# LATHAM & WATKINS LLP

March 26, 2021

VIA EDGAR

United States Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549-6010

Attention: Ada D. Sarmento and Dillon Hagius

Re: Biomea Fusion, Inc.

Draft Registration Statement on Form S-1 Confidentially submitted on February 12, 2021

CIK No. 0001840439

Ladies and Gentlemen:

On behalf of Biomea Fusion, Inc. (the "Company" or "Biomea"), we are hereby submitting a Draft Registration Statement on Form S-1 ("Registration Statement"). The Company previously submitted a Draft Registration Statement on Form S-1 on February 12, 2021 (the "Draft Submission") to the U.S. Securities and Exchange Commission (the "Commission") on a confidential basis pursuant to Title I, Section 106 under the Jumpstart Our Business Startups Act. The Registration Statement has been revised to reflect the Company's responses to the comment letter to the Draft Submission received on March 12, 2021 from the staff of the Commission (the "Staff").

For ease of review, we have set forth below each of the numbered comments of your letter in bold type followed by the Company's responses thereto.

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<u>Draft Registration Statement on Form S-1 submitted February 12, 2021</u>

#### **Prospectus Summary**

#### Overview, page 1

1. Please remove your statement that you believe that your capabilities and platform uniquely position you to be a leader in developing irreversible small molecules. Given the number of product candidates that never receive FDA approval, the time required to obtain approval and your current stage of development, this statement is not appropriate. Please remove any similar statements throughout the prospectus.

*Response*: The Company acknowledges the Staff's comment and advises the SEC that it has revised pages 1, 93 and 108 of the Registration Statement accordingly.

2. We note that you have included in your pipeline table two programs with undisclosed targets which appear to be in the discovery phase. Given the early-stage development of these programs, please explain why each program is sufficiently material to your business to warrant inclusion in your pipeline table. Please also explain what is involved in "Optimization" and why you believe this is a separate and distinct development phase, as opposed to part of IND-Enabling.

*Response*: The Company respectfully advises the Staff that the Company believes the inclusion of the two programs with undisclosed targets to be appropriate given the early stage of the Company's entire pipeline, with a lead development candidate for the first undisclosed program to be declared in 2022, shortly after the filing of an IND for the BMF-219 program in the second half of 2021. In addition, the Company anticipates using a material portion of the proceeds of the offering on the two programs with undisclosed candidates, and therefore believes their prominence to be appropriate and helpful for investors evaluating an investment decision.

The Company further respectfully advises the Staff that it has distinguished between the "optimization" and "IND-enabling" stages of development because it expects to undertake efforts to improve the chemistry of its potential lead development candidates during the "optimization stage" and prior to selecting a lead candidate from each program for IND-enabling studies. The Company views this step as being particularly important for its programs given the complex scaffold creation process required to promote irreversible binding. Upon commencement of such IND-enabling studies such underlying chemistry would not be subject to further change.

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#### Our FUSION System discovery platform, page 2

3. Please remove the reference to the transaction value for Pharmacyclics from this section. This is not appropriate disclosure for the Prospectus Summary where full and proper context is not provided. We note several references to the management team's experience developing ibrutinib. Please balance this disclosure throughout the prospectus by noting that past experiences are no guarantee of future success.

*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has removed the references to the transaction value for Pharmacyclics from and has added balancing disclosure to pages 3 and 106 of the Registration Statement.

#### Our Product Candidates, page 4

4. We note your statements throughout your filing that you believe BMF-219 is a potentially "first-in-class" irreversible menin inhibitor. These statements imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing marketing approval. Please remove the phrase "first-in-class" throughout your filing, including, but not limited to, on pages 107 and 108 in your Business section.

*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised pages 4, 107 and 108 of the Registration Statement to remove the phrase "first-in-class".

## Our Strategy, page 4

5. We note your disclosure here and in the Business section that your strategy is to "rapidly advance" BMF-219 into and through clinical development and to evaluate opportunities to "accelerate" development timelines. Please revise this disclosure to remove any implication that you will be successful in commercializing your product candidates in a rapid or accelerated manner as such statements are speculative.

*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised pages 4 and 108 of the Registration Statement so as not to suggest that the Company will be successful in commercializing its product candidates in a rapid or accelerated manner.

#### **Risk Factors**

If we are unable to obtain, maintain, enforce and adequately protect our patents and other intellectual property rights, page 55

6. You state here that you rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to your technology and product candidates, but you later disclose on page 125 that you currently do not own or in-license any issued patents with respect to any of your product candidates, including BMF-219. Please revise this risk factor accordingly.

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*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised page 55 of the Registration Statement to properly reflect that the Company relies on patent applications rather than issued patents.

## Our amended and restated certificate of incorporation and amended and restated bylaws will provide for an exclusive forum, page 73

7. Please revise this risk factor to disclose that there is also a risk that your exclusive forum provision may result in increased costs for investors to bring a claim.

*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised page 73 of the Registration Statement accordingly.

## Competition, page 123

8. Please disclose the basis for your belief that you are the only company with the ability to discover and develop irreversible binders specifically against menin. Please also revise your disclosure regarding the encouraging clinical benefit and strong pharmacologic validation of menin from preliminary Phase 1 results of other product candidates to avoid any suggestion that such product candidates have demonstrated safety or efficacy. Findings of safety and efficacy are solely within the authority of the FDA and are assessed throughout all clinical trial phases.

*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised page 123 of the Registration Statement to clarify the Company's belief that it is the only Company currently developing irreversible binders specifically against menin rather than the only company with the ability to do so.

Additionally, the Company respectfully acknowledges the Staff's comment regarding the suggestion of encouraging clinical benefit and pharmacological validation of menin from other product candidates and advises the Staff that it has revised page 123 of the Registration Statement to remove any suggestion that such product candidates have demonstrated safety or efficacy.

# Intellectual Property, page 124

9. Please revise to disclose the specific product candidates or technologies to which the patent applications relate and the type of patent protection you are trying to obtain (composition of matter, use or process). Please also briefly explain what an ex-U.S. patent application is. If that is meant to refer to a foreign patent application, please identify the jurisdiction.

*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised page 125 of the Registration Statement accordingly.

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# Principal Stockholders, page 157

10. Please revise to disclose how the entities listed in footnote 4 are affiliated with the Tavistock Group.

*Response*: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has revised page 157 of the Registration Statement accordingly.

#### **General**

11. 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.

*Response*: The Company acknowledges the SEC's comment and advises the SEC that it will supplementally provide the SEC with copies of all written communications, as defined in Rule 405 under the Securities Act, that the Company, or anyone authorized to do so on the Company's behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

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We hope the foregoing answers are responsive to your comments. Please do not hesitate to contact me by telephone at (415) 395-8198 or by fax at (650) 463-2600 with any questions or comments regarding this correspondence.

Very truly yours,

/s/ Miles P. Jennings

Miles P. Jennings of LATHAM & WATKINS LLP

CC: Thomas Butler, Biomea Fusion, Inc.
Rainer (Ramses) Erdtmann, Biomea Fusion, Inc.
Brian Cuneo, Latham & Watkins LLP
Charles Kim, Cooley LLP
Jonie Kondracki, Cooley LLP