May 7, 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 April 16, 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 April 16, 2021 letter are repeated herein, and the Company's responses are set forth immediately following such comments.

Financial Statements

Note 2 – Summary of Significant Accounting Policies

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.**

RESPONSE:

To clarify, our pre-BLA meetings with the FDA were about the presentation and analysis in the BLA of data regarding safety and efficacy, rather than the safety or efficacy of leronlimab itself. The safety and efficacy of our drug was determined solely by the results of our clinical trials. The statement in the July 2020 Refusal to File letter ("RTF Letter") that our BLA was missing certain analyses the FDA needed for its substantive review did not question leronlimab's clinically proven safety or efficacy or request new data, but asked only that we submit the complete data. The FDA did not request any additional trials or require any new scientific work, and we have not had any conversations or correspondence with the FDA where the FDA has questioned the drug's clinically proven safety or efficacy.

Furthermore, in response to your comment, management believes its prelaunch inventory represented an asset at each date it was capitalized primarily for the following reasons:

- The Company had successfully completed a Phase 3 clinical trial of leronlimab as a combination therapy for highly treatment experienced HIV patients with a p-value of 0.0032 based on a dosage of 350 mg;
- Leronlimab had been administered to over 1,200 patients in 11 clinical trials without any drug-related serious adverse events ("SAE's"), thus exhibiting a strong safety profile;
- Leronlimab also demonstrated safety and efficacy in a concurrent Phase 2b/3 investigative monotherapy trial using up to 700 mg which served as the basis for the FDA supporting a 700 mg dose in the BLA rather than the original 350 mg dose from the Phase 3 clinical trial;
- Leronlimab has been successfully manufactured in multiple batches at commercial scale consistent with cGMP standards; and
- The RTF Letter focused on presentation and omitted data and did not question the science, leronlimab's clinically proven safety or efficacy, or of the Company's proven ability to manufacture leronlimab at commercial scale in full compliance with cGMP standards.

In other words, the RTF Letter resulted from the FDA's conclusions that the Company's disclosures and presentations in the BLA were deficient, which was the unforeseen result of certain of the Company's prior regulatory consultants not performing work consistent with professional standards and their representations, including a third party laboratory's receptor occupancy analysis. In addition, and as noted in our previous letter, we are working with a new group of regulatory consultants to effectively address the deficiencies noted in the RTF Letter, which consisted of:

- 57% Administrative Corrections—Approximately 57% of the total comments addressed format errors, missing but available data, inoperable hyperlinks, and missing but available analysis as identified directly in the RTF Letter;
- 25% Scientific Clarifications—Approximately 25% of the total comments addressed required clarifications of analytics and assessments, including the revalidation of the receptor occupancy to assist the FDA in its substantive review of the BLA. None of those comments call into question the leronlimab's clinically proven safety or efficacy. Moreover, the revalidation of the receptor occupancy does not affect the efficacy of the drug, which our trials have proven is effective at either dose; and
- 18% Manufacturing Clarifications—Approximately 18% of the total comments addressed clarifications required by the FDA to understand the manufacturing controls used in production, container closure, media fills, labeling and packaging of leronlimab.

Therefore, the RTF Letter did not affect management's assessment of the timing of the recognition of prelaunch inventory as an asset and the Company's ability to realize future economic benefit in excess of each of the then-current carrying values of prelaunch inventory on the Company's reported balance sheet dates.

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

RESPONSE:

Our March 23, 2021 response letter imprecisely described the receptor occupancy analysis as "current scientific work being performed…" More precisely, the work involves revalidation of previously performed analyses from already available data. This revalidation is now being performed by a leading global healthcare diagnostics company pursuant to cGLP standards.

As all the deficiencies cited in the RTF Letter were curable, the Company initially anticipated it would be able to resubmit its BLA by the end of calendar year 2020. Numerous unforeseen events, however, pushed the projected resubmission date until mid-2021 or shortly thereafter. Those events include delays associated with the Company's unexpected pivot to focus on clinical trials to evaluate leronlimab as a potential therapeutic for COVID-19 (including numerous regulatory filings with many countries) thereby causing a redirection of Company resources, the difficulty of finding and engaging new qualified consultants to assist with the resubmission, and limited availability due to the ongoing COVID-19 pandemic of diagnostics laboratory capacity to revalidate the receptor occupancy analysis pursuant to cGLP standards. Despite these unanticipated delays, as of each reporting period, management believes it appropriately concluded it was, and continues to be, probable the Company will realize future economic benefit in excess of the carrying value of the prelaunch inventory.

- **You assert that you manufactured leronlimab consistent with cGMP standards. However, we note that the FDA's September 20, 2020[sic], 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.**

RESPONSE:

As noted above, the issues related to clinical and statistical data, and device related issues, are the result of curable presentation issues and omitted data in the submitted BLA. Indeed, many of the noted missing "device related issues" were contained in the original BLA, as confirmed by the FDA in subsequent correspondence. The "chemical, manufacturing and control related issues" were standard FDA review requests which were subsequently resolved post-BLA submission through written communications with the FDA and will be included in the BLA resubmission. These deficiencies and standard FDA review requests did not call into question the science, leronlimab's clinically proven safety or efficacy, or the Company's proven ability to manufacture leronlimab at commercial scale in full compliance with cGMP standards. As such, as of each reporting period, management believes it appropriately concluded it was and continues to be probable the Company will realize future economic benefit in excess of the carrying value of the prelaunch inventory.

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.

RESPONSE:

The examples cited by the Staff in the April 16, 2021 letter were the result of the Company's inadequate presentations and omitted data in the BLA and do not reflect any questioning by the FDA of the science, leronlimab's clinically proven safety or efficacy, or the Company's proven ability to manufacture leronlimab at commercial scale in full compliance with cGMP standards. The BLA deficiencies were the result of substandard work by certain prior regulatory consultants. The delays in the resubmission of the BLA are related primarily to the Company's unexpected pivot to focus on COVID-19 clinical trials, engaging new regulatory consultants to effectively address the noted deficiencies and the limited availability of diagnostics laboratory capacity due to the ongoing COVID-19 pandemic.

As noted in our previous response dated March 23, 2021, the Company relied on authoritative literature, including CON 6 R. 25 and 26, ASC330-10-20, ASC 330-10-10-1, ASC 330-10-30-1, and ASC 330-10-35, as well as the following five elements when evaluating its determination whether to capitalize prelaunch inventories for the quarter ended February 29, 2020 and each quarter thereafter:

a) the experience and history with regulatory approvals on the part of the management team and the Company's regulatory consultants;

b) the absence of any current or potential threatened or litigation challenges involving the drug;

c) the absence of any concerns by regulatory authorities or data to the contrary regarding the drug's clinically proven safety and efficacy;

d) current market factors;

e) the estimated timing of anticipated regulatory approval in comparison to the remaining shelf-life ofpre-launch inventories.

As the Company previously concluded, and giving consideration to the Staff's examples referenced herein, capitalization was appropriate at February 29, 2020 and, as discussed herein, there have been no changes in circumstances that give reason to revise its capitalization conclusion subsequent to that date.

Management's continuing conclusion that capitalization of prelaunch Inventories is appropriate is further underscored by the Company's extensive efforts and financial commitments (beginning in April 2019) to achieve commercial readiness upon FDA approval. Each quarter, the Company discloses, in Note 10 to its financial statements, its ongoing and increasing manufacturing commitments to Samsung BioLogics.

Please also propose revised disclosure that more fully conveys the points in the examples above.

RESPONSE:

The Company proposes adding the following disclosure to convey the points more fully in the example above:

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. None of the deficiencies cited related to the FDA's questioning the science, leronlimab's clinically proven safety and efficacy or the Company's ability to manufacture leronlimab at commercial scale consistent with cGMP standards. Management is working with new regulatory consultants to effectively cure the BLA deficiencies. Accordingly, management continues to believe the Company will realize future economic benefit in excess of the carrying value of its prelaunch inventory.

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 mmulholland@cytodyn.com.

Very truly yours,

/s/ Michael D. Mulholland
Michael D. Mulholland
Chief Financial Officer