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LATHAM & WATKINS LLP

December 4, 2023

VIA EDGAR

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

Re: CG Oncology, Inc.
Draft Registration Statement on Form S-1
Submitted October 27, 2023
CIK No. 0001991792

Dear Mr. McNamara:

We are in receipt of the letter dated November 24, 2023 from the staff of the U.S. Securities and Exchange Commission (the "***Staff***") with respect to the above-referenced confidential draft Registration Statement (the "***Registration Statement***"). We are responding to the Staff's comments on behalf of CG Oncology, Inc. ("***CG Oncology***" or the "***Company***") as set forth below. Simultaneously with the submission of this letter, the Company is confidentially submitting via EDGAR Amendment No. 1 to the draft Registration Statement (the "***Amended Registration Statement***") responding to the Staff's comments and updating the Registration Statement.

The Company's responses set forth in this letter are numbered to correspond to the numbered comments in the Staff's letter. All terms used but not defined herein have the meanings assigned to such terms in the Amended Registration Statement. For ease of reference, we have set forth the Staff's comments and the Company's response for each item below.

Draft Registration Statement on Form S-1 submitted on October 27, 2023
Prospectus Summary
Overview, page 1

1. *Please revise your prospectus summary to explain briefly at first use each of the scientific or technical terms. By way of example only, we note the following terms:*

    - *Transurethral resection*
    - *In situ*
    - *Duration of response*

CG Oncology's Response: The Company has revised pages 1, 4, 101 and 107 of the Amended Registration Statement in response to the Staff's comment to generally define such terms, and others, at first use. The Company respectfully advises the Staff that the definition of TURBT, or transurethral resection of the bladder tumor, is defined on page 4 and 107 of the Amended Registration Statement which the Company believes is appropriate given the context of the procedure and the surrounding disclosure within that section.

2. *We note your disclosure that you have observed "encouraging interim results in [y]our ongoing open-label Phase 2 CORE-001 clinical trial of cretostimogene in combination with pembrolizumab in high-risk BCG-unresponsive NMIBC patients." Please remove the term "encouraging" here, and elsewhere, regarding the results as this may create an inference that a product candidate is more likely to be found to be safe and effective. Please limit the discussion to the objective clinical data, such as the endpoints.*

CG Oncology's Response: The Company has revised pages 1, and 101 of the Amended Registration Statement to remove the above references in response to the Staff's comment.

3. *We note your reference to interim results. Please revise your disclosure to note, as you do on page 26, that interim, topline or preliminary results that you report may differ from future results of the same studies or trials.*

CG Oncology's Response: The Company has revised pages 2, 101 and 116 of the Amended Registration Statement in response to the Staff's comment.

4. *Please specify whether the referenced trials, here and elsewhere, were powered for statistical significance.*

CG Oncology's Response: The Company respectfully advises the Staff that for the single-arm trials disclosed in the Amended Registration Statement, the relevant statistical consideration is the 95% confidence interval ("***CI***") of the complete response rate, which is consistent with FDA's published 2018 guidance for the targeted indications under evaluation and discussed in the Amended Registration Statement. The Company has revised the Amended Registration Statement throughout, including pages 1, 2, 101, 111, 114, 116 and 117 of the Amended Registration Statement to disclose the CI for the relevant trial endpoints and inform investors of the meaning of the CI.

5. *Please disclose whether any of the observations of adverse events from the trails were considered serious adverse events. In addition, please advise, if true, that adverse events greater than or equal to Grade 3 TRAEs are considered serious adverse events or otherwise advise.*

CG Oncology's Response: The Company respectfully advises the Staff that serious adverse events in the Company's clinical trials are generally defined to include certain adverse events that are fatal or life-threatening, result in inpatient hospitalization or prolongation of an existing hospitalization, or result in persistent or significant disability or incapacity, as well as other medically significant events that may jeopardize the patient or require medical or surgical intervention. Serious adverse events are similar to, but distinguishable from, the grades of severity assigned to such adverse events. The Company has revised pages 1, 2, 101, 115 and 116 of the Amended Registration Statement to clarify the foregoing in response to the Staff's comment.

6. *We note that your ongoing open-label Phase 2 CORE-001 clinical trial, you observed "one TRAE leading to a patient discontinuation of pembrolizumab." Please revise your disclosure to specify the type of TRAE that was observed and how it was graded.*

CG Oncology's Response: The Company has revised pages 2, 101 and 188 of the Amended Registration Statement in response to the Staff's comment.

Management's Discussion and Analysis of Financial Condition and Results of Operations

7. *To the extent you track research and development expenses by indication or treatment setting as depicted in your pipeline table, revise to provide a breakdown on that basis. If you do not track by indication or treatment setting, disclose that fact.*

CG Oncology's Response: The Company has revised page 88 of the Amended Registration Statement to indicate it does not track expenses by indication or treatment setting, in response to the Staff's comment.

Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation, page 93

8. *Once you have estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. Please discuss with the staff how to submit your response. Revise your MD&A as well as Recent Sales of Unregistered Securities section on page II-2 to provide a tabular presentation of your option grants and how they were valued.*

CG Oncology's Response: The Company acknowledges the Staff's comment and will provide to the Staff on a supplemental basis the requested information with respect to the differences between recent valuations of the Company's common stock leading up to the initial public offering and the estimated offering price range once an estimated offering price range has been determined. The Company has also revised page 99 of the Amended Registration Statement in response to the Staff's comment. The Company respectfully advises the Staff that the Company does not believe disclosing the specific details of how options were valued or related grants in Item 15 of Part II of Form S-1, beyond what is currently disclosed, is necessary given the added disclosure in MD&A.

Combination of Cretostimogene Plus Pembrolizumab for High-risk BCG-unresponsive CIS-containing NMIBC, Page 113

9. *We note your disclosure regarding the clinical trial collaboration and supply agreement with Merck. Please describe the material terms of this agreement, and file this agreement in accordance with Item 601(b)(10) of Regulation S-K, or otherwise advise.*

CG Oncology's Response: The Company respectfully advises the Staff that the Company does not believe this agreement is material to its operations or clinical trials, but for the ability of the Company to obtain no-cost supply of the drug from Merck. There are no milestone, royalty or other payments required under the agreement by the Company or Merck, and the agreement will terminate upon conclusion of the clinical trial. Further, the Company could always elect to purchase the drug supply on the open market. In addition, the Company respectfully advises the Staff that the disclosure on page 117 of the Amended Registration Statement discloses the foregoing and provides the information that would be material to investors in understanding the agreement. For the foregoing reasons, the Company respectfully submits that it is not substantially dependent on the Merck agreement and such agreement is not required to be filed as a material agreement under Item 601(b)(10) of Regulation S-K.

Intellectual Property, Page 118

10. *Please revise your disclosure to specify the nature of your pending patent applications (e.g., composition of matter, method of use or process).*

CG Oncology's Response: The Company has revised page 122 of the Amended Registration Statement in response to the Staff's comment.

Management Executive Officers and Directors, page 129

11. *We note your disclosure that Mr. DiPalma worked as a consultant and senior advisor since March 2021 and became CFO in March 2023. We also note your disclosure on page 158 that Mr. DiPalma is a managing director at Danforth and appears to be compensated through this position. Please revise your disclosure to clarify whether Mr. DiPalma is working on a full-time basis for your company.*

CG Oncology's Response: The Company has revised pages 134 and 163 of the Amended Registration Statement in response to the Staff's comment.

General

12. *Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.*

CG Oncology's Response: The Company acknowledges the Staff's comment and will provide to the Staff on a supplemental basis under separate cover copies of all written materials that the Company, or anyone authorized to do so on the Company's behalf, has presented or expects to present to potential investors in reliance on Section 5(d) of the Securities Act of 1933.

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LATHAM & WATKINS LLP

Any comments or questions regarding the foregoing should be directed to the undersigned at (858) 523-3962. Thank you in advance for your cooperation in connection with this matter.

Very truly yours,

/s/ Matthew T. Bush

Matthew T. Bush of LATHAM & WATKINS LLP

cc: Arthur Kuan, *CG Oncology, Inc.*
Stephen DiPalma, *CG Oncology, Inc.*
Cheston J. Larson, *Latham & Watkins LLP*
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