

DIVISION OF CORPORATION FINANCE

April 16, 2021

Michael Mulholland Chief Financial Officer CytoDyn Inc. 1111 Main Street, Suite 660 Vancouver, Washington 98660

## Re: CytoDyn Inc. Form 10-K for the Fiscal Year ended May 31, 2020 File No. 000-49908

Dear Mr. Mulholland:

We have reviewed your March 23, 2021 response to our comment letter and have the following comment. In our comment, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this comment within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comment applies to your facts and circumstances, please tell us why in your response.

After reviewing your response to this comment, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our February 18, 2021 letter.

## Form 10-K for the Fiscal Year ended May 31, 2020

<u>Financial Statements</u> <u>Note 2 -- Summary of Significant Accounting Policies</u> Inventories Procured or Produced in Preparation for Product Launches, page 84

- 1. We do not believe your response to prior comment 2 from our letter dated February 18, 2021, provides a sufficient basis to support management's assertion that prelaunch inventory represented an asset at each date it was capitalized. For example:
  - You assert that your meetings with the FDA addressed safety and efficacy of the drug. However, the FDA's July 2020 Refusal to File letter states that your Biologics License Application omitted information necessary for the FDA to perform a substantive review of the product's safety and effectiveness.
  - You indicate that "...current scientific work being performed by the Company to complete a successful resubmission of the Company's BLA" is ongoing and that you

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do not expect to resubmit your BLA until mid-calendar year 2021 or shortly thereafter.

• You assert that you manufactured leronlimab consistent with cGMP standards. However, we note that the FDA's September 20, 2020, response to your list of questions related to the Refusal to File letter continued to reference issues with your clinical and statistical data, device related issues, and chemical manufacturing and control related issues.

We request that management reconsider the appropriateness of its capitalization conclusion in light of the examples above and tell us whether management believes there is any additional information bearing on these examples to support its capitalization conclusion. Please also propose revised disclosure that more fully conveys the points in the examples above.

You may contact Jeanne Baker at 202-551-3691 or Terence O'Brien at 202-551-3355 if you have questions regarding the comment.

Sincerely,

Division of Corporation Finance Office of Life Sciences