UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported) May 3, 2024

CG Oncology, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-41925**	**37-1611499**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

400 Spectrum Center Drive, Suite 2040
Irvine, CA 92618
(949) 409-3700
(Address and zip code; telephone number, including area code, of registrant's principal executive offices)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	CGON	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On May 3, 2024, CG Oncology, Inc. (the Company) announced that interim data from the Phase 3 BOND-003 study evaluating the efficacy and safety of cretostimogene monotherapy in patients with high-risk Non-Muscle-Invasive Bladder Cancer (NMIBC) unresponsive to Bacillus Calmette-Guerin (BCG), showed that 75.2% of patients (79 out of 105 [95% Confidence Interval (CI), 65-83]) achieved a complete response (CR) at any time, as of the cutoff date of April 1, 2024. These data were featured today at the Paradigm-Shifting, Practice-Changing Clinical Trials in Urology Plenary Session as an Oral Presentation (Abstract #24-11358) by Dr. Mark D. Tyson, urologic oncologist at Mayo Clinic, at the 2024 American Urological Association Annual Meeting, in San Antonio, TX. In addition, cretostimogene has shown durable responses over time with 29 patients maintaining a CR for 12 months or more, pending evaluation and assessment of ongoing responses in 22 additional patients as of the data cutoff. Median duration of response (DOR) was not reached as of the cutoff date. In addition, 53.8% of repeat induction patients converted to a CR as of the data cutoff. 92.4% cystectomy-free-survival was observed and none of the patients with a CR had undergone radical cystectomy or showed nodal or metastatic progression.

BOND-003 is a single-arm, Phase 3, monotherapy clinical trial for the treatment of patients with high-risk BCG-unresponsive NMIBC with carcinoma in-situ (CIS) with or without Ta or T1 papillary tumors. The fully enrolled global trial with a total of 112 patients is currently ongoing in North America and the Asia-Pacific region. The primary endpoint of the study is CR at any time, with DOR measured as a secondary endpoint. The highly pre-treated study population includes patients with prior intravesical chemotherapy and systemic immunotherapy. The Company expects to report topline data from BOND-003 by the end of 2024.

Cretostimogene has been generally well-tolerated in the trial as of the safety cutoff date of January 31, 2024. There were no Grade 3 or higher treatment-related adverse events (TRAEs) or deaths reported, and two patients (1.8%) had serious TRAEs (Grade 2), cystitis noninfective and clot retention. No treatment-related discontinuation of cretostimogene was observed. 94.5% of patients completed all expected treatments, and all patients that completed their expected treatments had a 100% successful instillation rate. TRAEs occurred in 70 patients (62.5% percent). The most common TRAEs (≥10%) were bladder spasm, pollakiuria, dysuria, micturition urgency, and hematuria, as of the safety cutoff date.

Forward Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to, the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients and the expected timing of topline data for the BOND-003 trial. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in our business, including, without limitation: interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data becomes available; potential delays in the commencement, enrollment, data readout and completion of clinical trials, including the BOND-003 trials our dependence on third parties in connection with manufacturing, shipping and clinical and preclinical testing; results from earlier clinical trials and preclinical studies not necessarily being predictive of future results; unexpected adverse side effects or inadequate efficacy of cretostimogene that may limit its development, regulatory approval, and/or commercialization; and other risks described in our filings with the SEC, including under the heading “Risk Factors” in our annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CG Oncology, Inc.

Date: May 3, 2024

By: /s/ Corleen Roche
Name: Corleen Roche
Title: Chief Financial Officer