CG Oncology Reports 2025 Year End Financial Results and Provides Business Updates

Feb 27, 2026

- *PIVOT-006 Phase 3 topline data evaluating cretostimogene monotherapy as an adjuvant therapy in intermediate-risk NMIBC expected first half 2026*
- *CORE-008 Cohort CX Phase 2 first results of combination cretostimogene with gemcitabine in high-risk (HR) NMIBC expected first half 2026*
- *Well-positioned to deliver on key milestones with approximately $903.0 million cash, cash equivalents and marketable securities sufficient to fund operations into the first half of 2029*

IRVINE, Calif., Feb. 27, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today reported financial results for the fourth quarter and year ended December 31, 2025, and provided business updates.

“In the coming months, we look forward to sharing topline data from PIVOT-006, the first randomized registrational trial to evaluate an investigational therapy in intermediate-risk NMIBC. We believe we have the opportunity to set the new standard in intermediate-risk NMIBC. I am extremely proud of our team for planning, enrolling and executing this important trial in record time. With cretostimogene’s unique best-in-disease profile, we remain laser-focused on advancing a comprehensive strategy designed to support an optimized product label and ensure success across 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. “We are also looking forward to sharing results from CORE-008 Cohort CX in high-risk BCG exposed from our first trial evaluating the combination of cretostimogene with gemcitabine in the coming quarter.”

Corporate Highlights

- **Updated timeline for Phase 3 topline data from PIVOT-006 clinical trial evaluating cretostimogene as an adjuvant therapy in intermediate-risk NMIBC.** In January 2026, the Company announced an expedited timeline for PIVOT-006, nearly a year ahead of schedule underscoring the excitement for cretostimogene and the significant unmet need in intermediate-risk NMIBC. PIVOT-006 is the first Phase 3 randomized trial in this patient population, encompassing the broadest range of patient types per AUA/SUO Guidelines including HG Ta solitary lesions ≤ 3cm.
- **Presented Late-Breaking Abstracts at the Society of Urologic Oncology (SUO) 26th Annual Meeting in December 2025.** Cretostimogene demonstrated HG-EFS at 3- 6- and 9-months of 95.7%, 84.6% and 80.4%, respectively, in HR BCG UR Ta/T1 disease in BOND-003 Cohort P. CORE-008 Cohort A Data in HR BCG-Naïve NMIBC demonstrates 88% CR and favorable safety.
- **Strengthened Board of Directors with the addition of life-science executive Christina Rossi.** In November 2025, the Company announced the addition of Christy Rossi, former Chief Operating Officer of Blueprint Medicines, to its board. Christy brings robust expertise in building high-performing commercial organizations, launching new medicines, and delivering impactful programs to HCPs and most importantly to patients.

Anticipated 2026 Milestones

- PIVOT-006 (intermediate-risk NMIBC): Phase 3 topline data in 1H’26
- CORE-008 Cohort CX (HR BCG-exposed and BCG-unresponsive NMIBC): First results from the Phase 2 clinical trial of the combination of cretostimogene with gemcitabine in 1H’26
- Completion of BLA submission in initial indication of HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease in 2026

- BOND-003 Cohort C (HR BCG-unresponsive NMIBC in Ta/T1 disease without CIS), BOND-003 Cohort P (HR BCG-unresponsive NMIBC in Ta/T1 disease without CIS), and CORE-008 Cohort A (HR BCG-naïve NMIBC with CIS +/- Ta/T1), durability data in 2026

Fourth Quarter and Year End Financial Highlights

- **Cash Position**: Cash and cash equivalents and marketable securities as of December 31, 2025, were $742.2 million, compared with $680.3 million as of September 30, 2025. The December 31, 2025 cash includes net proceeds of approximately $98.4 million from a total of 2,343,967 shares sold through the Company's at-the-market (ATM) facility in Q4 based on reverse inquiries from existing and new, high-quality funds.

  In addition, net proceeds of approximately $188.0 million was raised from a total of 3,623,101 shares sold in January 2026 through the Company's ATM facility, resulting in a cash, cash equivalents, and marketable securities balance as of February 26, 2026 of approximately $903.0 million. The Company anticipates its existing cash, cash equivalents and marketable securities as of this date will be sufficient to fund operations into the first half of 2029.

- **Research and Development (R&D) Expenses**: R&D expenses were $30.0 million for the fourth quarter of 2025, as compared to $26.8 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. For the full year 2025, R&D expenses were $116.6 million, which compares to $82.1 million for the full year 2024.
- **General and Administrative (G&A) Expenses**: G&A expenses were $18.0 million for the fourth quarter of 2025, as compared to $11.7 million for the prior year period. 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 marketing-related costs. For the full year 2025, G&A expenses were $73.5 million, which compares to $33.7 million for the full year 2024.
- **Net Loss**: Net loss attributable to common stockholders was $41.3 million, or ($0.52) per share, for the fourth quarter of 2025, as compared to $31.8 million, or ($0.46) per share, for the prior year period. For the full year 2025, net loss attributable to common stockholders was $161.0 million, or ($2.08) per share, as compared to $88.0 million, or ($1.41) per share, for the full year 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 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.

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

	Year Ended December 31,	
	2025	**2024**
Revenues		
Commercial and development revenue	$ 3,234	$ —
License and collaboration revenue	806	1,139
Total revenues	4,040	1,139
Operating costs and expenses		
Cost of sales	4,647	—
Research and development	116,641	82,102
General and administrative	73,526	33,703
Total operating costs and expenses	194,814	115,805
Loss from operations	(190,774)	(114,666)
Other income (expense), net:		
Interest income, net	29,931	26,624
Other (expense) income, net	(152)	3
Total other income, net	29,779	26,627
Net loss and comprehensive loss	$ (160,995)	$ (88,039)
Net loss per share, basic and diluted	$ (2.08)	$ (1.41)
Weighted average shares of common stock outstanding, basic and diluted	77,303,440	62,496,725

CG Oncology, Inc.

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2025	**December 31, 2024**
Cash, cash equivalents, and marketable securities	$ 742,155	$ 741,998
Total assets	791,592	754,797
Total liabilities	38,990	21,420
Total stockholders' equity	752,602	733,377