



DIVISION OF  
CORPORATION FINANCE

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

September 28, 2018

Mark Rothera  
President, Chief Executive Officer and Director  
Orchard Rx Ltd  
108 Cannon Street  
London EC4N 6EU  
United Kingdom

**Re: Orchard Rx Ltd**  
**Amended Draft Registration Statement on Form F-1**  
**Submitted September 14, 2018**  
**CIK No. 0001748907**

Dear Mr. Rothera:

We have reviewed your amended 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.

Amendment No. 1 to Draft Registration Statement on Form F-1 submitted September 14, 2018

Prospectus Summary  
Overview, page 1

1. We note your response to our prior comment 5. We also note your disclosure on pages 158, 162 and 165 that your discussions with relevant regulatory authorities are ongoing and that you do not yet have definitive feedback on the scope or adequacy of the requisite data necessary to justify approval and that you may be unable to demonstrate comparability between drug product manufactured using HSCs derived from mobilized

peripheral blood and HSCs derived from bone marrow and/or comparability between drug product that has been cryopreserved and fresh drug product. Please expand your disclosure in the Prospectus Summary to clarify that your table was prepared based on your hopes that the regulatory authorities will consider your trials to be sufficient and explain the consequences if they do not..

OTL-101 Program Safety, page 156

2. We note your revision in response to our prior comment 25 that there was one SAE, a product contamination, that was deemed by the investigator as being possibly related to protocol treatment or procedures. Please revise your disclosure to identify the SAE. To the extent known, explain the circumstances related to the contamination and consider whether the circumstances warrant risk factor disclosure.

UCLB/UCLA License Agreement, page 179

3. We note you are obligated to pay a non-refundable "low-double digit" royalty percentage to UCL on net sales of product candidates subject to the UCLB/UCLA Agreement. Please revise the royalty range to reflect no more than a 10% range.

Competition, page 180

4. We note that Généthon is sponsoring clinical trials with autologous *ex vivo* lentiviral gene therapy for WAS and for X-CGD in France, to which you have certain rights. We also note that you are party to a license agreement with Généthon with respect to OTL-102. Please provide a description of the rights and obligations of each party under this agreement, and clarify whether Généthon could be a competitor for the treatment of WAS and X-CGD.

Notes to Financial Statements

7. Shares-based compensation, page F-50

5. Please tell us why your expected volatility decreased from 80.00% in 2017 to 66.51% - 68.17% in 2018. Please provide us with the names and volatility of each of the peer companies you used to estimate expected volatility for 2018 and explain why you believe each company was similar to you. In your response, at a minimum, specifically tell us whether these peer companies have any product revenues, the number of product candidates in the pipeline, the general therapeutic area of these product candidates and the phase of development for these product candidates.

8. License and research arrangements

GSK asset purchase and license agreement, page F-52

6. You disclose that you allocated \$100.7 million of the total consideration to IPR&D based on the fair value of the underlying programs in development, and \$92.4 million to indefinite-life intangible assets related to the PRVs based on the fair value at the date of acquisition. Please tell us how your allocation complies with ASC 805-50-30-3 which requires the cost of the acquisition to be allocated on a relative fair value basis.
7. Please tell us how you applied the guidance in ASC 805-50-30 related to the contingent PRV liabilities and your basis for recording these amounts prior to when the contingency is resolved or becomes payable. In this regard, we note that your obligations to GSK, including transferring the first PRV to GSK and selling the subsequent PRVs to GSK or sharing with GSK the proceeds from the sale of the subsequent PRVs to third parties, are contingent on various uncertain factors including your ability to obtain the PRVs from the FDA.
8. With regard to the GSK acquisition, we note your disclosure of the total consideration of \$193.0 million as of the date of acquisition. Please tell us and disclose clearly all elements of your purchase consideration that reconcile to the total consideration amount.
9. You disclose on page F-45 that the indefinite-lived intangible assets you recorded on the balance sheets represent the acquired rights to receive a PRV. Please tell us why the rights are deemed indefinite-lived and explain the basis for assigning value to such rights. In this regard, we note that you have to use commercially reasonable efforts to obtain a PRV from the FDA and you will only be eligible for a PRV upon the approval of a BLA for OTL-101, OTL-200 and OTL-103 which are not expected to be submitted until 2020 and 2021. In addition, your disclosure on page 32 indicates that the PRV program, which has been subject to criticism including by the FDA, may no longer be in effect at the time when and if you qualify for such a PRV and that you may not be able to realize the benefits of such PRV.

Notes to Unaudited Condensed Consolidated Financial Statements

13. Subsequent events, page F-60

10. We note from your disclosure on page 138 that you granted stock options subsequent to June 30, 2018. Please disclose these grants and the total compensation expense attributed to them in your subsequent events note, and discuss in MD&A the anticipated impact on results of operations of this apparent known trend in share-based compensation.

You may contact Sisi Cheng at 202-551-5004 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,

Mark Rothera  
Orchard Rx Ltd  
September 28, 2018  
Page 4

Division of Corporation Finance  
Office of Healthcare & Insurance