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

May 08, 2026

- *Following alignment discussions with FDA, BLA completion for HR BCG-unresponsive NMIBC is expected fourth quarter 2026*
- *PIVOT-006 Phase 3 topline data evaluating cretostimogene monotherapy as an adjuvant therapy in intermediate-risk NMIBC anticipated first half 2026*
- *CORE-008 Cohort CX Phase 2 first results of combination cretostimogene with gemcitabine in high-risk (HR) NMIBC BCG-exposed and BCG-unresponsive to be presented at AUA 2026*
- *Well-positioned to deliver on key milestones with approximately $1.1 billion cash, cash equivalents and marketable securities sufficient to fund operations through 2029*

DALLAS, May 08, 2026 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON) today reported financial results for the first quarter ended March 31, 2026, and provided business updates.

"We have successfully completed non-clinical and clinical modules for our first BLA submission. The remaining CMC module is progressing as planned, and we are on track to finalize our submission in the fourth quarter 2026. We are pleased to provide this additional guidance on expected BLA completion following focused filing discussions with FDA. Manufacturing inspection readiness activities continue to progress, including our commitment to sustainable long-term supply. The quality and execution of the rolling BLA has been a top priority for us, and we are confident that we are taking all appropriate measures to ensure a successful package. This has been a tremendous undertaking, and I am extremely proud of the team for their unwavering commitment," stated Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology.

"We look forward to a number of meaningful near-term milestones for CG, including anticipated topline data from the Phase 3 PIVOT-006 trial in intermediate-risk NMIBC in the coming months, as well as the first results from the Phase 2 CORE-008 Cohort CX in high-risk BCG-exposed and BCG-unresponsive patients, to be presented at AUA."

Corporate Highlights

- **CORE-008 Cohort CX data podium and poster presentation at the Society of Urologic Oncology (SUO) session at the American Urological Association (AUA) 2026 Annual Meeting on May 16.**
  - **Title:** First Results from CORE-008 Cohort CX- Phase 2 Study of Intravesical Cretostimogene Grenadenorepvec with Gemcitabine in Patients with High-Risk BCG-Exposed or BCG-Unresponsive Non-Muscle Invasive Bladder Cancer
- **Strengthened Executive Leadership Team with the addition of life-science executive Jim DeTore.**
  - In April 2026, the Company appointed Jim DeTore to Chief Financial Officer. Jim brings over 30 years of life sciences expertise including executive leadership roles at Neurogastrx, Inc., Bluebird Bio, and Proteostasis Therapeutics, in each case leading the company's financing and investor relations strategies, helping to raise over a billion dollars in equity capital. He also served as vice president of corporate finance at Ironwood Pharmaceuticals where he worked directly on several debt and equity transactions, including the company's initial public offering. Jim received his M.B.A. and bachelor's degree in finance from Northeastern University in Boston.

Anticipated 2026 Milestones

- 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

- PIVOT-006 (intermediate-risk NMIBC): Phase 3 topline data in 1H'26
- 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 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

First Quarter Financial Highlights

- **Cash Position**: Cash, cash equivalents and marketable securities as of March 31, 2026 were $1.1 billion, compared with $742.2 million as of December 31, 2025. The March 31, 2026, cash includes net proceeds of approximately $391.4 million from a total of 6,941,407 shares sold through the Company's at-the-market (ATM) facility in Q1 based on reverse inquiries from existing and new, high-quality funds. 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 $43.7 million for the first quarter of 2026, as compared to $27.5 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 $20.8 million for the first quarter of 2026, as compared to $14.8 million for the prior year period. The increase was primarily attributed to an increase in personnel-related expenses, including compensation costs from increased headcount, and an increase in professional and consulting fees.
- **Net Loss**: Net loss was $60.2 million, or $(0.71) per share, for the first quarter of 2026, as compared to a net loss of $34.5 million, or $(0.45) 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.

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

	Three Months Ended March 31,	
	2026	**2025**
Revenues		
Commercial and development revenue	$ 1,069	$ —
License and collaboration revenue	14	52
Total revenues	1,083	52
Operating costs and expenses		
Cost of sales	2,962	—
Research and development	43,730	27,467
General and administrative	20,780	14,789
Total operating costs and expenses	67,472	42,256
Loss from operations	(66,389)	(42,204)
Other income (expense), net:		
Interest income, net	6,288	7,747
Other (expense) income, net	(101)	5
Total other income, net	6,187	7,752
Net loss and comprehensive loss	$ (60,202)	$ (34,452)
Net loss per share, basic and diluted	$ (0.71)	$ (0.45)
Weighted average shares of common stock outstanding, basic and diluted	84,518,512	76,187,621

CG ONCOLOGY, INC.
Consolidated Balance Sheet Data
(In thousands)

	March 31, 2026 (unaudited)	**December 31, 2025**
Cash, cash equivalents, and marketable securities	$ 1,076,242	$ 742,155
Total assets	1,135,262	791,592
Total liabilities	43,483	38,990
Total stockholders' equity	1,091,779	752,602

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