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): November 12, 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 2.02 Results of Operations and Financial Condition.

On November 12, 2024, CG Oncology, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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 November 12, 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: November 12, 2024

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

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

- Late-Breaking Abstract on Results of Phase 3 BOND-003 Trial of Cretostimogene Monotherapy in BCG-Unresponsive NMIBC Accepted at the Society of Urologic Oncology (SUO) 25th Annual Meeting -

IRVINE, Calif., November 12, 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 third quarter ended September 30, 2024, and provided business updates.

“This quarter, we’ve continued to make significant advancements across our pipeline to bring forward a potential backbone bladder-sparing therapy for patients with Non-Muscle Invasive Bladder Cancer (NMIBC),” said Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology. “As we reported earlier this year at the AUA and ASCO annual meetings, cretostimogene has the ability to induce a sustained and durable complete response in bladder cancer patients with a strong safety and tolerability profile. We believe that cretostimogene’s unique product profile differentiates it from current and investigational NMIBC treatments, and we look forward to sharing updated results from our BOND-003 registrational study at SUO.”

Third Quarter 2024 Financial Highlights

- **Cash Position**: Cash and cash equivalents and marketable securities as of September 30, 2024, were $540.7 million, compared with $552.9 million as of June 30, 2024. Based on current operating plans, the Company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund operations through 2027.
- **Research and Development (R&D) Expenses**: R&D expenses for the three months ended September 30, 2024 were $19.6 million compared with $11.7 million for the three months ended September 30, 2023. The increase was primarily due to an increase in clinical trial expenses, including CMC costs, and an increase in compensation costs due to increased headcount.
- **General and Administrative (G&A) Expenses**: G&A expenses for the three months ended September 30, 2024 were $8.7 million compared with $2.3 million for the three months ended September 30, 2023. The increase was primarily attributed to an increase in personnel-related expenses, including compensation costs from increased headcount, an increase in professional and consultant fees related to legal, accounting and consulting fees, and an increase in insurance and marketing-related costs.
- **Net Loss**: Net loss attributable to common stockholders was $20.4 million, or ($0.30) per share, for the three months ended September 30, 2024, compared to $17.5 million, or ($4.00) per share, for the three months ended September 30, 2023.

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 patients with intermediate-risk NMIBC. 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 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 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 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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