March 12, 2021

Thomas Butler Chief Executive Officer Biomea Fusion, Inc. 726 Main Street Redwood City, CA 94063

> Re: Biomea Fusion, Inc. Draft Registration

Statement on Form S-1

Submitted February

12, 2021

CIK No. 0001840439

Dear Mr. Butler:

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

 $\ensuremath{\mathsf{EDGAR}}.$  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.

 $\qquad \qquad \text{After reviewing the information you provide in response to these comments and your } \\$ 

amended draft registration statement or filed registration statement, we may have additional  $% \left( 1\right) =\left( 1\right) +\left( 1\right$ 

comments.

Draft Registration Statement on Form S-1

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.

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

Thomas Butler

FirstName LastNameThomas Butler

Biomea Fusion, Inc.

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12, 2021

March2 12, 2021 Page 2

Page

March

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these programs, please explain why each program is sufficiently material to your business  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +$ 

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  $\ensuremath{\mathsf{S}}$ 

opposed to part of IND-Enabling.

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  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

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  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +\left$ 

that past experiences are no guarantee of future success. 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

 $\dot{}$  regulatory approval and are inappropriate given the length of time and uncertainty with

respect to securing marketing approval. Please remove the phrase "first-in-  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

class" throughout your filing, including, but not limited to, on pages 107 and 108 in your  $\,$ 

Business section.

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. 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  $% \left( 1\right) =\left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right) \left($ 

BMF-219. Please revise this risk factor accordingly.

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.

Thomas Butler

Biomea Fusion, Inc.

March 12, 2021

Page 3

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  $% \left( 1\right) =\left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right) \left( 1\right) +\left( 1\right) \left( 1$ 

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.

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.
Principal Stockholders, page 157

10. Please revise to disclose how the entities listed in footnote 4 are affiliated with the  $\,$ 

Tavistock Group.

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.

You may contact Eric Atallah at 202-551-3663 or Daniel Gordon at 202-551-3486 if you  $\,$ 

have questions regarding comments on the financial statements and related matters. Please  $\,$ 

contact Dillon Hagius at 202-551-7976 or Ada D. Sarmento at 202-551-3798 with any other questions.

Sincerely,

FirstName LastNameThomas Butler

Division of

Corporation Finance Comapany NameBiomea Fusion, Inc.

Office of Life

Sciences

March 12, 2021 Page 3

cc: Miles P. Jennings, Esq.

FirstName LastName