March 23, 2021

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

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

Division of Corporate Finance:

CytoDyn Inc. ("CytoDyn" or the "Company") has received your letter dated February 18, 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 February 18, 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
Cover Page

1. **You indicated by checkmark that you are an accelerated filer pursuant to the definitions inRule12b-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.**

RESPONSE:

The Company had previously determined it was an accelerated filer under the old definition of accelerated filer in Rule12b-2. Based upon the amendments to the definition contained in Release No. 34-88365, effective April 27, 2020, the Company has determined it is not an accelerated filer because it is eligible to use the requirements for smaller reporting companies under the revenue test in paragraph (2) of the "smaller reporting company" definition in Rule 12b-2. The Company will correct its filing status on the cover page of subsequent filings.

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 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 you are 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 Form10-Q for the Quarter ended November 30, 2020, you disclose that you expect to resubmit the BLA in the 1st 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.**

RESPONSE:

The Company determined that FDA approval of leronlimab was probable during the quarter ended February 29, 2020 as a result of Company management, including its regulatory team, confirming that it believed the remaining two components of the Company's BLA (clinical and CMC) were nearly complete and the two remaining components would be filed before fiscal year ended May 31, 2020. The Company also took into account the fact that the FDA typically approves a new biologic eight to 12 months after BLA submission; however, the Company's drug, leronlimab, has a "fast track" designation, which was expected to potentially accelerate the time to approval. The subsequent receipt of the July 2020 Refusal to File letter ("RTF Letter") does not create a material risk or contingency such that the pre-launch inventory no longer qualifies for capitalization.

Background: Understanding the initial uncharted regulatory path is integral to understanding the delay in resubmission of the BLA and the current scientific work being performed by the Company to complete a successful resubmission of the Company's Biologics License Application ("BLA"). The Company's drug candidate, Vyrologix™, also known as leronlimab (PRO 140), is believed to represent the first monoclonal antibody with weekly subcutaneous dosing to successfully advance as a potential therapy for HIV patients. Consequently, the trial's design and the number of patients participating in the trial evolved materially in the early years of the trial as a result of the Company's ongoing discussions with the FDA. The Phase 3 trial to evaluate leronlimab's safety and efficacy for highly treatment experienced HIV patients was commonly referred to as the "Murray design," in recognition of the guidance provided by Jeffrey Murray, M.D., M.P.H., Deputy Director of the Division of Antivirals, Office of Infectious Diseases, Center for Drug Evaluation and Research, at the U.S. Food and Drug Administration ("FDA"). The importance of this trial is directed for the benefit of highly treatment experienced HIV patients because drug resistance develops after years of small molecule therapies for a number of reasons. Once an HIV patient has developed resistance to a certain number of available drug classes (of which there are primarily four available drug classes), there are no remaining antiviral agents available for treatment, which then leads to AIDS. Due to the challenging nature of enrolling HIV patients in this trial, i.e., concurrent with a patient's periodic visit with their treating physician to evaluate a change in the patient's drug regimen due to the onset of drug resistance, the treating physician offers enrollment in CytoDyn's Phase 3 trial for leronlimab to be introduced (for one week) and then in combination with a newly prescribed optimum background drug regimen (for 23 more weeks). The trial was initiated with the objective to enroll 300 patients. As subsequently discussed with the FDA in July 2016, due to the extreme difficulty to enroll the targeted patient, the enrollment was reduced to 150 patients. Following continued difficulties to enroll, the patient count was reduced to 30 patients in October 2016. Upon completion of enrolling 30 patients, the Company met with the FDA to review the trial's data. Due to various complexities of the data from 30 patients, the Company and the FDA agreed in October 2017 to continue patient recruitment in order to reach a total of 50 patients. In February 2018, the Company announced that its Phase 3 trial had achieved its primary endpoint with a 350 mg weekly dose of leronlimab. Of critical importance, the successful Phase 3 trial evaluated only 50 patients for safety and efficacy. Concurrent with this combination therapy trial, the Company was also conducting a Phase 2b/3 investigative trial with leronlimab as a monotherapy based upon initial success of a much smaller monotherapy clinical trial. The Phase 2b/3 investigative trial was investigating the cause of viral load failure in certain patients as compared to the successful viral load suppression in other patients. In the course of this evaluation, a Company key-opinion-leader ("KOL") recommended evaluating leronlimab dosage at higher levels of 525 mg and consequently 700 mg. During the pendency of this trial from approximately December 2016 to June 2020, the Company periodically reported the results of viral load suppression at the various dosage levels. In the later stages of this trial, it became clear that the optimum dosage level was 700 mg, which demonstrated it was over 90% effective in suppressing viral load post-first 10 weeks (the induction period). Following the recommendations of the FDA in December 2018, the Company changed its plan for BLA submission for 350 mg to a BLA submission at 700 mg. Per the FDA's recommendation, and recognizing the HIV patients in the Phase 3 trial were patients with a critical condition, the Company should use the most effective dose (700 mg) rather than the 350 mg dose in its BLA. The Company incorporated the safety data from over 500 patients in the Phase 2b/3 investigative trial to augment the safety data from the 50 patients in its Phase 3 trial and changed the dosage level in its BLA filing from 350 mg to 700 mg. As a consequence to the agreed upon change in dosage levels for the BLA filing, the Company committed to provide to the FDA empirical support for a Dose Justification Report.

The Company engaged a third-party laboratory to conduct receptor occupancy analyses to demonstrate why the higher dosage was more effective than the 350 mg dose in the successful Phase 3 trial. This agreed change of dose also required the Company to change its vials of 175 mg to 350 mg of leronlimab, which created a significant delay in the timeline for submitting the CMC (chemistry, manufacturing and control) section of the BLA, because the new size vials of drug require a stability analysis of at least six months. Note, the original 350 mg dose for the original 175 mg vials had already completed the six-month stability analysis. The Company submitted the last two sections (clinical and CMC/manufacturing) of the BLA to the FDA in April 2020, and the submission was completed on May 11, 2020.

It was brought to the Company's attention by the FDA in the RTF Letter that the third party laboratory's receptor occupancy analysis was not properly performed. Thereafter, the Company engaged a leading global healthcare diagnostics company, along with an expanded team of subject matter expert consultants, to conduct the receptor occupancy analysis to support the Dose Justification Report, which is currently contributing to the additional delay in the resubmission of its BLA. Concurrently, the Company is evaluating a traditional pharmacokinetics and pharmacodynamics ("PK/PD") approach as an alternative to the receptor occupancy analysis.

Although the Company is required to resubmit its receptor occupancy analyses to demonstrate why the higher dosage was more effective than the 350 mg dose in the successful Phase 3 trial, based upon the Company's correspondence and discussions with the FDA, management's assessment that regulatory approval was probable has not been affected. The FDA's requests for additional information and analyses in the RTF Letter and the correction of certain administrative submission deficiencies have been discussed orally and in writing with the FDA, and the Company has an expanded team of subject matter experts in place working to resolve the deficiencies as quickly as possible in order to resubmit its BLA. The FDA has not requested additional trials nor has the drug's efficacy or safety been questioned. Of particular significance, the FDA also offered the Company the opportunity to have a special analysis of the key elements of the BLA for 30 days to ensure the submission of the BLA is successfully filed. As discussed below, the potential and still pending approval, by several countries, of leronlimab as a therapeutic for critically ill COVID-19 patients diluted limited Company resources, thereby greatly adding to the delayed BLA resubmission.

A summary of the meetings with the FDA prior to the filing of the BLA regulatory applications follows:

Date	Type of Meeting	Purpose	Outcome
June 18, 2018	Type B, Pre-BLA meeting to discuss adequacy of Non-clinical, Clinical and CMC data in support of a planned BLA submission	Discuss adequacy of Non-clinical, Clinical and CMC data in support of a planned BLA submission	FDA reiterated potential review issues that could affect approvability of the BLA, which included, but were not limited to: the appropriateness of the patient population enrolled with respect to eligibility criteria, the adequacy of the study sample size, the lack of available safety laboratory data during the on-treatment interval and the requirement for full validation data from all PPQ lots at the time of the BLA submission.
December 14, 2018	Teleconference (Requested from FDA)	Follow-up to the Type B, Pre-BLA meeting held on June 18, 2018, to discuss specific and potential refuse to file issues identified to date to allow for corrective action in advance of planned BLA submission	FDA briefly reiterated the previous advice provided to CytoDyn regarding outstanding information to be completed prior to submission of BLA, where if not submitted in completed form, would be considered Refuse to File issues. These include final CMC information, an agreed upon iPSP and final results from a Human Factors study.
August 28, 2019	Teleconference (Informal)	Discuss Clinical and CMC data required for dose selection	FDA clarified data to support dose selection for HTE MDR patients; CytoDyn to provide FDA with timeline for submission of CMC and Clinical modules; agreement reached on drug stability data.

We will now address each of the Staff's questions.

We note that you began capitalizing inventories procured or produced in preparation for product launches during the quarter ended 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.

RESPONSE:

As noted above, the Company's Phase 3 trial achieved its primary endpoint in February 2018. Approximately 13 months later, in March 2019, the Company filed the non-clinical portion (the first component of a 3-component BLA). Subsequent to March 2019, the Company incurred both clinical and CMC-related delays, as described above under "Background." During the Company's third fiscal quarter ended February 29, 2020, management and its regulatory team confirmed that it collectively believed the remaining two components of the Company's BLA (clinical and CMC) were nearly complete and the two components would be filed before fiscal year ended May 31, 2020. Moreover, it is important to note the Company had manufactured leronlimab at commercial scale in 2018 and 2019 consistent with cGMP standards and such processes were fully validated, thereby qualifying such drug product batches for future commercial use, thereby successfully addressing a key criterion in the capitalization analysis and conclusion. With this information, the Company concluded the estimated future economic benefit of pre-launch inventory related costs were probable and therefore, capitalized certain qualified costs as pre-launch inventory consistent with ASC 330-10-20.

Discuss any contingencies that need to be resolved prior to obtaining FDA approval. Clarify the nature of any manufacturing, marketing or labeling issues outstanding.

RESPONSE:

The issue of unresolved contingencies or certain deficiencies to be cured in the resubmission of the BLA is addressed below in connection with the discussion surrounding the RTF Letter and the subsequent written correspondence between the Company and the FDA.

Your response should address how you are 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;**

RESPONSE:

The dates of, nature of the results from, meetings with the relevant regulatory authorities prior to the filing of the BLA are incorporated above in the "Background" section.

In summary, these meetings addressed safety and efficacy of the drug, along with plans for submission of the BLA. Moreover, none of the meetings questioned the safety or efficacy of the Company's drug candidate leronlimab. The final meeting was primarily focused on additional analyses to justify the proposed 700 mg dose, as well as the presentation of the analyses.

The Company's accounting of inventory as of the periods ended February 29, 2020, May 31, 2020, August 31, 2020 and November 30, 2020 relied specifically on the following authoritative literature which supports the Company's capitalization of pre-launch inventories:

- CON 6 R. 25, which states that assets are probable future economic benefits obtained or controlled by a company as a result of past transactions, and further states that the term *probable* is used with its usual general meaning, rather than in a specific accounting or technical sense (i.e. ASC 450-20), and refers to that which can reasonably be expected or believed on the basis of available evidence or logic but is neither certain nor proved acknowledging that business and other economic activities occur in an environment characterized by uncertainty in which few outcomes are certain.

- CON 6 R. 26, which states an asset has three essential characteristics: (a) it embodies a probable future benefit that involves a capacity, singly or in combination with other assets, to contribute directly or indirectly to future net cash inflows, (b) a particular entity can obtain the benefit and control others' access to it, and (c) the transaction or other event giving rise to the entity's right to or control of the benefit has already occurred.

    (a) Management expects upon approval of its drug for either the HIV indication orCOVID-19 indication, the available inventory will be sold quickly at very profitable gross margins,
    (b) Leronlimab is protected through a strong and robust patent portfolio in the U.S. and abroad. Moreover, a third party's ability to replicate the drug through an alternative manufacturing process is extremely remote if not improbable, and

    (c) The Company has executed commercial supply and distribution agreements with Vyera Pharmaceuticals, LLC in the U.S. for HIV and American Regent, Inc. for COVID-19 in the U.S.

- ASC 330-10-20, which states inventories are assets that are held for sale in the ordinary course of business, in the process of production for such sale, or currently consumed in the production of goods or services to be available for sale.
- ASC 330-10-10-1, which states a major objective of accounting for inventories is the proper determination of income through the process of matching appropriate costs against revenues.
- ASC 330-10-30-1, which states that the primary basis of accounting for inventories is cost. Cost is understood to mean acquisition and production cost.
- ASC 330-10-35-1, which states that the measurement of losses is accomplished by applying the rule of pricing inventories at cost or net realizable value, whichever is lower.

As disclosed in the Company's Quarterly Report on Form10-Q starting for the quarter ended February 29, 2020, as well as those subsequently filed, and in its Annual Report on Form 10-K for the fiscal year ended May 31, 2020, the Company concludes that when results of a clinical trial has reached a status sufficient to support regulatory approval (primary endpoint achieved in the Phase 3 trial in February 2018, coupled with the imminent completion of the remaining two sections of the BLA in April and May 2020), uncertainties regarding ultimate regulatory approval have been significantly reduced and the Company began capitalizing inventoriable costs and determined these capitalized costs will provide future economic benefit in excess of capitalized costs. The material factors considered by the Company in evaluating these uncertainties include the achievement of the primary endpoint of the Phase 3 clinical trial for leronlimab, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications, and the nearly completed BLA filing. If the Company becomes aware of any specific material risks or contingencies, other than the normal regulatory review process, or if there are identified any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory may no longer qualify for capitalization. Consistent with industry practice, the Company then began to capitalize pre-launch inventories following its determination the BLA approval was probable.

The Company determined it was probable thatpre-launch inventories have future economic benefit based on FDA approval being reasonably expected on the basis of available evidence and factors further discussed below, consistent with CON 6 R. 25 and 26. There was not one single factor that served as the singular determinant that FDA approval is probable; the Company arrived at this conclusion based on the collective effect of the following factors:

a) the experience and history with regulatory approvals with the expanded management team and 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 (see responses to Staff Comments 3. and 4. below); and

e) the estimated timing of anticipated regulatory approval in comparison to the remaining shelf-life ofpre-launch inventories (see response to Staff Comment 4. below).

a) The experience and history with regulatory approvals with the expanded management team and regulatory consultants

First and foremost, when evaluating the factors related to determining the probability of BLA approval, the Company relies heavily on the industry and regulatory specific experience of its management team, subject matter experts, capable advisors and consultants, along with its clinical research organization ("CRO"), Amarex Clinical Research, LLC. Since receipt of the RTF Letter, in October 2020, the Company hired a Chief Scientific Officer (with a M.D. and Ph.D.), who has over 30 years of academic and industry clinical research and development experience and his 18 years in pharmaceutical industry includes 16 successful BLA/NDAs and BLAs. More recently, the Company appointed a Chief Operating Officer (M.D.), who previously served as a principal investigator in over 100 clinical trials for numerous global pharmaceutical companies. The Company's incumbent Chief Technology Officer has over 30 years of drug development and manufacturing experience, including manufacturing the first GMP batch of leronlimab (PRO 140) while in a similar role at Progenics several years ago, where leronlimab was first developed. His deep experience with the Company's drug product candidate is the primary reason there have been no significant issues in the manufacturing process. In addition, the Company engaged additional highly qualified regulatory consultants to address and cure the administrative deficiencies cited in the RTF Letter.

b) The absence of any current or potential threatened or actual litigation.

Secondly, the Company evaluated any current or the potential for future threatened litigation with regard to leronlimab. While there are no such current or threatened actions, the Company believes the likelihood of any challenges to the patent portfolio surrounding leronlimab is remote. The Company's robust patent portfolio includes approximately 60 patents covering formulations, composition, methods, dosage regimes, treatments and use of modulators in CCR5, in addition to over 15 pending patent applications. In furtherance of preparation for its commercial launch of leronlimab, the Company obtained the registered name of Vyrologix™ and a trademark. In summary, the Company concludes the risk of an enforceable challenge to its patents continues to be remote.

c) Any implications related to correspondence with regulatory agencies regarding issues concerning the drug or approval of the product during the approval process.

As previously disclosed in its Form10-Q and Form 10-K filings, the Company believes approval is probable due to the absence of material uncertainties, including among others, no drug safety issues, demonstrated drug efficacy and the Company's ability to produce the drug at commercial scale consistent with fully validated cGMP standards and processes. The cited administrative deficiencies in the RTF Letter have been or continue to be addressed by the Company's expanded team of regulatory and subject matter experts:

- The result of a clinical trial has reached the status sufficient to support regulatory approval;
    - The Phase 3 clinical trial for leronlimab met its primary endpoint as a combination therapy for highly treatment experienced HIV patients and the FDA granted a rolling review for its original BLA submission and a decision for a rolling review is still pending for the resubmission.
- Uncertainties regarding ultimate regulatory approval have been significantly reduced;
    - Meetings with the relevant regulatory authorities prior to the filing of regulatory applications did not question the drug's safety or demonstrated efficacy.
    - The preparation and submission of the regulatory application.
    - In the opinion of management, the deficiencies cited in the RTF Letter are curable as there were no comments about the drug's safety, efficacy or manufacturing processes or standards.
- Of particular significance, the FDA offered the Company the opportunity to have a special analysis of the key elements of the BLA for 30 days to ensure the resubmission of the BLA is successfully filed.
- There are no issues related to the drug's safety or efficacy for the intended indication.

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.

RESPONSE:

The FDA noted in the RTF Letter the BLA omitted certain information and had various inadequacies in data analyses which rendered the application incomplete for the FDA's review, and which required substantial amounts of additional analyses along with corrections to datasets. The FDA noted the four following "basic deficiencies":

1. An absence of analyses needed to permit substantive clinical, statistical, clinical virology and clinical pharmacology review of the proposed dose. As noted above in the "Background" section, this issue arose as a consequence of a concurrently running clinical trial to investigate alternative dosages. The Phase 3 CD02 trial net its primary endpoint with a 350 mg dose and concurrently, the Company's Phase 2b/3 CD03 investigative trial was demonstrating a higher dose of 700 mg was over 90% more effective, thus the Company agreed to change its BLA filing from 350 mg to 700 mg.

2. Quality issues regarding electronic datasets, specifically an absence of certain variables and analysis group flags in files containing primary efficacy data needed for substantive review of the product's effectiveness and safety. The Agency also noted numerous instances of missing data and files not adequately defined or properly indexed.

3. The submission did not include demographic analyses of subpopulations with regard to effectiveness, and the Integrated Summary of Effectiveness was omitted from the submission. Certain sections regarding adverse effects on certain subgroups were not sufficiently detailed and/or did not include analyses of safety by race or ethnicity.

4. The submission did not include data from studies conducted with the drug in the device or information on the manufacturer of the syringe and needles.

In addition, the FDA provided extensive information to the Company regarding the nature of the additional material required for processing the BLA. That information related to the presentation of safety data; "human factor" issues; product quality ("356h") issues—which the FDA has since recognized have been resolved; prescribing information, exclusivity claims; and updated financial disclosure.

The primary deficiencies noted related to the writing of the clinical sections of the submission. The Company has retained additional internal and external experts to address those issues. In particular, with respect to the FDA's comments regarding receptor occupancy, the Company promptly addressed the deficiencies in the work product of the outside consultant who had originally performed that work and, as noted above, has engaged a global healthcare diagnostics company, along with an expanded team of regulatory subject matter expert consultants to re-perform the analyses, thereby curing the deficiency. In addition, the Company believes that receptor occupancy may be of marginal relevance given other clinical findings regarding dosage and is and will concurrently continue its discussions with the FDA on this issue. Nevertheless, the Company continues with the analysis suggested by the FDA. Finally, the Company has already resolved, or has substantially progressed in resolving, all device issues mentioned by the Agency in point 4 above and support for those resolutions will be included in the resubmission of the BLA.

The deficiencies noted in the RTF Letter did not create a material risk or contingency such that the relatedpre-launch inventory would no longer qualify for capitalization because those deficiencies were primarily the result of the inadequate portrayal of clinical data and the misinterpretation of certain of the FDA's policies regarding data submission and verification. The FDA had no comments about the drug's safety, efficacy or manufacturing processes or standards. The Company continues to fully believe that the product can be and will be approved for treatment of HIV patients.

Lastly, it should be noted the FDA did not "refuse to schedule a Type A meeting." On August 5, 2020, the Company submitted the following request to the FDA: "We would like to have a WebEx meeting on the first available date within 30 days from the date of submission of this request (Any date between August 3rd and August 31st). If a WebEx meeting is not possible within the requested dates, we request a Written Response Only." On September 1, 2020, the FDA acknowledged in their written responses the following: "On August 5, 2020, CytoDyn submitted a request for a Type A Meeting with the FDA. The meeting request included the meeting briefing package and outlined additional clarifying questions for the FDA. CytoDyn indicated that if scheduling difficulties preclude a teleconference between the dates of August 3 to August 31, 2020, that receipt of FDA written responses would be the preference."

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.

RESPONSE:

On September 1, 2020, the FDA responded to the list of questions the Company submitted on August 5, 2020 relating to the RTF Letter for the Company's drug candidate leronlimab. The FDA's response, which consisted of 18 pages, addressed 17 of the Company's questions and explained the nature of the additional information the FDA would require in a re-submitted BLA (and were further clarified in a teleconference on September 8, 2020). Following is a description of the nature of the FDA's response and requests for additional information:

Clinical and Statistical Data:

- The revised BLA should include a comprehensive, integrated assessment of efficacy, but the FDA does not expect the Company to pool CD02 efficacy data with CD03 efficacy data. It does expect integrated results per its Integrated Summary of Effectiveness guidance.
- The BLA should include an integrated assessment the proposed dose, as well as detailed data regarding the determination of the proposed optimal dose. The FDA provided extensive guidance on these issues (referred to herein above by CytoDyn as "Dose Justification Report").
- The FDA provided additional guidance as to presentation of the duration of exposure for all efficacy and safety analyses, the presentation of "human factors" analyses, and of clinical trial data.

Device Related Issues

- The FDA confirmed that testing on the Company's device filled with its drug is required to show that the device functions properly and safely with the drug.

Chemical Manufacturing and Control Related Issues

- The FDA requested additional information from a recent media fill using the product-specific container closure system, including monitoring procedures. Additional information regarding endotoxin specifications was also requested.

Additional Comments

- The FDA's written responses also included additional information regarding its standards for future submissions. None of those comments, however, identified any deficiencies in the Company's prior submissions.

The FDA's comments in its September 1, 2020 written responses did not create a material risk or contingency such that the related pre-launch inventory should no longer qualify for capitalization because none of the comments suggest that the drug is not safe or will not meet efficacy standards, as previously demonstrated in a successful Phase 3 trial.

Explain why your projected date for resubmitting the BLA keeps slipping. In this regard, in your Form10-Q for the Quarter ended November 30, 2020, you disclose that you expect to resubmit the BLA in the 1st 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.

RESPONSE:

The reasons for the delays in the resubmission of the BLA has been a combination of factors unrelated to the efficacy or safety of the drug and, therefore, we believe does not affect the probability of realizing future estimated economic benefit in excess of the capitalized value of pre-launch inventory. Among the challenges the Company has faced in its resubmission of the BLA, in order of significance are:

- The impact of the COVID-19 pandemic not only on the Company's own internal resources, but on its outside contractors and on the availability of laboratories to perform additional analyses;
- The failure of a highly reputable outside contractor to properly perform their contractual obligations in a timely and compliant manner in connection with receptor occupancy analyses;
- Delays in conducting tests at contractors' laboratories which are necessary for comprehensive analyses of inter-relation between different matters addressed by the FDA, such as virology data, pharmacokinetics/pharmacodynamics, and receptor occupancy to justify proposed 700 mg dose.

Early in the COVID-19 pandemic, the Company was advised by a group of physicians to evaluate leronlimab as a possible therapeutic treatment for COVID-19. The Company initiated two trials, a Phase 2 for mild-to-moderate and a Phase 3 for severe-to-critically ill COVID-19 patients, and later a recently initiated trial for long-haulers COVID-19 symptoms. The results from the Phase 3 severe-to-critical trial were reported in a Current Report on Form 8-K on March 8, 2021, and the positive results for a sub-population of this trial of 390 patients serves as the basis for a potential approval in one or more countries. The immediate re-direction of limited Company resources during the resubmission of the BLA and receipt of the RTF Letter towards trials for treatment of COVID-19 further delayed the collective efforts for a timelier resubmission of the BLA.

As previously stated, since the receipt of the RTF Letter, the Company has hired several management level employees with extensive experience in submission of BLA and sBLAs, including a Chief Scientific Officer and a Chief Operating Officer. To address and cure the administrative deficiencies cited in the RTF Letter, the Company has engaged additional highly qualified regulatory consultants. Although the Company has faced the setbacks outlined above, most of which were unanticipated, the Company expects to resubmit its BLA in mid-calendar year 2021 or shortly thereafter.

It is important to note that the potential of an immediate and still pending approval of leronlimab, as a potential treatment to COIVD-19, was never incorporated into the Company's ongoing assessment of the appropriateness of capitalizing pre-launch inventory. If leronlimab receives some form of conditional approval or full approval for COVID-19 by one or more countries, such a regulatory decision simply accelerates the commercial use of the drug on an earlier timeline.

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

RESPONSE:

When the Company evaluated whether it was probable that pre-launch inventory had probable future economic benefit prior to regulatory approval, it determined that future FDA approval (as discussed in the response to Comment 2. above) and the assumptions used to assess the lower of cost or net realizable value of pre-launch inventory were probable and reasonable expectations based on the available evidence and rationale as defined by CON 6 R. 25. The Company included the inadvertently conservative term "some," which obviously has no meaning or context, other than simply (and conservatively) referring to an estimated amount of the probable future economic benefit of its pre-launch inventory. The Company will remove the term "some" from future filings to eliminate any ambiguity.

Raw material inventories are purchased to be consumed during the production of finished goods and are not held for sale in current form. However, they are not specialized or specific to the Company's production of its biologic and could be salable. Work-in-progress ("WIP") inventories are manufactured bulk drug substance awaiting further processing, packaging and regulatory approval until they are salable. However, WIP in all material respects, approximates the product and value of finished goods in salable state. WIP inventories consist of manufactured drug in bulk form waiting to be filled into vials, or in filled vials awaiting labeling and packaging for distribution immediately upon approval. Thus, the Company determined the future probable economic benefit using the method as described in our disclosure of finished goods inventory for which net realizable value exceeds reasonably expected and known finished goods costs, as provided by studies conducted by two global drug research and marketing consulting firms.

Based on the Company's determination FDA approval is probable, its pre-launch inventory will provide future economic benefit based on the following evidence and rationale: (i) the various factors noted in the response to Comment 2. above, (ii) the anticipated market adoption, continued acceptance and forecast demand for leronlimab based on studies provided by two global drug research and marketing consulting firms, as discussed in the response to Comment 4. below, and (iii) the net realizable value will exceed the reasonably expected and known costs of finished salable goods as discussed above.

4. We note that you consider the product stability data of all of thepre-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.

RESPONSE:

The Company believes market acceptance of the Company's drug for HIV will be rapid, far outstripping the immediately availableon-hand inventory. In addition, management has a very clear estimate of remaining shelf-life after incorporating a potential range of worst- and best-case FDA approval dates for each category of inventory: raw materials (12-48 months, depending on types of raw materials), bulk drug substance (96 months) and finished drug product in vials (48 months). Estimated shelf-life of bulk drug substance and finished drug product are based on historical stability data under normal storage conditions. As each category of inventory is scheduled to move forward in processing to the filled vial stage (finished goods) to meet anticipated market demand, there will be no risk of obsolescence. Notwithstanding this overall summation of market demand for the drug and the availability of inventory, management will address the Staff's questions.

The Company evaluates the estimated timing of anticipated regulatory approval in comparison to the remaining shelf-life ofpre-approval inventory to determine whether adequate shelf-life remains to realize pre-approval inventory. Pre-approval inventory currently has an expected shelf-life of 4 years for finished drug product filled in vials (stored refrigerated) and up to 8 years if it is in bulk drug substance form, which is stored frozen, thus pre-approval inventories would reach their expiration between the quarters ending November 30, 2024 and November 30, 2028. As of the quarter ended November 30, 2020, the Company held pre-approval inventory of approximately $30 million of WIP drug product in unlabeled vials, approximately $41 million of WIP bulk drug substance, and approximately $28 million of raw materials. Further, the Company expects that as it continues to perform future stability studies and re-testing of shelf-lives, the current estimated shelf-lives may be further extended. The FDA typically approves a new biologic eight to 12 months after BLA submission; the Company, however, was granted a rolling review for its original BLA submission (a decision is still pending on a rolling review for the resubmission) and the drug, leronlimab, has a "fast track" designation, which could accelerate the time to approval. As noted herein above, the FDA also offered the Company the opportunity to have a special analysis of the key elements of the BLA for 30 days to ensure the resubmission of the BLA is successfully filed. As of the date of this letter, the Company expects to resubmit its BLA to the FDA in mid-2021 or shortly thereafter, thus the Company could receive approval in a best-case scenario in late 2021 or more conservatively in the first quarter of calendar 2022.

Based upon third-party market acceptance projections, the number of patients conservatively forecast to accept the drug during the initial launch period far exceeds the pre-launch inventory, and thus will be consumed prior to the estimated expiration. This same scenario continues to hold true and becomes even more conservative, as the estimated shelf-life of the other categories of inventory is not less than two times the remaining life of finished goods. As discussed above, the Company currently does not have sufficient quantities on-hand of WIP inventory to meet its conservative demand forecast and will continue to consume the raw materials on-hand as manufacturing accelerates upon regulatory approval. The Company has confidence it will realize full economic benefit of pre-launch inventories, as the conservative forecast acceptance rate of average number of monthly patients during the estimated shelf-life horizons far exceeds the available inventory.

The Company confidently believes the risks and uncertainties surrounding market acceptance of the product once approved and its effect on the realization of pre-launch inventory prior to shelf-life expiration has been adequately considered, evaluated and is considered remote. The number of patients required to adopt the drug during the initial product launch in order to realize all pre-launch inventory on-hand prior to expiration is far less than the conservative estimated number of patients expected to actually be adopting leronlimab. When determining the expected market acceptance of leronlimab, including the various risks and uncertainties surrounding market acceptance, the Company engaged two industry leading consulting firms, which specialize in assisting pharmaceutical companies in assessing market size, market risk and acceptance issues, and successfully developing successful commercialization plans to overcome risks and uncertainties. Based on the identification of the pertinent market risk and uncertainties identified during the consultants' analyses, they prepared for the Company expected patient's acceptance using the methodology described below. Their methodology and findings are supported by primary and secondary research they performed including focus groups and surveys with patients and doctors, and research of similar drugs. The methodology consisted of first determining the population of patients who could clinically benefit from leronlimab, then this population was adjusted for various patient specific, market, and drug failure factors. This then derived an estimated number of patients expected to adopt leronlimab for treatment. This number of patients was adjusted based on the anticipated adoption rate from the Company's launch plans and launches of other similar drugs.

The population of patients who could clinically benefit from leronlimab was projected based on the number of individuals in the US population: 1) with HIV, 2) with HIV diagnosis, 3) under physician care, and 4) treated with medications. Starting with the U.S. population, set percentages were applied to arrive at the number of individuals with HIV, with diagnosed HIV, under physician care, and treated with medications. The current number of prescribed patients were broken into drug resistance level, compliance, and treatment complexity-based segments, by excluding untreated patients from the patient breakdown which was obtained in physician quantification research. Leronlimab will be indicated for patients with exclusively CCR5-tropic strain of HIV. Thus, reductions were made to the target population segments to account for this fact. Further, physicians need to believe that patients can clinically benefit from leronlimab to consider prescribing it, and to account for physicians' belief in clinical benefit for patients and willingness to consider leronlimab, physician responses from the quant survey were applied to further narrow the target population segments. This resulted in an estimate of the number of patients who would clinically benefit from leronlimab.

The number of patients who would clinically benefit from leronlimab was then adjusted for the following various patient specific, market, and drug failure factors: leronlimab is a self-injectable biologic and patients' personal factors are likely to influence physician views on medication's suitability such as stable living with access to refrigeration and the lack of needle aversion. The target population size was reduced by the percentages of patients without stable enough living to support the use of refrigerated products and patients with needle aversion, to derive maximum achievable patient share of leronlimab. The analyses also incorporated the various payor models. After applying these adjustments, among several others, to number of patients who would clinically benefit from leronlimab, the estimated number of patients expected to adopt leronlimab for treatment was derived. Based upon the analyses conducted by two firms, the Company confidently believes it will realize future economic benefit from pre-launch inventories as

the forecast number of patients expected to adopt leronlimab during the estimated period of inventory obsolescence far exceeds the current inventory on-hand. As disclosed in the Company's Form10-Qs beginning with the quarter ended February 29, 2020 and Form10-K for the year ended May 31, 2020, the Company evaluates its inventory levels on a quarterly basis and writes down inventory that has become obsolete or has a cost in excess of its expected net realizable value, and inventory quantities in excess of expected requirements. Thus, if in the future, the Company determines any pre-launch inventories are no longer realizable, it will accordingly write down the appropriate amount of the pre-launch 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
Chief Financial Officer