



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

February 18, 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 limited our review of your filing to the financial statements and related disclosures 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 these comments 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 comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

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

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1. You indicated by checkmark that you are an accelerated filer pursuant to the definitions in Rule 12b-2 of the Exchange Act. Pursuant to the March 12, 2020 revisions to these definitions, it appears that you are no longer an accelerated filer. Please confirm and ensure that you appropriately identify your filing status. In this regard, we note that an accelerated filer definition triggers the external auditor attestation requirement over internal control over financial reporting (ICFR) under Section 404(b) of the Sarbanes Oxley Act and you indicated by checkmark that you did not provide this attestation.

Financial Statements

Note 2 – Summary of Significant Accounting Policies

Inventories Procured or Produced in Preparation for Product Launches , page 84

2. We note that you began capitalizing inventories procured or produced in preparation for product launches during the quarter ended February 29, 2020. Tell us the

specific point during the FDA approval process that you determined the approval by the FDA was probable. Discuss any contingencies that need to be resolved prior to obtaining FDA approval. Clarify the nature of any manufacturing, marketing or labeling issues outstanding. Your response should address how your accounting for your inventory as of May 31, 2020, August 31, 2020 and November 30, 2020 complies with ASC 330-10-30 as well as paragraph 26 of Concepts Statement 6. Ensure your response also addresses the following:

- Tell us the dates of, and nature of the results from, meetings with the relevant regulatory authorities prior to the filing of your regulatory applications. In this regard, we note that you filed the non-clinical portion of your BLA on March 18, 2019 and your CMC portions of the BLA in April and May of 2020, but that you began to capitalize inventory during your quarter ended February 29, 2020;
  - Explain how the July 2020 Refusal to File Letter you received from the FDA and their refusal to schedule a Type A meeting impacted your analysis. Explain the nature of the deficiencies raised in the letter and why those deficiencies did not create a material risk or contingency such that the related inventory should no longer qualify for capitalization;
  - Explain the nature of the written responses received from the FDA related to your September 2020 submission. Explain the nature of additional information required by the FDA in order for you to resubmit the BLA. Address why the FDA's request for this information did not create a material risk or contingency such that the related inventory should no longer qualify for capitalization; and
  - Explain why your projected date for resubmitting the BLA keeps slipping. In this regard, in your Form 10-Q for the Quarter ended November 30, 2020, you disclose that you expect to resubmit the BLA in the 1<sup>st</sup> half of 2021, in your Form 10-Q for the quarter ended August 31, 2020, you disclose that you anticipate resubmitting the BLA by the end of the 2020 and in Form 10-K for the year ended May 31, 2020, you disclose that you hope to resubmit your BLA as soon as possible. Address whether your apparent inability to timely resubmit your BLA creates a material risk or contingency such that the related inventory should no longer qualify for capitalization.
3. Explain how you determined it is probable that this inventory will provide "some future economic benefit" in excess of capitalized costs. In doing so, please address the following:
- Please explain your term "some";
  - Based on the nature of your raw materials and work-in-progress, indicate whether these inventories are salable in their current form; and
  - We note that in assessing the lower of cost or net realizable value to pre-launch inventory, the Company relies on independent analysis provided by a third-party knowledgeable of the range of likely commercial prices comparable to current comparable commercial product. However, we note that you currently do not have

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finished goods inventory. Please provide a detailed explanation of how you determined the future economic benefit of your raw materials and work-in-progress.

4. We note that you consider the product stability data of all of the pre-approval inventory to determine whether it has an adequate shelf life. With reference to this data and expected approval date for your product, address how you determined that you will be able to realize the inventory prior to the expiration of the shelf life. Address the risks and uncertainties surrounding market acceptance of the product once approved and how this will effect the realization of your inventory.

In closing, we remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

You may contact Jeanne Baker 202-551-3691 or Terence O'Brien at 202-551-3355 with any questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences