



DIVISION OF  
CORPORATION FINANCE

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

June 3, 2020

Chris Hollowood  
Executive Chairman  
Freeline Therapeutics Holdings Ltd  
Stevenage Bioscience Catalyst  
Gunnels Wood Road  
Stevenage, Hertfordshire SG1 2FX

**Re: Freeline Therapeutics Holdings Ltd**  
**Draft Registration Statement on Form F-1**  
**Filed May 7, 2020**  
**File No. 377-03158**

Dear Dr. Hollowood:

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 F-1

Summary, page 1

1. We note your disclosure that the AAVS3 capsid has been observed to have up to six-fold higher transduction efficiency in human liver cells as compared to wild-type AAV serotypes in both preclinical and clinical settings, but the only head to head comparison discussed in your document is a preclinical study. To the extent your statement is not based on a head to head comparison in the clinic, please revise accordingly.
2. We note your statement that FLT180a has shown potential to provide patients with a functional cure for hemophilia B and your statement on page 131 that you believe FLT190

has the potential to provide a functional cure to Fabry disease. Please delete these statements here and throughout the document given the fact that FLT180a and FLT190 are each still at an early stage of development and only a small number of patients have been dosed.

3. We note your disclosure here and throughout the prospectus referencing the "rapid adoption of [y]our products," your plan to "accelerate" timelines for your product candidates, "rapidly advancing the clinical development of FLT190," the "rapid development of new liver-directed AAV gene therapy candidates," and the ability to "rapidly advance" your earlier stage products and your proprietary programs into the clinic. Please revise this disclosure and similar disclosure throughout the prospectus to remove any implication that you will be successful in commercializing your product candidates in a rapid or accelerated manner as such statements are speculative.

Our Pipeline, page 4

4. Please include a column for each of Phase 1, Phase 2 and Phase 3 in your pipeline chart both here and on page 133.

Our Strengths, page 6

5. Please revise your statements here and elsewhere in the prospectus that certain of your therapeutic solutions and your technology are potentially "best-in-class." These statements imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing such approval.
6. We note your disclosure that your strengths will allow you to build upon your "leadership position in treating inherited systemic diseases." We note that you have only dosed a limited number of patients in the Phase 1 portions of your ongoing clinical trials and do not have any approved products. Please substantiate this statement or revise your disclosure.

Our Strategy, page 8

7. We note your statement here that you have retained development and worldwide commercial rights to all of your liver-directed gene therapy product candidates, which is repeated on page 143, and your statement on page 168 that you have retained global rights to all of your programs. Please balance these statements to make clear that you in-license intellectual property rights that are key to your product candidates and your manufacturing process.

Implications of Being an Emerging Growth Company and a Foreign Private Issuer, page 11

8. 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.

Material Weaknesses, page 89

9. Please disclose an estimate of when you expect to hire the personnel needed to remediate the material weakness. Disclose also your estimate of how many additional personnel are required.

Use of Proceeds, page 100

10. Please clarify whether you anticipate that the proceeds from the offering will also sufficient to complete the Phase 1/2 MARVEL-1 trial for FLT190. If not, please disclose the amount and sources of funds that will be required to complete MARVEL-1.

Dilution , page 108

11. We note that the historical net tangible book value should be \$85 million using total assets less total liabilities, excluding intangible assets. Please clarify the net tangible book value of \$90 million disclosed on page 108 or advise.

Business

Overview, page 131

12. We note your disclosure that there are approximately 9,000 individuals with hemophilia B in the United States and five major European markets and your disclosure on page 152 that Fabry disease affects approximately one in 40,000 males. We further note your statement on page 151 that patients with antibodies to AAVS3 above a certain threshold are not eligible for treatment with your product candidates. Please clarify your disclosure on page 131 and page 152 to discuss how many patients you believe you will be able to treat with your product candidates.

Our Lead Gene Therapy Product Candidate: FLT180a for the Treatment of Hemophilia B, page 143

13. We note your statement that you believe that FLT180a is the only hemophilia B gene therapy currently under clinical development that has potential to bring patients into the normal FIX range and to provide patients with WFH-recommended FIX levels over time. We further note that you cite uniQure and Spark Therapeutics as competitors with treatments for hemophilia B in Phase 3 clinical trials. Please tell us why you believe that those competing therapies will not bring patients into the normal FIX range.

Chris Hollowood  
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Our Strategy, page 143

14. We note your disclosure that you are at the "forefront" of CMC and manufacturing. Please substantiate this statement or revise to make it clear that this is management's belief.

Collaborations and License Agreements, page 175

15. We note your disclosure regarding the license agreements with The Rockefeller University, Children's GMP LLC and St. Jude Children's Research Hospital. Please file these agreements as exhibits to your registration statement or tell us why you believe they are not required to be filed.

Management

Share Option Scheme, page 208

16. We note your disclosure in the prospectus that you intend to adopt a share option scheme in connection with your offering. On page 14 of the document, you state that you intend to adopt a 2020 Equity Incentive Plan in conjunction with the consummation of the offering. If these are two separate equity incentive plans, please clarify the disclosure. If the references are to the same plan, please standardize the language.

You may contact Christie Wong at 202-551-3684 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at 202-551-4224 or Celeste Murphy at 202-551-3257 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Marcel Fausten