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 9, 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 2.02 Results of Operations and Financial Condition.

On May 9, 2024, CG Oncology, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2024. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Dated May 9, 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 9, 2024

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

Exhibit 99.1

CG Oncology Reports First Quarter 2024 Financial Results and Provides Business Updates

• Cretostimogene Monotherapy Demonstrated 75.2% Complete Response (CR) Rate at Any Time in Bacillus Calmette Guerin (BCG)-Unresponsive, High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC)

• First Patient Dosed in PIVOT-006 Phase 3 Clinical Trial of Cretostimogene in Intermediate-Risk NMIBC (IR-NMIBC)

• Final Results from CORE-001 Phase 2 Clinical Trial of Cretostimogene in Combination with Pembrolizumab in BCG-Unresponsive HR-NMIBC will be presented at ASCO 2024

• Completed Oversubscribed and Upsized $437 Million Initial Public Offering that Extends Expected Runway Through 2027

IRVINE, Calif., May 9, 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 reported financial results for the first quarter ended March 31, 2024, and provided business updates.

“2024 is a transformative year for CG Oncology, with our oversubscribed and upsized $437 million IPO on NASDAQ and our recent presentation at AUA of interim data showing a 75.2% CR rate at any time in BCG-Unresponsive HR-NMIBC from our BOND-003 Phase 3 clinical trial, which potentially supports cretostimogene monotherapy as backbone therapy in this disease with significant unmet need,” said Arthur Kuan, Chairman & Chief Executive Officer of CG Oncology. “In the coming months we look forward to sharing final results from our CORE-001 Phase 2 clinical trial of crestostimogene in combination with pembrolizumab and final results from our BOND-003 Phase 3 registrational clinical trial of cretostimogene monotherapy by the end of the year.”

Corporate Highlights

- **Completed Oversubscribed and Upsized Initial Public Offering that extends expected runway through 2027.**
- **Cretostimogene Monotherapy Demonstrated 75.2% CR Rate at Any Time in BCG-Unresponsive HR-NMIBC.** On May 3rd at AUA in the paradigm-shifting, practice-changing clinical trials in urology session, the Company announced data from the BOND-003 Phase 3, single arm, open label, registrational study evaluating the efficacy and safety of cretostimogene monotherapy in patients with HR-NMIBC unresponsive to BCG, showed that 75.2% of patients (79 out of 105 [95% confidence interval (CI), 65-83]) achieved a CR at any time, as of the cutoff date of April 1, 2024.
- **First Patient Dosed in PIVOT-006 Phase 3 Clinical Trial of Cretostimogene in IR-NMIBC.** In February, the Company announced the first patient was dosed in PIVOT-006, a Phase 3, open-label, two-arm trial enrolling up to 364 IR-NMIBC patients, one arm to be administered cretostimogene following the standard of care TURBT with the second arm receiving the standard of care TURBT only. The primary endpoint of this trial is overall recurrence-free survival (RFS), with secondary endpoints including RFS at 12 and 24 months and progression-free survival.
- **Final Results from CORE-001 Phase 2 Clinical Trial of Cretostimogene in Combination with Pembrolizumab in BCG-Unresponsive HR-NMIBC to be presented at ASCO 2024.**

Anticipated Next Milestones

- BOND-003 (BCG-Unresponsive, HR-NMIBC): Final results from the Phase 3 clinical trial of cretostimogene monotherapy by the end of 2024.
- CORE-001 (BCG-Unresponsive, HR-NMIBC): Final results from the Phase 2 clinical trial of crestostimogene in combination with pembrolizumab in June 2024 at the 2024 ASCO Annual Meeting.

First Quarter 2024 Financial Highlights

- **Cash Position**: Cash and cash equivalents and marketable securities as of March 31, 2024, were $566.5 million, compared with $187.7 million as of December 31, 2023. Based on cash, cash equivalents and marketable securities, as of March 31, 2024, and current operating plans, the Company expects its cash runway to be sufficient to fund operations through 2027.

- **Research and Development (R&D) Expenses**: R&D expenses for the first quarter ended March 31, 2024 were $17.2 million compared with $7.8 million for the first quarter ended March 31, 2023 due to the progression of and increase in clinical trials expense supporting the development of cretostimogene in multiple indications.
- **General and Administrative (G&A) Expenses**: G&A expenses for the first quarter ended March 31, 2024 were $5.8 million compared with $2.1 million for the first quarter ended March 31, 2023. The increase in G&A is primarily attributed to an increase in headcount in the company's general and administrative functions to support the business as a public company.
- **Net Loss**: Net loss attributable to common stockholders was $16.9 million, or ($0.36) per share, for the first quarter ended March 31, 2024, compared to $12.4 million, or ($3.22) per share, for the first quarter ended March 31, 2023.

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, statements regarding our anticipated cash runway, future results of operations and financial position; the anticipated timing and conduct of our ongoing and planned clinical trials and preclinical studies for cretostimogene, including anticipated next milestones in our development pipeline; and the timing and likelihood of regulatory filings and approvals for cretostimogene. 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: 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 and completion of clinical trials,

including the CORE-001, BOND-003 and PIVOT-006 trials; we may use our capital resources sooner than expected and they may be insufficient to allow us to achieve our anticipated milestones; 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.

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