

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

September 16, 2017

Alexey Margolin Chief Executive Officer Allena Pharmaceuticals, Inc. One Newton Executive Park, Suite 202 Newton, Massachusetts 02462

Re: Allena Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted August 18, 2017
CIK No. 0001624658

Dear Mr. Margolin:

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 S-1 submitted August 18, 2017

## Prospectus Summary Overview, page 1

1. Where you refer to your clinical development program for ALLN-177 as "robust" and state that your lead product candidate "can substantially reduce urinary oxalate excretion" and "has demonstrated significant reductions of urinary oxalate excretion," please place your statements in appropriate context by disclosing that statistical significance was limited to secondary endpoints and post-hoc analyses in your largest Phase 2 trial and a proof of concept Phase 2 trial involving 16 subjects, of whom five presented with your target indication of enteric hyperoxaluria.

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#### <u>Implications of Being an Emerging Growth Company, page 6</u>

2. 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 62

3. Please reconcile your planned use of proceeds in the second bullet point with the disclosure on page 34 indicating that you intend initially to seek regulatory approval to market ALLN-177 solely for the treatment of enteric hyperoxaluria in adults. Please also amend your disclosure to include the interest rate and maturity of debt to be repaid. Refer to Instruction 4 to Item 504 of Regulation S-K. Additionally, please revise your disclosure, if applicable, to state the amounts and sources of additional funds needed to develop your product candidates to marketing approval. Refer to Instruction 3 to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Use of Estimates

Stock-Based Compensation, page 75

4. 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 92

- 5. Please provide support for your statement on pages 1 and 93 that a therapeutic agent that reduces urine oxalate levels in your target population presents a potential multi-billion dollar U.S. market.
- 6. Please briefly describe the sources of data cited in the last sentence in the third paragraph on page 96. Please also amend your disclosure to indicate the time period of measurement for which 20% reduction in oxalate excretion is meaningful in this context.

### Summary of Completed Phase 2 Clinical Trials, page 100

7. Please amend the graphics throughout this section to clearly indicate the number of test subjects for which data in each table is depicted. Additionally, please provide appropriate context for the graphic presented on page 103 by explaining how the graphic illustrates the physiological benefit of metabolic control of UOx excretion over time.

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## Principal Stockholders, page 152

8. Please revise Note 6 to disclose the individuals with voting and investment control over the shares held by affiliates of Partner Fund Management, L.P.

#### General

9. 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 Keira Nakada at 202-551-3659 or Lisa Vanjoske at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Christine Westbrook at 202-551-5019 or Mary Beth Breslin at 202-551-3625 with any other questions.

Division of Corporation Finance Office of Healthcare & Insurance

cc: Daniel A. Lang