



DIVISION OF
CORPORATION FINANCE

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

November 24, 2023

Arthur Kuan
Chief Executive Officer
CG Oncology, Inc.
400 Spectrum Center Drive, Suite 2040
Irvine, CA 92618

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

Dear Arthur Kuan:

We have reviewed your draft registration statement and have the following comment(s).

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

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
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.

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.
4. Please specify whether the referenced trials, here and elsewhere, were powered for statistical significance.
5. Please disclose whether any of the observations of adverse events from the trials 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.
6. We note that in 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 88

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.

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

8. Once you have an 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.

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.

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).

Arthur Kuan
CG Oncology, Inc.
November 24, 2023
Page 3

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.

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.

Please contact Eric Atallah at 202-551-3663 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at 202-551-7349 or Joshua Gorsky at 202-551-7836 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Matthew T. Bush