United States securities and exchange commission logo

April 14, 2021

Jeremy Bender, Ph.D., M.B.A.
Chief Executive Officer
Day One Biopharmaceuticals Holding Co LLC
395 Oyster Point Blvd., Suite 217
South San Francisco, CA 94080

Re: Day One Biopharmaceuticals Holding Co LLC
Draft Registration Statement on Form S-1
Submitted March 19, 2021
CIK No. 0001845337

Dear Dr. Bender:

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 March 19, 2021

Prospectus Summary
Overview, page 1

1. We note your statement on page 1 that your lead product candidate has the potential to be first-in-class and several other references to first-in-class on pages 2, 3, 104, 121, 126, and elsewhere in the prospectus. This term suggest that the product candidate is effective and likely to be approved by the FDA. Please delete these references throughout your registration statement. To the extent your use of this term was intended to convey your belief that the product is based on a novel technology or approach and/or is further along in the development process, you may discuss how your technology differs from technology used by competitors and, as applicable, that you are not aware of competing



products that are further along in the development process. Statements such as these should be accompanied by cautionary language that the statements are not intended to give any indication that the product candidate has been proven

effective or that it will
receive regulatory approval.
2. We note on page 2 that you plan to further [y]our leadership position. Please
substantiate this and other claims of leadership throughout the prospectus or revise them
to state them as your beliefs.
3. Please balance your statements that your portfolio is wholly-owned and that you hold
worldwide exclusive rights to DAY101 for all oncology indications and to pimasertib for
all therapeutic areas with reference to your milestone and royalty obligations under the
Viracta license agreement, as discussed on page 148.

Our Product Candidates, page 3

4. We note your statement on page 20 that you expect that the Phase 2 trial of DAY101 in
pLGG will provide a sufficient dataset to support marketing approval with only 60
patients. Please revise to state the basis for your claim and your references to the
FIREFLY-1 trial as pivotal.
5. Please shorten the arrows in the pipeline chart to correspond to the current stage of
development. For example, neither you nor the investigator has completed any Phase 2
clinical trial of DAY 101 for pediatric relapsed pLGG or as a frontline therapy in pLGG.
We will not object to footnote or explanatory disclosure to describe your anticipated
development plans.
6. The third product candidate disclosed in your pipeline table, MSC201503B, has not been
associated with a target disease. Please tell us why you believe it is material to your
business or remove it from your pipeline table. In this regard, we note that there does not
appear to be any discussion of this product candidate or your development efforts other
than in the disclosure of your license and patent agreements.

Our Strategy, page 5

7. We note your references to rapidly advancing your lead product candidate through
clinical development, the potential for expedited clinical execution and the ability to
rapidly advance clinical development of oncology product candidates in pediatric
patients. Please revise these statements here and throughout your registration statement to
remove any implication that you will be successful in commercializing your product
candidates in a rapid or accelerated manner.

Summary Consolidated Financial Data, page 11

8. Please revise to provide pro forma EPS in your consolidated statements of operations and
comprehensive loss data which reflects the conversion of your preferred shares. Refer to
Rule 11 of Regulation S-X.



Risk Factors
Risks related to our common stock and this offering, page 78

9. Please revise the exclusive forum risk factor on page 85 to disclose that investors cannot
waive compliance with the federal securities laws and the rules and regulations thereunder
and that there is also a risk that your forum selection provisions may result in increased
costs for investors to bring a claim.

Business, page 121

10. Revise your graphics throughout this section so that the fonts are large enough to be
legible.

Clinical trial results for pLGG, page 135

11. We note you have disclosed some treatment emergent adverse events here and some adverse events related to the pimasertib study on page 144. Please revise to identify all treatment-related serious adverse events and the number of patients that experienced them for each clinical trial you discuss.

12. Please tell us whether the MRI images on page 137 are representative of results observed in your Phase 1 trial of DAY101. If this graphic is not representative, please remove it.

Intellectual Property, page 150

13. In the third paragraph, you state you own or co-own a patent portfolio consisting of seven patent families, however, in the following paragraph it appears you only discuss five patent families. Please revise to clarify. Also, for each patent family, please disclose the applicable jurisdictions for your granted patents, rather than generalizing foreign patents.

Consolidated Financial Statements

Note 17. Subsequent Events, page F-31

14. Please revise to disclose the key terms for the Series B redeemable convertible preferred shares.

General

15. Please 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 Li Xiao at (202) 551-4391 or Kevin Kuhar at (202) 551-3662 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at (202) 551-6902 or Christine Westbrook at (202) 551-5019 with any other questions.

Sincerely,

Division of Corporation Finance

Office of Life Sciences

cc: Julia Forbess, Esq.