



May 21, 2021

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street N.E.
Washington, D.C. 20549

**Re: CytoDyn Inc.
Form 10-K for the fiscal year ended May 31, 2020
File No. 000-49908**

Division of Corporation Finance:

CytoDyn Inc. ("CytoDyn" or the "Company") has received your letter dated May 19, 2021 with respect to the limited review by the staff ("Staff") of the Securities and Exchange Commission (the "Commission") of the Company's Form 10-K for the fiscal year ended May 31, 2020. CytoDyn understands the importance of providing accurate and adequate disclosures in its 1934 Act filings and appreciates this feedback from the Staff. For your convenience, the comments from your May 19, 2021 letter are repeated herein, and the Company's responses are set forth immediately following such comments.

Form 10-K for the fiscal year ended May 31, 2020

Note 2 — Summary of Significant Accounting Policies

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

1. We note your response to prior comment 1. Please expand your proposed disclosures to clarify that, due to their RTF letter, the FDA has not yet commenced their review of your BLA, including leronlimab's safety and efficacy. Ensure you also discuss and update the risks and uncertainties surrounding market acceptance and salability of leronlimab in your future periodic reports.
2. We note your response to prior comment 4 from our letter dated February 18, 2021. Given the significant delays in resubmitting your BLA, please expand your disclosures to provide detailed disaggregated information related to the remaining shelf lives of your inventory. As of each balance sheet date, please quantify the remaining shelf life of your raw materials, finished drug product in vials and bulk drug substance. To the extent material, separately quantify raw material that has a 12 month shelf life from raw materials with longer shelf lives. Please also disclose the point at which inventory may no longer be accepted by potential customers due to limited remaining shelf life.

RESPONSE:

The Company will expand its future disclosures as of each balance sheet date as follows, for illustration purposes the next report filing period end date of May 31, 2021 is used:

ITEM 1. BUSINESS.

The deficiencies cited by the FDA in its July 2020 Refusal to File letter consisted of administrative deficiencies, omissions, corrections to data presentation and related analyses and clarifications of manufacturing processes. While none of the deficiencies cited by the FDA related to leronlimab's clinically proven safety and efficacy, or the Company's ability to manufacture leronlimab at commercial scale consistent with cGMP standards, due to the deficiencies the FDA has not yet commenced their review of our BLA, including the clinical data that supports its safety and efficacy. Management believes, based on the results of our Phase 3 and Phase 2b/3 clinical trials, leronlimab is safe and effective. The Company is working with new consultants to effectively cure the BLA deficiencies and resubmit the BLA by mid-calendar year 2021 or shortly thereafter, in order to allow the FDA to perform their substantive review.

ITEM 1A. RISK FACTORS.

Risks Related to Our Business.

We have capitalized pre-launch inventories prior to receiving FDA marketing approval. If either FDA approval or market acceptance post-approval do not occur at all or on a timely basis prior to shelf-life expiration, the Company will be required to write-off pre-launch inventories which would materially and adversely affect our business, financial condition and stock price.

Pre-launch inventories consist of costs of raw materials and work-in-progress related to our product candidate leronlimab, which have been capitalized prior to the date that we anticipate that such product will receive FDA final marketing approval. The BLA resubmission will require updating the previously provided analyses which could result in significant delay in obtaining approval. If FDA approval is significantly delayed, the shelf-life of our pre-launch inventory may be limited, and the salability of our product may be affected. In addition, market acceptance of our product could fall short of our expectations, as a result of the introduction of a competing product, as a result of physicians being unwilling or unable to prescribe leronlimab to their patients, or if our target patient population is reluctant to try leronlimab as a new therapy. If any of these risks were to materialize with respect to our product, or if the launch of such product is significantly postponed, the salability of our pre-launch inventories would be adversely affected and may require write-off of the carrying value of our pre-launch inventories in amounts that could have a material adverse effect on our results of operations and financial condition.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Critical Accounting Policies and Estimates.

For inventories capitalized prior to FDA marketing approval in preparation of product launch, anticipated future sales, shelf-lives, and expected approval date are considered when evaluating realizability of pre-launch inventories. The shelf-life of a product is determined as part of the regulatory approval process; however, in assessing whether to capitalize pre-launch inventory

the Company considers the stability data of all inventories. As inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration. We also consider potential delays associated with regulatory approval in determining whether pre-approval inventory remains salable. See Note 4 – Inventories for information regarding the remaining shelf-lives of our pre-launch inventory, by each category of inventory. Although we believe our product will receive market acceptance, the introduction of a competing product could negatively impact the demand for our product and affect the realizability of our inventories. In addition, if physicians are unwilling or unable to prescribe leronlimab to their patients, or the target patient population was reluctant to try leronlimab as a new therapy, the salability of our pre-launch inventory would be adversely affected.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Note 2 – Summary of Significant Accounting Policies

Inventories Procured or Produced in Preparation for Product Launches

As inventories approach their shelf-life expiration the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Note 4 – Inventories

The deficiencies cited by the FDA in its July 2020 Refusal to File letter consisted of administrative deficiencies, omissions, corrections to data presentation and related analyses and clarifications of manufacturing processes. While none of the deficiencies cited by the FDA related to leronlimab's clinically proven safety and efficacy, or the Company's ability to manufacture leronlimab at commercial scale consistent with cGMP standards, due to the deficiencies the FDA has not yet commenced their review of our BLA, including the clinical data that supports its safety and efficacy. Management believes, based on the results of our Phase 3 and Phase 2b/3 clinical trials, leronlimab is safe and effective.

The Company is working with new consultants to effectively cure the BLA deficiencies and resubmit the BLA in order to allow the FDA to perform their substantive review. The Company anticipates when the FDA completes their review, leronlimab will be approved, and we will achieve market acceptance of leronlimab as a treatment for HIV, realizing the amount of pre-launch inventory on-hand, and occurring prior to shelf-life expiration. Accordingly, Management believes the Company will realize future economic benefit in excess of the carrying value of its pre-launch inventory.

The expiration of remaining shelf-life of the Company's inventory consists of the following as of May 31, 2021:

<u>Expiration period ending May 31,</u>	<u>Remaining Shelf-Life</u>	<u>Raw materials</u>	<u>Work-in-progress bulk drug product</u>	<u>Work-in-progress finished drug product in vials</u>	<u>Total inventory</u>
2022	12 or less months	\$ —	\$ —	\$ —	\$ —
2023	12 to 24 months	—	—	—	—
2024	24 to 36 months	—	—	—	—
2025	36 to 48 months	—	—	—	—
2026	48 to 60 months	—	—	—	—
Thereafter	60 or more months	—	—	—	—
Total		<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

When the remaining shelf-life of inventory is less than xx months, it is likely that it will not be accepted by potential customers. However, as inventories approach their shelf-life expiration the Company may perform additional stability testing to determine if the inventory is still viable which can result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration, which as of May 31, 2021 and May 31, 2020 was ## and ##, respectively. If the Company determines it is not likely shelf-life will be able to be extended or the inventory cannot be sold prior to expiration, the Company will write-down the inventory to its net realizable value. For the fiscal years ended May 31, 2021, May 31, 2020, and May 31, 2019, the Company recognized expense related to the write-down of obsolete inventory of ##, ##, and ##, respectively.

We appreciate your consideration of the responses provided herein and look forward to hearing from you regarding any additional comments based upon such responses. Please contact me by telephone at 360-980-8524 or by e-mail at amigliarese@cytodyn.com.

Very truly yours,

/s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer