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October 4, 2018

#### VIA EDGAR AND FEDERAL EXPRESS

United States Securities and Exchange Commission Division of Corporation Finance Office of Healthcare & Insurance Mail Stop 4720 100 F Street, N.E. Washington, D.C. 20549 Attention: Irene Paik

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

Dear Ms. Paik:

This letter is submitted on behalf of Orchard Rx Limited (the "Company") in response to the comments of the staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission with respect to the Amendment No. 1 to the Draft Registration Statement on Form F-1 confidentially submitted on September 14, 2018 ("Amendment No. 1"), as set forth in your letter dated September 28, 2018 addressed to Mark Rothera, President, Chief Executive Officer and Director of the Company (the "Comment Letter"). The Company is concurrently filing the Registration Statement on Form F-1 (the "Registration Statement"), which includes changes to reflect responses to the Staff's comments.

For reference purposes, the text of the Comment Letter has been reproduced herein with responses below each numbered comment. For your convenience, we have italicized the reproduced Staff comments from the Comment Letter. Unless otherwise indicated, page references in the descriptions of the Staff's comments refer to Amendment No. 1, and page references in the responses refer to the prospectus included in the Registration Statement (the "**Prospectus**"). All capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Prospectus.

The responses provided herein are based upon information provided to Goodwin Procter LLP by the Company. In addition to submitting this letter via EDGAR, we are sending via Federal Express four (4) copies of each of this letter and the Registration Statement (marked to show changes from Amendment No. 1).

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

<u>Prospectus Summary</u> <u>Overview, page 1</u>

COMMENT NO. 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.

RESPONSE: The Company has revised the Prospectus on page 3 of the Prospectus.

# OTL-101 Program Safety, page 156

COMMENT NO. 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.

RESPONSE: The Company has revised the Prospectus on pages 23 and 160 of the Prospectus.

#### UCLB/UCLA License Agreement, page 179

COMMENT NO. 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.

RESPONSE: The Company has revised the Prospectus on page 183 of the Prospectus. The Company advises the Staff that the reference to "low-double digit" royalties was an error and has been corrected in the revised Prospectus.

## Competition, page 180

COMMENT NO. 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.

RESPONSE: The Company advises the Staff that the Company is party to an exclusive option and license agreement with Généthon for certain intellectual property and clinical data rights associated with the three clinical studies sponsored by Généthon for autologous ex vivo lentiviral gene therapy for X-CGD at sites in the United States, United Kingdom and France. As of the date of this prospectus, the Company has exercised its option with respect to the clinical trials conducted in the United States and the United Kingdom but not yet an ongoing trial in France. The Company advises the Staff that, in the event the Company elects not to exercise its option with respect to the French trial, it does not expect this would have a material adverse effect on the Company's X-CGD program. The Company advises the Staff that it does not have rights or an option to acquire rights to the clinical trials sponsored by Généthon for WAS. The Company has revised the Prospectus on pages 170 and 185 in response to the Staff's comment.

#### Notes to Financial Statements

# 7. Shares-based compensation, page F-50

COMMENT NO. 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.

RESPONSE: The Company advises the Staff that our expected volatility decreased from 80.00% to 66.51% - 68.17% due to a change in the composition of the peer companies used in 2017 versus 2018. The Company adjusted its peer set in 2018 due to the growth in the breadth of its programs, the complexity of an international organization and the increased number of programs in development as a result of the transaction to acquire the gene therapy programs from GSK in 2018. As a result, some companies in the peer set used in 2017 were no longer an appropriate comparable for Orchard Therapeutics, however of the ten companies used to determine volatility in 2018, six of them were also used as peer companies in 2017. The peer set in 2018 included the ten companies listed below.

Company	(1-	Market Cap -Jan-18) millions	(28	Market Cap S-Sep-18) millions	Volatility*	Re (las	roduct evenue st fiscal rear) nillions	Number of Product Candidates	Therapeutic Area or Focus of Research	Phase of Development (most advanced)
uniQure N.V.	\$	620	\$	1,160	74.5%	\$	0	4	In vivo gene therapy	Phase 3
Applied Genetic Tech Corp	\$	68	\$	130	63.7%	\$	0	6	In vivo gene therapy	Phase 1/2
Voyager Therapeutics	\$	480	\$	610	68.9%	\$	0	6	In vivo gene therapy	Phase 1
REGENXBIO	\$	1,080	\$	2,410	64.0%	\$	0	5	In vivo gene therapy	Phase 1/2
Spark Therapeutics	\$	1,970	\$	2,040	69.1%	\$	12.1	9	In vivo gene therapy	Commercial
bluebird bio	\$	8,340	\$	7,320	75.5%	\$	0	6	Ex vivo gene therapy	Phase 2/3
GenSight Biologics S.A.	\$	180	\$	53	34.3%	\$	0	3	In vivo gene therapy	Phase 3
Audentes Therapeutics	\$	1,010	\$	1,450	47.1%	\$	0	4	In vivo gene therapy	Phase 1/2
Editas Medicine	\$	1,450	\$	1,500	77.2%	\$	0	7	Gene editing	Preclinical
Intellia Therapeutics	\$	780	\$	1,230	68.1%	\$	0	7	Gene editing	Preclinical
Mean	\$	1,598	\$	1,790	64.2%	\$	1.2	5.7		
Median	\$	895	\$	1,340	64.0%	\$	0	6.0		
Orchard Therapeutics	\$	850**		TBD***	68.17%	\$	0	8	Ex vivo gene therapy	Commercial

- \* Volatility has been calculated using available historical data of the respective peer company as measured over the expected term used to value the Company's stock options.
- \*\* This is the assumed market capitalization based on the Company's latest post-money valuation, which closed in August 2018.
- \*\*\* The Company has not yet established a valuation for the IPO.

As noted from the table above, the Company is in a similar situation as the peer group companies in terms of market capitalization and product revenue. The Company also has eight disclosed programs which are described in the Form F-1 (one commercial, five clinical and two preclinical). This compares to a mean of 5.7 programs across the peer set that are disclosed publicly. All of the peer companies have a focus of research in gene therapy or gene editing. In addition, while the phases of development vary among the peers, the Company notes that eight of the ten peers are in clinical stages of development, with one of them having a commercial product. Finally, the Company also examined factors such as operating expenses and number of employees noting that the means and medians of peer companies using those metrics were well aligned with the Company.

# 8. License and research arrangements

GSK asset purchase and license agreement, page F-52

COMMENT NO. 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.

RESPONSE: The Company advises the Staff that an independent valuation specialist was engaged by the Company to assist it in estimating the fair value of each of the identifiable tangible and intangible assets acquired and liabilities incurred in the GSK Agreement. The total cost of the acquisition, including transaction costs, was allocated to the individual tangible and intangible assets acquired based on their relative fair values. The fair value of each asset approximated the cost allocated to each asset and no significant adjustments to the fair values of the identifiable assets were required to comply with ASC 805-50-30-3.

COMMENT NO. 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.

RESPONSE: The Company advises the Staff that the PRV liabilities represent liabilities that the Company incurred in order to obtain the various rights under the GSK Agreement. In this regard, the Company concluded that these liabilities represent a portion of the cost of the assets acquired in the GSK Agreement and, in accordance with ASC 805-50-30-2, these liabilities incurred should be measured based on their fair value. While the Company's obligations to GSK are contingent on various uncertain factors, the Company also considered the SEC Staff's longstanding position (discussed at ASC 815-10-S99-4) that written options that do not qualify for equity classification should be reported at fair value. The accounting treatment for the asset underlying the PRV obligation (i.e., the PRV asset) is discussed in the response to comment no. 9 below.

COMMENT NO. 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.

RESPONSE: The Company advises the Staff that it has revised its disclosures on pages F-38 and F-52 to disclose all elements of consideration related to the GSK transaction in tabular format. It has also provided a table showing how the consideration was allocated to each of the identifiable assets.

COMMENT NO. 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.

RESPONSE: The Company advises the Staff that two of the programs acquired from GSK, OTL-200 and OTL-103, as well as Strimvelis, meet the criteria for the FDAs Rare Pediatric Disease Program and are eligible to receive a PRV upon approval by the FDA (although the Company is not intending to seek marketing approval for Strimvelis in the United States).

Due to their Rare Pediatric Disease designation, both OTL-200 and OTL-103 each have a regulatory right to receive a PRV upon marketing approval by the FDA. This right was acquired by the Company from GSK when it acquired the underlying programs and the Company evaluated these rights to determine whether they represent intangible assets that meets the identifiable criteria, the first test being whether they meet the contractual-legal criterion. While ASC 805 does not define the term "contractual or other legal rights", the list of contractual-legal intangible assets included at ASC 805 makes it clear that the definition is intended to be broad. Accordingly, the Company concluded that the right to receive a PRV meets the contractual-legal criterion at ASC 805-20-25-10 since it represents a legal right to receive, and should therefore be assessed as a separate identifiable asset and recorded at its relative fair value at the transaction date. Judgements related to the timing and limitations involved in the PRV program are inputs included in the measurement of the initial fair value of these contractual rights.

The Company concluded that the right to receive a PRV for these programs represents an indefinite-lived asset on the basis that there are no legal, regulatory, contractual, competitive, economic or other factors that limit the useful life of the PRV to the Company. While the program in place that regulates the granting of vouchers is dependent on the program's reauthorization by Congress, and as disclosed on page 33 may no longer be in effect if and when the programs qualify for such a PRV, the PRVs themselves to not expire.

Based on the factors above, and because the Company believes that market participants ultimately expect the renewal or extending of the program, the Company does not currently limit the useful life associated with the right to receive a PRV in accordance with ASC 350-30-35-3(d). The rights to receive a PRV is reassessed each reporting period to determine whether events or circumstances continue to support an indefinite useful life in accordance with ASC 350-30-35-16.

# Notes to Unaudited Condensed Consolidated Financial Statements

13. Subsequent events, page F-60

COMMENT NO. 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.

RESPONSE: The Company respectfully advises the Staff that it has revised its disclosures on page 142 of MD&A and page F-61 of the financial statements to include the requested disclosure in response to the Staff's comment.

If you should have any questions concerning the enclosed matters, please contact the undersigned at (617) 570-3953.

Sincerely,

/s/ Michael H. Bison Michael H. Bison, Esq. Goodwin Procter LLP

cc: Mark Rothera, *Orchard Rx Limited*Frank E. Thomas, *Orchard Rx Limited*John Ilett, *Orchard Rx Limited*Mitchell S. Bloom, Esq., *Goodwin Procter LLP*Courtney Hetrick, Esq., *Goodwin Procter LLP*