primate testing. In this regard, your disclosures on pages 105-107 indicate that no efficacy testing has been conducted on non-human primates.

Implications of Being an Emerging Growth Company, page 4

6. 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.

Risk Factors

Our amended and restated certificate of incorporation that will become effective upon the closing of this offering designates. . ., page 66

7. We note that several statements regarding your exclusive forum provision appear inconsistent with your disclosures on page 156. Accordingly please reconcile your disclosures and note that we may have further comment after reviewing these revised disclosures and your Exhibit 3.3 when filed.

Use of Proceeds, page 71

8. Please expand your disclosure to state how far the proceeds of the offering will allow you to proceed with the development of your product candidates.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation, page 85

9. Please revise your disclosure of how you estimate the fair value of common stock on page 86 to:
   - Describe the methods you used and the nature of the material assumptions involved. In this regard, your disclosure that your board of directors considered valuations performed by a third-party valuation specialist provides no real insight into how the valuations were derived.
   - Indicate the extent to which your estimates are complex and subjective. In this regard, your statement that your board of directors considered a number of objective and subjective factors provides no real insight into the level of objectivity or subjectivity inherent in your estimates.

10. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to your offering and the estimated offering price. In your response tell us for each equity award (including stock options) granted since January 1, 2018 the following:
    - The date of the award;
    - The number of awards granted;
    - The exercise price of the award;
    - The deemed fair value of common stock on the grant date; and
    - The grant date fair value of the award.

Business
Our Approach, page 91

11. We note your statements on pages 93-94 and elsewhere in your prospectus that AAV-based viral vectors have a well-established safety profile and that an AveXis trial has shown life-saving efficacy. We also note your disclosures concerning third party trials demonstrating acceptable safety profile and efficient gene delivery. Safety and efficacy determinations are solely within the authority of FDA and comparable regulatory authorities. Accordingly, please revise to provide support for each of these statements by identifying relevant clinical trial results and discussing the regulator status of the referenced drug. Alternatively, please revise to remove these statements concerning safety and efficacy.

Preclinical Studies, page 99

12. Please expand your narrative discussion of the preclinical studies in CBE-treated mice to explain the dosage amounts administered, including an explanation of the formulas you provide below the accompanying charts.

Safety and Biodistribution in Non-Human Primates, page 105

13. Expand your narrative discussion to state the number of test subjects used in these studies. In addition, revise the "Safety" subsection to describe the dosages used in these studies, including the toxicology studies in healthy non-human primates.

PR006, Our Gene Therapy Product Candidate for the Treatment of FTD-GRN, page 107

14. Please expand your disclosure on page 109 concerning the preclinical studies you are conducting. With respect to the GRN knock-out mouse model, please explain the observed results in greater detail, including whether these results are statistically significant.

License Agreements, page 110

15. Please revise your descriptions of the GBA1 License and the Option Genese License to disclose the duration of the underlying intellectual property. Also disclose the upfront fees that are payable upon exercise of the options.

Manufacturing, page 112

16. We note your disclosure indicating that UPenn and GSK retain certain exclusive and non-exclusive rights under your license agreement. Please revise your discussion here and, if necessary, in your risk factor discussion on page 48, to clarify how these upstream rights impact the development and commercialization of your product candidates.

Intellectual Property, page 113

17. We note your disclosures on page 114 concerning pending international patent applications relating to each of your three product candidates. Please revise these disclosures to identify the relevant jurisdictions where you have filed the applications. Also, revise your disclosure on page 114 to indicate whether any of the nine pending U.S. patent applications referenced on page 113 specifically relate to these three product candidates.

General

18. 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. Please note that we may have comments regarding this material.

You may contact Mark Brunhofer at 202-551-3638 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Dorrie Yale at 202-551-8776 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Divakar Gupta - Cooley LLP