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

Aug 06, 2026

- *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, Aug. 06, 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