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May 4, 2021

### **VIA EDGAR**

U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, NE Washington, DC 20549

Attention: Abby Adams

Christine Westbrook

Li Xiao Kevin Kuhar

Re: Day One Biopharmaceuticals Holding Company, LLC

**Draft Registration Statement on Form S-1** 

Submitted March 19, 2021 CIK No. 0001845337

#### Ladies and Gentlemen:

On behalf of Day One Biopharmaceuticals Holding Company, LLC (the "Company"), we are concurrently transmitting herewith and filing on EDGAR a copy of the Company's updated Registration Statement on Form S-1 (CIK No. 0001845337) (the "Updated Registration Statement"), the draft of which was originally confidentially submitted by the Company to the U.S. Securities and Exchange Commission (the "Commission") on March 19, 2021 (the "Draft Registration Statement"). In this letter, we respond to the comments of the staff of the Commission (the "Staff") contained in the Staff's letter dated April 14, 2021 (the "Letter") with respect to the Draft Registration Statement. The numbered paragraphs below correspond to the numbered comments in the Letter and the Staff's comments are presented in bold italics.

In addition to addressing the comments raised by the Staff in the Letter, the Company has revised the Updated Registration Statement to update certain other disclosures.

# **Draft Registration Statement on Form S-1**

# **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.

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The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 1, 3, 106, 127, 128, 129, 132, 134 and F-7 of the Updated Registration Statement to remove references to the phrase "has the potential to be first-in-class" and references to "first-in-class".

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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 3, 131 and 133 of the Updated Registration Statement to clarify that it is the Company's belief that it is in a leadership position.

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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 2, 106, 127 and 132 of the Updated Registration Statement to make reference to the milestone and royalty payments, and to cross reference this disclosure to the discussion of the licensing agreement in the Business section on pages 154 through 157 of the Updated Registration Statement.

### 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."

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 4, 21, 129, 133, 134 and 144 of the Updated Registration Statement to clarify that the basis for this claim is certain discussions the Company has had with regulatory agencies.

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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 3, 107, 129 and 134 of the Updated Registration Statement to shorten the arrows in the pipeline chart to correspond to the current stage of development for each of the respective product candidates.

6. The third product candidate disclosed in your pipeline table, MSC2015[1]03B, 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.

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The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 3, 107, 129 and 134 of the Updated Registration Statement to remove references to MSC2015103B from the pipeline chart.

### 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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 2, 5, 128, 131, 132 and 133 of the Updated Registration Statement to remove references to "rapid advancements", the potential for "expedited" clinical execution and other similar language implying that the Company will be successful in commercializing its product candidates in a rapid or accelerated manner, and has inserted language clarifying which favorable regulatory pathways may be available to its product candidates on pages 2 and 128 of the Updated Registration Statement.

### **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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 12, 104, 117 and 118 of the Updated Registration Statement to provide pro forma EPS in its consolidated statements of operations and comprehensive loss data to reflect the conversion of its preferred shares.

#### **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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on page 86 of the Updated Registration Statement 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 the Company's 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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 135, 136, 137, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150 and 152 of the Updated Registration Statement to increase the font size in the graphics in the Business section.

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# 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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 142, 143 and 151 of the Updated Registration Statement to identify all treatment-related serious adverse events for both DAY101 and pimasertib.

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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on page 144 of the Updated Registration Statement to remove the MRI images.

# **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."

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages 157 and 158 of the Updated Registration Statement to clarify the discussion of the seven patent families, including identifying which patent families are owned versus co-owned, and to disclose the applicable foreign jurisdictions for its granted 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.

The Company respectfully acknowledges the Staff's comment and has revised its disclosure on pages F-44 through F-47 of the Updated Registration Statement 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.

The Company respectfully acknowledges the Staff's comment and will supplementally provide to the Staff, under separate cover, copies of all written communications, as defined in Rule 405 under the Securities Act, that the Company, or anyone the Company authorized to on its behalf, presented to potential investors in reliance of Section 5(d) of the Securities Act.

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Should the Staff have additional questions or comments regarding the foregoing, please do not hesitate to contact the undersigned at (415) 875-2420.

Sincerely,

FENWICK & WEST LLP

/s/ Julia Forbess

Julia Forbess Partner

cc: Jeremy Bender, Ph.D., M.B.A Chief Executive Officer **Day One Biopharmaceuticals Holding Co LLC** 

Effie Toshav, Esq. Robert Freedman, Esq. **Fenwick & West LLP**