

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

June 1, 2018

Philip Astley-Sparke
President and Chief Executive Officer
Replimune Group, Inc.
10 Commerce Way
Woburn, MA 01801

Re: Replimune Group, Inc.
Draft Registration Statement on Form S-1
Submitted on May 3, 2018
CIK No. 0001737953

Dear Mr. Astley-Sparke:

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.

#### <u>Draft Registration Statement on Form S-1</u>

# Prospectus summary, page 1

- 1. Please expand your disclosure to discuss any serious adverse events observed in your ongoing trial.
- 2. We note your disclosure on page 3 and in the Business section that you plan to initiate multiple Phase 2 clinical trials of RP1 and a Phase 1 trial of RP2 in the first half of 2019. Please clarify whether you have active INDs for these trials. Additionally, you indicate that you plan to enter a Phase 1 clinical trial of RP3 in 2020. Please revise your disclosure to describe the current status of your RP3 development.

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## Our strategy, page 4

3. Given that it takes years to obtain regulatory approval for a product candidate, please explain your strategy of "rapidly advancing the development of and obtaining approval for your lead candidate.

# Risks affecting our business, page 4

4. Please add a bullet to disclose that your Phase 1/2 clinical trial of RP1 is on clinical hold with the FDA and may not commence at U.S. sites until you submit the results of a preclinical toxicology and biodistribution study with a longer follow-up period and the FDA provides you with clearance to proceed with the trial. Additionally, revise the description of this trial throughout your registration statement to clarify that the trial is currently on clinical hold, rather than stating that it is ongoing.

## <u>Implications of being an emerging growth company, page 6</u>

5. 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.

# Market data, page 69

6. Your statement in the last paragraph that you have not independently verified third party market and industry data and forecasts may imply an inappropriate disclaimer of responsibility with respect to the third party information. Please either delete the statement or specifically state that you are liable for such information.

# Use of Proceeds, page 70

7. You currently state that you expect the current proceeds, together with your cash and cash equivalents, to fund the development of RP1 through completion of the ongoing Phase 1/2 clinical trial. Additionally, you expect the proceeds to fund a clinical trial with RP1 in CSCC; ongoing development of RP2 and RP3 and capital expenditures associated with establishing, equipping and operating your planned manufacturing facility. Please clarify whether you expect the proceeds to be sufficient to complete these additional items. If you do not, please clarify the stages in development process you expect to complete with the proceeds and currently available cash.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgements and Estimates
Stock-Based Compensation, page 93

8. Once you have an estimated offering price or range, please explain to us the reasons for any differences between the recent valuations of your common stock leading up to the

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initial public offer 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 99

- 9. We note your disclosures reference "response rates" and "complete responses." Please revise your disclosure to explain what constitutes a "complete response" and how you determine the "response rate." Additionally, delete the reference to "primary efficacy" as efficacy is a determination that is within the sole authority of the FDA or equivalent foreign regulator. You should identify the primary endpoints and may indicate that you will be assessing the achievement of such endpoints.
- 10. Please revise your characterization of the Amgen clinical trial in melanoma patients to discuss the data from the trial, rather than drawing conclusions from the results.

#### Our Immulytic platform, page 104

11. We reference your disclosure on page 107 on prior trial results, including trial results from T-Vec in combination with ipilimumab, which were "highly statistically significant." To provide context, please expand your disclosure to provide information regarding the trials, including the phase of the trials, the number of patients tested, duration of the trials, and endpoints, as well as an explanation of the term "statistically significant," and how it relates to the FDA's evidentiary standards of efficacy.

### Intellectual property, page 120

12. Please revise your disclosure to discuss the type of protection being sought in your applications (e.g., composition of matter, use).

#### Manufacturing, page 122

- 13. Please revise your disclosure to discuss the material terms of your collaboration agreement with BristolMyers Squbb, including a description of each party's rights and obligations under your agreement, a quantification of any payment obligations, the contract term and any termination provisions. Please also file the agreement as an exhibit or provide us with an analysis supporting a determination that you are not required to file it as an exhibit. If your agreement is limited to BMS supplying you with nivolumab in exchange for payments for the materials, then please revise the disclosure throughout the registration statement to reference the agreement as a supply agreement, rather than a collaboration agreement.
- 14. We note your risk factor disclosure indicating that shortages of key raw materials may result in delays or the inability to meet demand. Please expand your disclosure to discuss the sources and availability of the raw materials for your product candidates, including the strain of virus you use. Refer to Item 101(h)(4)(v) of Regulation S-K.

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# Notes to Consolidated Financial Statements

# 4. Short-term investments, page F-21

15. Please reconcile the \$8.8 million fair value of your corporate debt securities as of December 31, 2017 as presented on page F-21 with the \$13.3 million fair value disclosed on page F-20.

# General

16. 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 Bonnie Baynes at 202-551-4924 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Dorrie Yale at 202-551-8776 or Suzanne Hayes at 202-551-3675 with any other questions.

Division of Corporation Finance Office of Healthcare & Insurance