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): August 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 August 6, 2026, CG Oncology, Inc. issued a press release announcing its financial results for the quarter ended June 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 8.01 Other Events.

On August 6, 2026, the Company filed Amendment No. 2 to Prospectus (the "Amendment No. 2") with the Securities and Exchange Commission (the "SEC") for the offer and sale of shares of its common stock, par value $0.0001 per share (the "Shares"), pursuant to that certain Open Market Sale Agreement, dated March 28, 2025, by and between the Company and Jefferies LLC (the "Sale Agreement"), to increase the Shares available to be sold pursuant to the terms of the Sale Agreement by an additional $500.0 million (the "Additional Shares"). The Amendment amends and supplements the information in the prospectus dated March 28, 2025 (the "Prospectus") filed with the SEC as part of the Company's Registration Statement on Form S-3ASR (File No. 333-286230) and Amendment No. 1 to Prospectus dated January 13, 2026 (the "Amendment No. 1"), pursuant to which the Company previously registered and sold approximately $550.0 million of shares of the Company's common stock pursuant to the Sale Agreement.

The Amendment should be read in conjunction with the Prospectus and Amendment No. 1, and is qualified by reference thereto, except to the extent that the information therein amends or supersedes the information contained in the Prospectus and Amendment No. 1. The Amendment is not complete without, and may only be delivered or utilized in connection with, the Prospectus, Amendment No. 1 to Prospectus and any future amendments or supplements thereto.

A copy of the opinion of Cooley LLP relating to the validity of the Additional Shares is attached as Exhibit 5.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
5.1	Opinion of Cooley LLP
23.1	Consent of Cooley LLP (included in Exhibit 5.1)
99.1	Press release, dated August 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: August 6, 2026

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

Cooley

Divakar Gupta
T: +1 212 479 6474
dgupta@cooley.com

Exhibit 5.1

August 6, 2026

CG Oncology, Inc.
3000 Pegasus Park Drive
Suite 1640
Dallas, TX 75247

Ladies and Gentlemen:

We have acted as counsel to CG Oncology, Inc., a Delaware corporation (the "***Company***"), in connection with the offering by the Company of shares (the "***Shares***") of its common stock, par value $0.0001 per share (the "***Common Stock***"), having an aggregate offering price of up to $500,000,000 pursuant to the Registration Statement on Form S-3 (File No. 333-283260) (the "***Registration Statement***") filed with the Securities and Exchange Commission (the "***Commission***") under the Securities Act of 1933, as amended (the "***Securities Act***"), the prospectus relating to the Shares included in the Registration Statement (the "***Base Prospectus***"), and the prospectus supplement relating to the Shares dated August 6, 2026, filed with the Commission pursuant to Rule 424(b) under the Securities Act (together with the Base Prospectus, the "***Prospectus***"). The Shares are to be sold by the Company in accordance with the Open Market Sale Agreement, dated March 28, 2025 by and between the Company and Jefferies LLC (the "***Agreement***"), as described in the Prospectus.

In connection with this opinion, we have examined and relied upon (a) the Registration Statement and the Prospectus, (b) the Agreement, (c) the Company's certificate of incorporation and bylaws, each as currently in effect, and (d) such other records, documents, opinions, certificates, memoranda and instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures; the authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies; the accuracy, completeness and authenticity of certificates of public officials; and the due authorization, execution and delivery of all documents by all persons other than the Company. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

We have assumed (i) that each sale of Shares will be duly authorized by the Board of Directors of the Company, a duly authorized committee thereof or a person or body pursuant to an authorization granted in accordance with Section 152 of the General Corporation Law of the State of Delaware (the "***DGCL***"), (ii) that no more than 50,000,000 Shares will be sold under the Agreement pursuant to the Prospectus and (iii) that the price at which the Shares are sold will equal or exceed the par value of the Common Stock. We express no opinion to the extent that future issuances of securities of the Company, anti-dilution adjustments to outstanding securities of the Company or other matters cause the number of shares of Common Stock issuable under the Agreement to exceed the number of shares of Common Stock available for issuance by the Company.

Our opinion is expressed solely with respect to the DGCL. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, in reliance thereon and subject to the assumptions, qualifications, limitations and exceptions set forth herein, we are of the opinion that the Shares, when sold and issued against

payment therefor in accordance with the Agreement, the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable.

This opinion is limited to the matters expressly set forth in this letter, and no opinion has been or should be implied, or may be inferred, beyond the matters expressly stated. This opinion speaks only as to law and facts in effect or existing as of the date hereof, and we have no obligation or responsibility to update or supplement this letter to reflect any facts or circumstances that may hereafter come to our attention or any changes in law that may hereafter occur.

We consent to the reference to our firm under the heading “Legal Matters” in the Prospectus and to the filing of this opinion as an exhibit to the Company’s Current Report on Form 8-K to be filed with the Commission for incorporation by reference into the Registration Statement. In giving such consents, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

Cooley LLP

By: /s/ Divakar Gupta
Divakar Gupta

Exhibit 99.1

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

- *PIVOT-006 Phase 3 topline data evaluating cretostimogene monotherapy as an adjuvant therapy in intermediate-risk NMIBC anticipated in the near-term*
- *BLA completion for HR BCG-unresponsive NMIBC expected fourth quarter 2026*
- *Phase 3 BOND-003 Cohort C Study Results published in The Lancet Oncology, further validating the strength of the clinical evidence supporting cretostimogene*
- *Well-positioned to deliver on key milestones with approximately $1.0 billion cash, cash equivalents and marketable securities sufficient to fund operations through 2029*

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

“This quarter we have made significant progress across our clinical, regulatory, manufacturing and commercial-readiness initiatives, positioning the Company for long-term success. PIVOT-006 has accrued the vast majority of the target events, and we look forward to sharing topline results soon. We are confident in the potential of cretostimogene and are committed to delivering what we believe will be a backbone therapy for patients,” stated Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology.

Corporate Highlights

- In July, BOND-003 Cohort C Study Results were published in *The Lancet Oncology* validating the strength of the clinical evidence supporting cretostimogene
    - **Title:** *Intravesical cretostimogene grenadenorepvec oncolytic immunotherapy in high-risk, BCG-unresponsive, non-muscle invasive bladder cancer with carcinoma in situ (BOND-003 Cohort C): a single-arm, phase 3 trial*
- In July, the Superior Court of the State of Delaware denied ANI's post-trial motion for a new trial and judgment as a matter of law, upholding the jury's verdict in favor of CG Oncology that the invalidated royalty provision was properly severed and that the remainder of the agreement with ANI remains in force, while rejecting ANI's challenges to the verdict and related claims
- In May, CORE-008 Cohort CX data were presented at the Society of Urologic Oncology (SUO) session at the American Urological Association (AUA) 2026 Annual Meeting

Anticipated 2026 Milestones

- PIVOT-006 (intermediate-risk NMIBC): Phase 3 topline data
- Completion of BLA submission in initial indication of HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease in 4Q'26
- BOND-003 Cohort C (HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease), BOND-003 Cohort P (HR BCG-unresponsive NMIBC in Ta/T1 disease without CIS), CORE-008 Cohort CX (HR BCG-exposed and BCG-unresponsive NMIBC) and CORE-008 Cohort A (HR BCG-naïve NMIBC with CIS +/- Ta/T1), durability data

Second Quarter Financial Highlights

- **Cash Position**: Cash, cash equivalents and marketable securities as of June 30, 2026 were $1.0 billion, compared with $1.1 billion as of March 31, 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 $54.7 million for the second quarter of 2026, as compared to $31.3 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 $29.0 million for the second quarter of 2026, as compared to $17.4 million for the prior year period. The increase was primarily attributed to an increase in personnel-related expenses, including compensation costs from increased headcount.
- **Net Loss**: Net loss was $79.1 million, or $(0.90) per share, for the second quarter of 2026, as compared to a net loss of $41.4 million, or $(0.54) 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 600 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 multi-cohort 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 a best-in-disease product profile. 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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CG ONCOLOGY, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenues				
Commercial and development revenue	$ 1,147	$ —	$ 2,216	$ —
License and collaboration revenue	10	—	24	52
Total revenues	1,157	—	2,240	52
Operating costs and expenses				
Cost of sales	3,925	—	6,887	—
Research and development	54,657	31,331	98,387	58,799
General and administrative	28,976	17,410	49,756	32,198
Total operating costs and expenses	87,558	48,741	155,030	90,997
Loss from operations	(86,401)	(48,741)	(152,790)	(90,945)
Other income (expense), net:				
Interest income, net	7,329	7,319	13,617	15,066
Other income (expense), net	16	(4)	(85)	1
Total other income, net	7,345	7,315	13,532	15,067
Net loss and comprehensive loss	$ (79,056)	$ (41,426)	$ (139,258)	$ (75,878)
Net loss per share, basic and diluted	$ (0.90)	$ (0.54)	$ (1.61)	$ (1.00)
Weighted average shares of common stock outstanding, basic and diluted	88,200,023	76,226,829	86,369,437	76,207,333

CG ONCOLOGY, INC.

Consolidated Balance Sheet Data
(In thousands)

	June 30, 2026 (unaudited)	December 31, 2025
Cash, cash equivalents, and marketable securities	$ 1,028,278	$ 742,155
Total assets	1,085,655	791,592
Total liabilities	56,537	38,990
Total stockholders' equity	1,029,118	752,602