UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): December 5, 2024

CG Oncology, Inc.
(Exact name of Registrant as Specified in Its 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, California**	**92618**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (949) 409-3700

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:

☐ Written communications 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 7.01 Regulation FD Disclosure.

On December 5, 2024, CG Oncology, Inc. (the Company) issued a press release entitled "Groundbreaking Cretostimogene Grenadenorepvec Monotherapy Data Demonstrates Sustained, Durable Complete Responses in High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

On December 5, 2024, the Company posted an updated corporate presentation on the Company's website. Investors may access the presentation by visiting the "Investor Relations" section of the Company's website at www.cgoncology.com. The Company plans to use its website to disseminate future updates to its corporate presentation and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information furnished under this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

By furnishing the information in this Item 7.01, the Company makes no admission as to the materiality of Item 7.01 in this report or the presentation available on the Company's website. The information contained in the corporate presentation is summary information that is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Item 7.01, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases, by updating its website or through other public disclosure.

Item 8.01 Other Events.

On December 5, 2024, the Company reported topline data from the BOND-003 Phase 3 clinical trial evaluating the efficacy and safety of cretostimogene as monotherapy in patients with high-risk BCG-unresponsive non-muscle invasive bladder cancer (NMIBC). These topline data showed that 74.5% of patients (82 out of 110) (95% confidence interval (CI), 65.4-82.4%) achieved a complete response (CR) at any time, as of the data cutoff date on September 30, 2024. Median duration of response (DOR) was not reached as of the cutoff date, but was greater than 27 months. Median follow-up in responders was also not yet reached, but was at least 14.5 months as of the data cutoff.

Additionally, as of the data cutoff date on September 30, 2024, the CR rate of patients at 12 months was 46% (51 out of 110) (95% CI, 36.9-56.1%) including two additional responders confirmed after the data cutoff. There are 25 confirmed CRs that have reached the 24-month timepoint and beyond. The Kaplan-Meier estimates for CR rate at 12 and 24 months were 50% (95% CI, 39.6-58.9%) and 41% (95% CI, 30.4-50.8%), respectively. Progression-free survival (PFS) at 12 months was 97.3% with no patients progressing to muscle invasive cancer, and cystectomy-free survival (CFS) at 12 months was 90.0%. The estimated DOR probability at 12 months and 24 months was 63.5% (95% CI, 51.2-73.4%) and 56.6% (95% CI, 43.3-67.8%), respectively. 50.0% of patients reinduced with oncolytic immunotherapy converted to CR, 64.3% remained in durable response after conversion to CR and patients continued in CR after treatment completion. A CR is defined as having a negative cystoscopy, a negative urine cytology and a negative biopsy. In addition, all patients at the 12-month timepoint undergo mandatory, systematic bladder mapping of five locations, biopsy of the prostatic urethra and upper tract-imaging to confirm CR and detect possible occult disease in the bladder.

Cretostimogene has been generally well-tolerated in the trial as of the safety cutoff date of September 30, 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) of noninfective cystitis and clot retention. No treatment-related discontinuations of cretostimogene were observed. 97.3% of patients completed all protocol-defined treatments, demonstrating favorable patient adherence and compliance. The most common TRAEs (≥10%) were bladder spasm (25.0%), pollakiuria (20.5%), dysuria (19.6%), micturition urgency (15.2%) and hematuria (13.4%), as of the safety cutoff date of September 30, 2024.

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* 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. Two patients were not evaluable due to discontinuations unrelated to study drug. The primary endpoint of the study is CR at any time, with DOR, PFS and CFS among the secondary endpoints. The highly pre-treated study population includes patients with prior intravesical chemotherapy and systemic immunotherapy.

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 the Company's 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 its potential to have best-in-class durable response and meaningfully improve patient outcomes, and the importance of the data as they relate to addressing bladder cancer. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Company's business, including, without limitation: additional patient data related to cretostimogene that continues to become available may be inconsistent with the data produced as of the data cutoff, and further analysis of existing data and analysis of new data may lead to conclusions different from those established as of the date hereof; 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; potential delays in the commencement, enrollment and completion of clinical trials; competitive developments with respect to current and other investigational NMIBC treatments may adversely affect the commercial opportunity of cretostimogene; and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC (which are available at http://www.sec.gov). You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated December 5, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: December 5, 2024

By: /s/ Josh Patterson
Name: Josh Patterson
Title: General Counsel and Chief Compliance Officer

Groundbreaking Cretostimogene Grenadenorepvec Monotherapy Data Demonstrates Sustained, Durable Complete Responses in High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

– 74.5% of patients achieved a complete response at any time –

– Median duration of response is greater than 27 months and not reached –

– Latest data update continued to show favorable safety and tolerability results –

– Company hosting virtual investor event with lead investigator at 8 am EST today –

IRVINE, Calif., December 5, 2024 — CG Oncology, Inc. (NASDAQ: CGON), a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients with bladder cancer, today announced topline data from the Phase 3 BOND-003 trial in patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) unresponsive to Bacillus Calmette Guerin (BCG) demonstrating 74.5% of patients (82 out of 110, 95% CI, 65.4% - 82.4%) achieved a complete response (CR) at any time, after receiving treatment with cretostimogene as a single agent. The median duration of response (DOR) has not been reached but exceeds 27 months as of the data cutoff of September 30, 2024. These data will be presented today as a Late-Breaking Abstract at the Society of Urologic Oncology (SUO) 25th Annual Meeting. Additionally, the company is hosting a virtual investor event today at 8 am EST and details to join are included below.

“There continues to be a significant need for new treatment options for patients with bladder cancer,” said Gary D. Steinberg, M.D., Professor, Department of Urology at Rush University Medical Center. “Therefore, I am very encouraged by the latest data from the BOND-003 study, which demonstrates cretostimogene’s compelling efficacy as well as its potential to induce a best-in-class durable response in NMIBC patients, with 63.5% of patients remaining in response at 12 months or greater and 56.6% of patients remaining in response at 24 months or greater, by K-M estimate. Additionally, 97.3% of patients were free from progression to Muscle Invasive Bladder Cancer (MIBC) at 12 months. If approved by the FDA, cretostimogene may represent an important, bladder-sparing, advancement in the bladder cancer treatment paradigm, and meaningfully improve patient outcomes.”

There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. No treatment-related discontinuation of cretostimogene was observed. 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria.

"The BOND-003 monotherapy data underscores our novel investigational oncolytic immunotherapy's unique product profile, including its dual mechanism of action, which we believe differentiates it from current and investigational NMIBC treatments," said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. "Based upon the latest data, we are confident that cretostimogene is well positioned to address an unmet need for patients as a potential backbone bladder-sparing therapeutic if approved by the FDA."

About the BOND-003 Phase 3 Trial

BOND-003 (NCT04452591) 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 trial is CR at any time, with DOR measured as a secondary endpoint. The highly pre-treated trial population includes patients with prior intravesical chemotherapy and systemic immunotherapy.

Cretostimogene monotherapy received FDA Fast Track and Breakthrough Therapy Designations in BCG-Unresponsive, high-risk NMIBC patients with CIS in December 2023. On May 3, 2024, CG Oncology presented preliminary data from the Phase 3 BOND-003 trial at the 2024 American Urological Association Annual Meeting.

Investor Conference Call

CG Oncology will host a conference call and live webcast at 8 am EST today, December 5, 2024. Individuals interested in listening to the live conference call may do so by using the webcast link in the "Investor Relations" section of the company's website at https://ir.cgoncology.com. A webcast replay will be available in the investor relations section on the company's website following the completion of the call.

About Bladder Cancer

More than 83,000 people are estimated to be diagnosed with bladder cancer in 2024. NMIBC is the most common form of bladder cancer, representing approximately 75% of newly diagnosed cases. Bladder cancer is the sixth most common form of cancer in the United States, and men account for three quarters of newly diagnosed cases.

About Cretostimogene Grenadenorepvec

Cretostimogene grenadenorepvec is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 250 patients with Non-Muscle Invasive Bladder Cancer (NMIBC). This program includes two Phase 3 clinical trials: BOND-003 for high-risk BCG-unresponsive NMIBC and PIVOT-006 for intermediate-risk NMIBC. CG Oncology also has a Phase 2 trial, CORE-008, evaluating the safety and efficacy of cretostimogene in high-risk NMIBC. Additionally, we have initiated an Expanded Access Program for cretostimogene in North America for patients who are unresponsive to BCG and meet certain program eligibility requirements. Cretostimogene is an investigational candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

About CG Oncology

CG Oncology is a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients afflicted with bladder cancer. CG Oncology sees a world where urologic cancer patients may benefit from our innovative immunotherapies to live with dignity and have an enhanced quality of life. To learn more, please visit: www.cgoncology.com.

Forward-Looking Statements

CG Oncology cautions you that statements contained in this press release 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 its potential to have a best-in-class durable response and meaningfully improve patient outcomes. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: additional patient data related to cretostimogene that continues to become available may be inconsistent with the data produced as of the data cutoff, and further analysis of existing data and analysis of new data may lead to conclusions different from those established as of the date hereof; 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; potential delays in the commencement, enrollment and completion of clinical trials; competitive developments with respect to current and other investigational NMIBC treatments may adversely affect the commercial opportunity of cretostimogene; and other risks described in our filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our annual report on Form 10-K and other filings that we make with the SEC from time to time (which are available at http://www.sec.gov). 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.

Contacts:

Media
Sarah Connors
Vice President, Communications and Patient Advocacy, CG Oncology
(508) 654-2277
sarah.connors@cgoncology.com

Investor Relations
Chau Cheng
Vice President, Investor Relations, CG Oncology
(949) 342-8939
chau.cheng@cgoncology.com