

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

February 8, 2019

Joseph Oliveto Chief Executive Officer Milestone Pharmaceuticals Inc. 6000 Fairview Road, Suite 1200 Charlotte, NC 28210-2252

Re: Milestone Pharmaceuticals Inc.
Draft Registration Statement on Form S-1
Filed December 21, 2018
CIK 0001408443

Dear Mr. Oliveto:

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.

#### DRS Form S-1

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

- 1. We note your reference to statistical significance in the second paragraph of this section. Please expand your discussion to explain the term and discuss how statistical significance relates to the FDA's evidentiary standards of efficacy.
- 2. We note your disclosure that you expect top-line data for the Phase 3 trial of etripamil in the first half of 2020. Please also clarify that your Phase 3 clinical program includes two safety trials and the expected timing for those trials.

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### Our Pipeline, page 1

- 3. We note the inclusion in your pipeline table of etripamil for atrial fibrillation and angina and that you do not intend to use any of the net proceeds of this offering to conduct clinical trials of etripamil for these indications. Please revise your table to remove these programs, or alternatively, explain how you are currently pursuing etripamil in atrial fibrillation and angina.
- 4. It appears from the pipeline chart that you have completed separate Phase 1 clinical trials of etripamil for atrial fibrillation and angina. Please separately describe the trials for these indications in the Business section.

### <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.

### Use of Proceeds, page 53

6. Please disclose whether the amount of funds allocated for the Phase 3 clinical trial of PSVT will be sufficient to complete the Phase 3 trial. If any material amounts of other funds are necessary, please disclose the amount of funds needed to complete Phase 3. Refer to Instruction 3 to Item 504 of Regulation S-K.

## Management's Discussion and Analysis of Financial Condition and Results of Operations Overview, page 63

7. Please reconcile your disclosure here that you expect to initiate a Phase 2 clinical trial of etripamil in atrial fibrillation in the first half of 2020 with your disclosure on pages 1 and 71 that you are planning the Phase 2 trial for atrial fibrillation for the second half of 2019.

### <u>Components of Results of Operations</u> <u>Research and Development Expenses, page 64</u>

8. We note your product candidate, etripamil, is being developed for multiple development projects, including paroxysmal supraventricular tachycardia, atrial fibrillation, and angina. Please revise your disclosure to separately break out research and development costs by each project for each period presented and to date. Your disclosure should also provide explanation of period to period fluctuations. If you do not track costs by these measures, please disclose that fact. Provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on each project.

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### Critical Accounting Policies and Estimates

Share-Based Compensation, page 69

9. 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 initial public offering 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.

### **Management**

Limitation on Liability and Indemnification Matters, page 102

10. You disclose that you entered into indemnity agreements with your directors and officers. Please file a copy of the form of indemnity agreement as an exhibit to this registration statement as required under Item 601(b)(10) of Regulation S-K.

### Principal Shareholders, page 121

11. Please revise your disclosure to identify the natural person or persons, if any, who have voting and investment control of the shares held by BDC Capital, Inc. and affiliates.

### General

12. 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 William Demarest at (202) 551-3432 or Yolanda Trotter at (202) 551-3472 if you have questions regarding comments on the financial statements and related matters. Please contact Elizabeth Walsh at (202) 551-3696 or Chris Edwards at (202) 551-6761 with any other questions.

Sincerely,

Division of Corporation Finance Office of Healthcare & Insurance

cc: Jaime L. Chase