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): May 24, 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 May 24, 2024, CG Oncology, Inc. (the "***Company***") issued a press release entitled "CG Oncology to Present Positive Final Results from Phase 2 CORE-001 Study of Cretostimogene Grenadenorepvec in Combination with Pembrolizumab in BCG-Unresponsive High-Risk NMIBC at ASCO 2024 Annual Meeting." The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

On May 24, 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 May 24, 2024, the Company announced final results from the Phase 2 CORE-001 clinical trial of its oncolytic immunotherapy candidate, cretostimogene, in combination with pembrolizumab for the treatment of BCG-Unresponsive, High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC) with Carcinoma in Situ (CIS). The data will be presented at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting, held May 31-June 4, in Chicago, IL.

CORE-001 final results:

- As of the data cutoff on February 5, 2024, the complete response (CR) rate in the intention-to-treat (ITT) population at 12-months and any time, was 57% (20/35) [95% confidence interval (CI), 40-73%] and 83% (29/35) (95% CI, 70-95%), respectively. As of May 17, 2024, the CR rate in the ITT population at 24 months was 54% (19/35) (95% CI, 37-71%).
- Of the patients in a CR at 12 months, 95% of patients (19/20) maintained a CR for another 12 months.
- Median duration of response (DoR) has not been reached but exceeds 21 months.
- Additionally, the Kaplan-Meier estimates for CR rate at 12 and 24 months were 77.3% (95% CI, 58.1-88.5%) and 69.6% (95% CI, 49.4-83.0%), respectively.
- Progression-free survival (PFS) at 24 months is 100% with no patients progressing to muscle invasive cancer or metastatic disease; Cystectomy-free survival (CFS) at 24 months was 80%; for patients in CR, CFS at 24 months was 100%.
- Treatment-related adverse events (TRAEs) were consistent with the individual agents and demonstrate no synergistic toxicity. Results to be presented are an update from previously reported data in the abstract.

CORE-001 is a Phase 2 single-arm, open-label clinical trial of cretostimogene administered in 35 patients with high-risk, BCG-Unresponsive NMIBC that have CIS, in combination with pembrolizumab, following disease resection. CORE-001 was conducted pursuant to a clinical collaboration and supply agreement with Merck (known as MSD outside the United States and Canada).

Additionally, the Company believes these results support further investigation of cretostimogene in combination with checkpoint inhibitors and it plans to incorporate these findings into its planned CORE-008 trial in high-risk NMIBC.

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 in combination with pembrolizumab for high-risk NMIBC patients 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 our business, including, without limitation: reported topline data is based on preliminary analysis of key efficacy and safety data is subject to more audit and verification procedures that could result in material changes in the final data; additional patient data related to cretostimogene in combination with pembrolizumab that continues to become available may be inconsistent with the data produced as of the date hereof, 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; 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 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated May 24, 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: May 24, 2024

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

CG Oncology to Present Positive Final Results from Phase 2 CORE-001 Study of Cretostimogene Grenadenorepvec in Combination with Pembrolizumab in BCG-Unresponsive High-Risk NMIBC at ASCO 2024 Annual Meeting

– 54% complete response (CR) rate at 24-month landmark and meets primary endpoint of the phase 2 study –

IRVINE, Calif., May 24, 2024 (GLOBE NEWSWIRE) -- 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 final results from the Phase 2 CORE-001 clinical trial of its oncolytic immunotherapy candidate, cretostimogene, in combination with pembrolizumab for the treatment of BCG-Unresponsive, High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC) with Carcinoma in Situ (CIS). The data will be presented at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting from May 31-June 4, in Chicago, IL.

“There is a significant unmet need for new and innovative treatments for patients suffering with bladder cancer. We are encouraged by the final safety and efficacy data from our CORE-001 Phase 2 trial which showed a class-leading complete response (CR) and duration of response (DoR) compared to existing FDA-approved therapies and other investigational candidates,” said Vijay Kasturi, MD, Chief Medical Officer, CG Oncology. “We look forward to sharing these data at ASCO, as they reinforce the potential use of cretostimogene as a bladder-sparing backbone therapy for NMIBC, which is generally well tolerated by patients, either as monotherapy or in combination. Additionally, we believe these results support further investigation of cretostimogene in combination with checkpoint inhibitors and we plan to incorporate these findings into our planned CORE-008 trial in high-risk NMIBC.”

CORE-001 Final Results:

- As of the data cutoff on February 5, 2024, the CR rate in the intention-to-treat (ITT) population at 12-months and any time, was 57% (20/35) [95% confidence interval (CI), 40-73%] and 83% (29/35) (95% CI, 70-95%), respectively. As of May 17, 2024, the CR rate in the ITT population at 24 months was 54% (19/35) (95% CI, 37-71%).
- Of the patients in a CR at 12 months, 95% of patients (19/20) maintained a CR for another 12 months.
- Median DoR has not been reached but exceeds 21 months.
- Additionally, the Kaplan-Meier estimates for CR rate at 12 and 24 months were 77.3% (95% CI, 58.1-88.5%) and 69.6% (95% CI, 49.4-83.0%), respectively.
- Progression-free survival (PFS) at 24 months is 100% with no patients progressing to muscle invasive cancer or metastatic disease; Cystectomy-free survival (CFS) at 24 months was 80%; for patients in CR, CFS at 24 months was 100%.
- Treatment-related adverse events (TRAEs) were consistent with the individual agents and demonstrate no synergistic toxicity. Results to be presented are an update from previously reported data in the abstract.

Details of the ASCO poster are as follows:
Title: Final results of CORE-001 trial of Cretostimogene Grenadenorepvec in Combination with Pembrolizumab in Patients with BCG-Unresponsive, High-Risk, Non-Muscle Invasive Bladder Cancer with Carcinoma in Situ
Abstract Number: 4601
Session & Primary Track: Poster Session, Genitourinary Cancer - Kidney and Bladder
Presenter: Roger Li, M.D., lead study investigator and Urologic Oncologist at Moffitt Cancer Center
Presentation Date & Time: June 2, 2024, 9:00-10:00am Central Daylight Time
Location: McCormick Place Convention Center, Hall A

The Phase 2 CORE-001 trial was conducted in collaboration with Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. The combination of cretostimogene and pembrolizumab received FDA Breakthrough Therapy Designation in May 2023.

Cretostimogene monotherapy received FDA Fast Track and Breakthrough Therapy Designations in BCG-Unresponsive, HR-NMIBC with CIS in December 2023. CG Oncology recently presented data from the Phase 3 BOND-003 trial at the 2024 American Urological Association Annual Meeting which showed sustained durable responses over 12 months and a 75.2% complete response rate. Topline data from BOND-003 is expected by the end of 2024, and the Company is on track for a regulatory approval submission. To learn more about the results from BOND-003 you may read the Company's press release issued on May 3, 2024.

About Cretostimogene Grenadenorepvec
Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy being evaluated in BOND-003, a Phase 3 clinical trial for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to Bacillus Calmette Guerin (BCG) therapy. Cretostimogene is also being evaluated in a Phase 3 monotherapy clinical trial (PIVOT-006) in intermediate-risk NMIBC patients. In addition, cretostimogene is being evaluated in an investigator-sponsored clinical trial in combination with nivolumab for the treatment of muscle invasive bladder cancer.

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

About the CORE-001 Study
CORE-001 was a Phase 2 single-arm, open-label clinical trial of cretostimogene administered in 35 patients with high-risk, BCG-Unresponsive NMIBC that have carcinoma in situ-containing tumors, in combination with pembrolizumab, following disease resection. CORE-001 was conducted pursuant to a clinical collaboration and supply agreement with Merck (known as MSD outside the United States and Canada). More information about the study, CORE-001 (NCT04387461), along with other studies sponsored by CG Oncology, can be found at www.clinicaltrials.gov or www.cgoncology.com.

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 in combination with pembrolizumab for high-risk NMIBC patients and the importance of the data as they relate to addressing bladder cancer and supporting further investigation in combination with checkpoint inhibitors; the anticipated timing of BOND-003 final data; and the Company's expectations on a regulatory approval submission. 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 in combination with pembrolizumab 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; 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.

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