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 06, 2026

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.)**
3000 Pegasus Park Drive Suite 1640		
Dallas, Texas		**75247**
(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 6, 2026, CG Oncology, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2026. 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 6, 2026
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 6, 2026

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

Exhibit 99.1



CG Oncology Reports Third Quarter 2026 Financial Results and Provides Business Updates

- *PIVOT-006 Phase 3 topline data evaluating cretostimogene monotherapy as an adjuvant therapy in intermediate-risk and high-grade Ta NMIBC anticipated November 2026*
- *BOND-003 Cohort P and CORE-008 Cohort CX 12-month data anticipated December 2026*
- *BLA completion for BCG-unresponsive NMIBC anticipated Q4 2026*
- *Well-positioned to deliver on key milestones with approximately $984.5 million of cash, cash equivalents and marketable securities sufficient to fund operations through 2029*

DALLAS, Texas, November 6, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today reported financial results for the third quarter ended September 30, 2026, and provided business updates.

“We are entering an eventful period for CG Oncology as we look forward to sharing PIVOT-006 topline data this month. As a reminder, PIVOT-006 is the first randomized registrational trial in intermediate-risk and high-grade Ta NMIBC. Additionally, we expect to have 12-month data from both CORE-008 Cohort CX and BOND-003 Cohort P in December, which further strengthens the growing body of evidence for cretostimogene across the NMIBC landscape and supports our goal to address the broadest number of patients. We remain confident in cretostimogene’s potential to become a backbone therapy for patients and to create long-term value for shareholders,” stated Arthur Kuan, Chairman, President & Chief Executive Officer at CG Oncology.

Corporate Highlights

- **Strengthened Executive Leadership Team with the addition of life-science executive Isabel Kalofonos as Chief Commercial Officer**
    - In October, the Company appointed Isabel Kalofonos as Chief Commercial Officer. Ms. Kalofonos brings more than 20 years of experience driving successful launches including PALSONIFY™ (paltusotine) and ELAHERE® (mirvetuximab soravtansine) through strong commercial execution, helping bring innovative therapies to patients at scale across the biotechnology and pharmaceutical industries.

Anticipated 2026 Milestones

- PIVOT-006 (intermediate-risk and high-grade Ta ≤ 3cm NMIBC): Phase 3 topline data November 2026
- CORE-008 Cohort CX (BCG-exposed HR and BCG-unresponsive NMIBC) 12-month data December 2026
- BOND-003 Cohort P (BCG-unresponsive papillary only NMIBC) 12-month data December 2026
- Completion of BLA submission in initial indication of BCG-unresponsive NMIBC with CIS with or without papillary disease Q4 2026

Third Quarter Financial Highlights

- **Cash Position**: Cash, cash equivalents and marketable securities as of September 30, 2026 were $984.5 million, compared with $1.0 billion as of June 30, 2026. The Company anticipates its existing cash, cash equivalents and marketable securities as of this date will be sufficient to fund operations through 2029.
- **Research and Development (R&D) Expenses**: R&D expenses were $39.2 million for the third quarter of 2026, as compared to $27.9 million for the prior year period. 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 were $23.0 million for the third quarter of 2026, as compared to $23.3 million for the prior year period. The decrease was primarily due to a decrease in professional and consultant fees, partially offset by an increase in personnel-related expenses, including compensation costs from increased headcount, and an increase in other general G&A expenses.
- **Net Loss**: Net loss was $56.9 million, or $(0.64) per share, for the third quarter of 2026, as compared to a net loss of $43.8 million, or $(0.57) per share, for the prior year period.

About Cretostimogene Grenadenorepvec

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 700 patients with Non-Muscle Invasive Bladder Cancer (NMIBC). This program includes two Phase 3 clinical trials: BOND-003 for BCG-unresponsive NMIBC and PIVOT-006 for intermediate-risk and high-grade Ta ≤ 3cm NMIBC. Cretostimogene has received FDA Fast Track and Breakthrough Therapy designations for BCG-unresponsive NMIBC. CG Oncology also has a multi-cohort trial, CORE-008, evaluating the safety and efficacy of cretostimogene in BCG-exposed HR and BCG-unresponsive 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; our future results of operations and financial position; the timing, progress, conduct and completion of our ongoing and planned clinical trials and preclinical studies of cretostimogene; the timing, availability, announcement, presentation and results of clinical data, including topline data from PIVOT-006 and 12-month data from BOND-003 Cohort P and CORE-008 Cohort CX; anticipated milestones in our development pipeline; the timing, completion, acceptance, review and outcome of regulatory filings and submissions for cretostimogene, including the anticipated completion of our BLA submission for BCG-unresponsive NMIBC; the timing or likelihood of regulatory approvals and the scope of any approved indication or product label; the potential safety, efficacy, therapeutic benefits, clinical utility, commercial potential and market opportunity of cretostimogene for patients with BCG-unresponsive, BCG-exposed, intermediate-risk and high-grade Ta NMIBC; and the potential for cretostimogene to address a broad range of NMIBC patients or become a backbone therapy. 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: topline, preliminary, interim or 12-month clinical-trial results may not be complete, may differ from final results, may not be confirmed upon full analysis of the data, and may not predict future or longer-term results; data from one trial, patient population, cohort or

time point may not be predictive of results from other trials, populations, cohorts or time points; potential delays in the commencement, enrollment, conduct or completion of clinical trials, including the BOND-003, PIVOT-006 and CORE-008 trials; potential delays in the completion, submission, acceptance or review of our BLA, and the possibility that the FDA may not approve cretostimogene on the anticipated timeline, for the anticipated indication or label, or at all; we may use our capital resources sooner than expected, and our existing capital resources may be insufficient to achieve our anticipated milestones or fund operations for the period anticipated; our cash-runway estimates are based on assumptions regarding our current operating plans, expenses and capital requirements that may prove to be incorrect or may change; our dependence on third parties in connection with manufacturing, shipping, clinical and preclinical testing activities; results from earlier clinical trials and preclinical studies may not be predictive of future results; unexpected adverse side effects or inadequate efficacy of cretostimogene may limit or prevent its development, regulatory approval or commercialization; we may be unable to successfully develop, obtain approval for, manufacture or commercialize 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
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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenues				
Commercial and development revenue	$ 1,604	$ 1,508	$ 3,820	$ 1,508
License and collaboration revenue	—	158	24	210
Total revenues	1,604	1,666	3,844	1,718
Operating costs and expenses				
Cost of sales	2,669	1,577	9,556	1,577
Research and development	39,221	27,884	137,608	86,683
General and administrative	22,963	23,334	72,719	55,532
Total operating costs and expenses	64,853	52,795	219,883	143,792
Loss from operations	(63,249)	(51,129)	(216,039)	(142,074)
Other income (expense), net				
Interest income, net	6,423	7,421	20,040	22,487
Other (expense) income, net	(65)	(100)	(150)	(99)
Total other income, net	6,358	7,321	19,890	22,388
Net loss and comprehensive loss	$ (56,891)	$ (43,808)	$ (196,149)	$ (119,686)
Net loss per share, basic and diluted	$ (0.64)	$ (0.57)	$ (2.25)	$ (1.57)
Weighted average shares of common stock outstanding, basic and diluted	88,871,135	76,729,726	87,212,504	76,383,376

CG ONCOLOGY, INC.

Consolidated Balance Sheet Data
(In thousands)

	September 30, 2026 (unaudited)	December 31, 2025
Cash, cash equivalents, and marketable securities	$ 984,458	$ 742,155
Total assets	1,046,670	791,592
Total liabilities	55,704	38,990
Total stockholders' equity	990,966	752,602