
**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 14, 2025

CG Oncology, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41925
(Commission File Number)

37-1611499
(IRS Employer
Identification No.)

**400 Spectrum Center Drive
Suite 2040
Irvine, California**
(Address of Principal Executive Offices)

92618
(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 14, 2025, CG Oncology, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2025. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated November 14, 2025
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.

Date: November 14, 2025

CG Oncology, Inc.

By: /s/ Josh Patterson

Name: Josh Patterson

Title: General Counsel and Chief
Compliance Officer



CG Oncology Reports Third Quarter 2025 Financial Results and Provides Business Updates

- *Initiated rolling Biologics License Application (BLA) submission to U.S. FDA for cretostimogene monotherapy in high-risk (HR) BCG-unresponsive non-muscle invasive bladder cancer (NMIBC)*
- *Demonstrated continued best-in-disease durability and tolerability in BOND-003 Cohort C with robust 24-month complete response (CR) rate of 41.8% observed for cretostimogene monotherapy in patients with HR NMIBC unresponsive to Bacillus Calmette Guerin (BCG)*
- *Completed enrollment of PIVOT-006, one of the largest randomized Phase 3 studies in intermediate risk (IR) NMIBC encompassing broadest range of patients per AUA/SUO Guidelines*
- *Well-positioned to deliver on key milestones with \$680.3 million cash and cash equivalents and marketable securities sufficient to fund operations into the first half of 2028*

IRVINE, Calif., November 14, 2025 (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, 2025, and provided business updates.

“I am proud of the meaningful progress we have made over the last few months, most notably, the initiation of our BLA submission of cretostimogene for our lead indication of HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease. With cretostimogene’s unique profile, we remain committed to advancing a robust clinical, regulatory, and technical strategy designed to support an optimized label and expansion into additional indications—positioning cretostimogene as a potential backbone therapy for a broad range of NMIBC patients,” said Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology.

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“We look forward to sharing additional data from BOND-003 Cohort P and CORE-008 Cohort A before year-end.”

Corporate Highlights

- **Initiated BLA submission for cretostimogene monotherapy in HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease.** The Company initiated its rolling BLA submission for cretostimogene with complete submission expected in 2026. Cretostimogene has both Fast Track and Breakthrough Therapy Designations which are intended to accelerate the path to U.S. FDA submission.
- **Presented Best-in-Disease Durability and Tolerability Data from BOND-003 Cohort C.** In September, the Company presented best-in-disease durability and tolerability data on BOND-003 Cohort C showing 12 additional patients with HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease were in complete response (CR) at 24 months. The robust 24-month complete response landmark rate of 41.8% (CR rate observed in 46 out of 110 patients) for cretostimogene monotherapy reaffirms the best-in-disease durability, with 90% of 12-month responders remaining disease free at 24 months. The safety profile remained consistent with no Grade 3 or greater treatment-related adverse events or deaths reported.
- **Completed enrollment of PIVOT-006 clinical trial of cretostimogene in IR NMIBC.** In September, the Company completed enrollment of PIVOT-006, approximately 10 months ahead of schedule underscoring patients’ and physicians’ interest in cretostimogene and the significant unmet need in IR NMIBC. PIVOT-006 is one of the largest randomized Phase 3 studies in this patient population and encompasses the broadest range of patient types per AUA/SUO guidelines.

Anticipated Upcoming Milestones

- BOND-003 Cohort P (HR BCG-unresponsive NMIBC in Ta/T1 disease without CIS): Topline data from the Phase 3 clinical trial of cretostimogene monotherapy in 4Q’25
- CORE-008 Cohort A (HR BCG-naïve NMIBC with CIS +/- Ta/T1): First results from the Phase 2 clinical trial of cretostimogene monotherapy in 4Q’25

- CORE-008 Cohort CX (HR BCG-exposed NMIBC): Topline data from the Phase 2 clinical trial of the combination of cretostimogene with gemcitabine in 1H'26
- Completion of BLA submission in initial indication, HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease, in 2026

Third Quarter 2025 Financial Highlights

- **Cash Position:** Cash and cash equivalents and marketable securities as of September 30, 2025 were \$680.3 million, compared with \$661.1 million as of June 30, 2025, which includes net proceeds of approximately \$48.7 million from the sale of 1,515,151 shares through the Company's at-the-market (ATM) facility based on reverse inquiry from an existing, high-quality fund. Based on current operating plans, the Company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund operations into the first half of 2028.
- **Research and Development (R&D) Expenses:** R&D expenses for the three months ended September 30, 2025 were \$27.9 million compared with \$19.6 million for the three months ended September 30, 2024. The increase was primarily due to an increase in clinical trial expenses 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, 2025 were \$23.3 million compared with \$8.7 million for the three months ended September 30, 2024. The increase was primarily attributed to an increase in legal expenses and other professional fees and an increase in personnel-related expenses, including compensation costs from increased headcount.
- **Net Loss:** Net loss was \$43.8 million, or (\$0.57) per share, for the three months ended September 30, 2025, compared to a net loss of \$20.4 million, or (\$0.30) per share, for the three months ended September 30, 2024.

About Cretostimogene Grenadenorepvec

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 400 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, 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; the timing and likelihood of regulatory filings and approvals for cretostimogene; the potential therapeutic benefits of cretostimogene for high-risk and intermediate-risk NMIBC patients; and that cretostimogene has best-in-disease durability and tolerability data. 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, as supplemented in Part II, Item 1A, “Risk Factors” of our quarterly report on Form 10-Q for the quarter ended June 30, 2025, 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

sarah.connors@cgoncology.com

Investor Relations

Megan Knight

Vice President, Investor Relations, CG Oncology

megan.knight@cgoncology.com

CG ONCOLOGY, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2025	2024	2025	2024
Revenues				
Commercial and development revenue	\$ 1,508	\$ —	\$ 1,508	\$ —
License and collaboration revenue	158	43	210	683
Total revenues	<u>1,666</u>	<u>43</u>	<u>1,718</u>	<u>683</u>
Operating costs and expenses				
Cost of sales	1,577	—	1,577	—
Research and development	27,884	19,622	86,683	55,302
General and administrative	23,334	8,716	55,532	21,998
Total operating costs and expenses	<u>52,795</u>	<u>28,338</u>	<u>143,792</u>	<u>77,300</u>
Loss from operations	(51,129)	(28,295)	(142,074)	(76,617)
Other income (expense), net:				
Interest income, net	7,421	7,892	22,487	20,379
Other (expense) income, net	(100)	(2)	(99)	(3)
Total other income, net	<u>7,321</u>	<u>7,890</u>	<u>22,388</u>	<u>20,376</u>
Net loss and comprehensive loss	<u>\$ (43,808)</u>	<u>\$ (20,405)</u>	<u>\$ (119,686)</u>	<u>\$ (56,241)</u>
Net loss per share, basic and diluted	<u>\$ (0.57)</u>	<u>\$ (0.30)</u>	<u>\$ (1.57)</u>	<u>\$ (0.93)</u>
Weighted average shares of common stock outstanding, basic and diluted	<u>76,729,726</u>	<u>67,143,744</u>	<u>76,383,376</u>	<u>60,311,003</u>

CG ONCOLOGY, INC.

Consolidated Balance Sheet Data
(In thousands)

	September 30,	December 31,
	2025	2024
	(unaudited)	
Cash, cash equivalents, and marketable securities	\$ 680,263	\$ 741,998
Total assets	729,913	754,797
Total liabilities	42,270	21,420
Total stockholders' equity	687,643	733,377

