

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

Mail Stop 4546

August 8, 2016

Dr. Lynn Seely Principal Executive Officer Myovant Sciences Ltd. Clarendon House 2 Church Street Hamilton HM 11, Bermuda

Re: Myovant Sciences Ltd.

**Draft Registration Statement on Form S-1** 

Submitted July 11, 2016 CIK No. 0001679082

Dear Dr. Seely:

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.

#### Prospectus Summary, page 1

- 1. At first use, please explain the meaning of the term "depot" and "first-in-class". Also, revise the Summary, where appropriate, to explain briefly the terms "uterine fibroids" and "endometriosis."
- 2. We refer to your disclosure on page 1 indicating that you expect to initiate a Phase 1 study for RVT-602 in women during the second half of 2017. Accordingly, please revise the table on page 2 to reflect that you have not started Phase 1. Please make conforming changes to the corresponding table on page 68.

- 3. We refer to the final sentence on page 1 and your disclosures on pages 92-93. Please revise the final sentence on page 1 to clarify, if true, that there is no pre-clinical or clinical data to support your belief concerning the potential safety or efficacy of RVT-602 for the treatment of infertility in females.
- 4. We refer to the first bullet point on page 4 and your disclosure in the first full risk factor on page 18. Please revise the Summary to highlight and clarify that you expect clinical trials to take at least several years to complete.
- 5. We refer to your disclosures on pages 16, 19 and 55-56. Please revise the Summary to explain your operations and balance your presentation by highlighting that:
  - your operations to date have been limited to organizing and staffing the company and acquiring drug candidates;
  - you presently have one employee; and
  - you have not been involved in the development of either drug candidate and are dependent on Takeda having "correctly collected and interpreted data" from relugolix and RVT-602 trials.
- 6. We refer to your disclosures on pages 14 and 72. Please revise to discuss the importance of formulating relugolix as a fixed-dose combination and the limitation of the commercial opportunity if you instead must formulate as a monotherapy. Also, discuss here, or elsewhere as applicable, whether there are barriers preventing your competitors from similarly pursuing add-back therapy formations for existing or pipeline GnRH antagonists. Discuss, as applicable, whether FDA approval of one fixed-dose combination GnRH antagonist would materially impact the ability and timeframe for competitors to achieve regulatory approvals of fixed-dose combination drug candidates targeting the same indications.

# The Offering, page 7

7. Please revise the disclosure on pages 8 and 41 to indicate the warrant exercise price.

#### We are an emerging growth company, and we cannot be certain . . . , page 42

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.

#### Use of Proceeds, page 50

9. Please revise the first bullet point to disclose the amount for each intended Phase 3 clinical program.

10. With respect to each of the indicated uses, please clarify whether you expect the allocated proceeds will be sufficient to complete the indicated study or activity.

# General and Administrative Expenses, page 59

11. Please revise to quantify the amount attributable to each of the three primary expense categories you identify.

## Critical Accounting Policies and Significant Judgments and Estimates, page 61

12. 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.

# Business, page 65

13. Please revise the Business section to ensure that the dates for each clinical trial are disclosed as well as the country or countries where they took place.

#### Phase 3 Clinical Development for Women's Health Indications, page 76

14. We refer to your statement in the second paragraph on page 66 that you expect to submit Takeda's Phase 3 data as part of your new drug application to the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids. We also note your disclosure on page 76 that Takeda's current Phase 3 trials for this indication are taking place in Japan. Accordingly, please revise to discuss Takeda's efforts, if any, to obtain FDA approval, including whether it has filed an IND with FDA for this indication.

#### Existing Clinical Data in Women's Health Indications, page 79

15. We refer to your disclosures on page 74-75 and 91 concerning bone mineral density loss observed in trials for relugolix and elagolix and your disclosures throughout the prospectus concerning the significance of this side effect to advancing therapies. Accordingly, please revise the table on page 82 to compare the bone density loss observed for each drug candidate and, if material, any other adverse effects for these two products.

# Existing Clinical Data, page 85

16. Regarding the Phase 2 clinical trials (Study C27002 and C27003), please explain whether the results disclosed are statistically significant.

# Summary of Pharmacokinetic..., page 90

17. We note the disclosure on page 91 indicating that there were 36 serious adverse events as of December 31, 2015. Please revise to disclose how many of these adverse events were either Grade 4 or Grade 5 events. Identify the grade for each of the three events that the investigator reported as possibly linked to relugolix. Also, revise to update the disclosure to a more recent date.

### RVT-602, page 92

- 18. We note your disclosure concerning your timeline for commencing Phase 1 and Phase 2 clinical trials. Please revise to clarify whether you plan to initiate both sets of trials in the second half of 2017. Also, disclose, if applicable, when you would submit an IND for this indication.
- 19. We note your reference at the top of page 92 to your collaboration with Takeda. Please revise to discuss whether you are collaborating with Takeda with respect to RVT-602. Also, disclose when Takeda conducted its Phase 1 clinical trials and, if known, whether Takeda is actively conducting or planning any RVT-602 development. Also, revise the second sentence of the first full risk factor on page 30 to clarify this status.

#### License Agreement with Takeda Pharmaceuticals International AG, page 94

20. Please revise the carryover paragraph at the top of page 95 and the second full paragraph on that same page to disclose the duration of the referenced royalty term.

#### Relationship with Takeda Pharmaceuticals International AG, page 116

21. Please disclose the approximate dollar value of the amounts involved in the Manufacture and Supply Agreement with Takeda Limited.

#### Related Person Transaction Policy, page 118

22. Please revise to indicate whether future transactions with Roivant Sciences, including the Option Agreement, will be subject to the related person transaction policy.

#### Principal Shareholders, page 120

23. Please revise footnote 1 to identify each of the Roivant Sciences Ltd. board members.

# Common Shares, page 122

24. Please revise the first full paragraph on page 123 to disclose the purpose of the bye-law provision. Discuss whether the 9.5% threshold has particular legal significance and also explain why the bye-law provision is limited to U.S. holders. Revise the second full paragraph on page 123 to discuss whether Bermuda law or applicable stock exchange listing standards limit the board's ability to unilaterally alter shareholder voting rights. Also, revise the "Shareholders' Voting Rights" section on page 133, as applicable, to summarize any differences with Delaware law.

You may contact Christine Torney at 202-551-3652 or Lisa Vanjoske, Assistant Chief Accountant, at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Dorrie Yale at 202-551-8776 or Joseph McCann at 202-551-6262 with any other questions.

Sincerely,

/s/ Joseph McCann for

Suzanne Hayes Assistant Director Office of Healthcare and Insurance

cc: Frank F. Rahmani, Esq. — Cooley LLP