CG Oncology Reports Second Quarter 2025 Financial Results and Provides Business Updates

Aug 08, 2025

- Announced best-in-disease durability data in BOND-003 Cohort C and promising early signal in Cohort P for cretostimogene grenadenorepvec at the American Urological Association Annual Meeting -

- Initiated CORE-008 Cohort CX evaluating the combination of cretostimogene and gemcitabine in patients with high-risk (HR) BCG-exposed NMIBC -

- Announced unanimous verdict that CG Oncology owes no future royalties or other payments to ANI Pharmaceuticals -

IRVINE, Calif., Aug. 08, 2025 (GLOBE NEWSWIRE) -- CG Oncology, Inc. (NASDAQ: CGON), a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients with bladder cancer, today reported financial results for the second quarter ended June 30, 2025, and provided business updates.

"In the second quarter, we announced best-in-disease durability and tolerability from the Phase 3 BOND-003 Cohort C registrational trial, building upon the body of evidence demonstrating the power of cretostimogene's unique dual mechanism of action, and its potential to treat intermediate-risk and high-risk NMIBC," said Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology. "We remain laser focused on bringing forward cretostimogene, our potentially breakthrough backbone treatment to patients. The recent positive outcome of the ANI litigation allows us to continue to focus our resources and energy on delivering this innovative therapy. We are poised to initiate our BLA submission for cretostimogene in the fourth quarter of the year for the treatment of patients with HR NMIBC unresponsive to BCG."

Corporate Highlights

- **Presented Best-in-Disease Durability and Tolerability Data in BOND-003 Cohort C and Promising Early Signal in Cohort P for Cretostimogene at a Plenary Session at the American Urological Association (AUA) Annual Meeting**: On April 26th at the AUA Annual Meeting, the Company presented best-in-disease durability and tolerability data from Cohort C of the Phase 3 BOND-003 clinical trial that showed a 75.5% complete response (CR) at any time, with 34 confirmed CRs at 24 months and 9 patients pending their 24-month assessment as of the cutoff date of March 14, 2025. The 12- and 24-month CR rates are 50.7% and 42.3% by K-M estimation respectively. Median duration of response is 28 months and is ongoing. Notably, 97.3% of patients were free from progression to muscle invasive disease at 24 months. Additionally, Cohort P, which is in patients with BCG-unresponsive Ta/T1 papillary disease without carcinoma in situ (CIS), showed an estimated 90.5% high-grade recurrence-free survival at 3 and 9 months in 24 treated patients.

- **Initiated CORE-008 Cohort CX clinical trial of cretostimogene + gemcitabine in HR BCG-exposed NMIBC**: In April, the Company initiated CORE-008 Cohort CX evaluating the combination of cretostimogene and gemcitabine, given either concurrently or sequentially, in patients with HR BCG-exposed NMIBC, including patients with CIS and with or without Ta/T1 disease and patients with only Ta/T1 disease.

- **Announced Unanimous Verdict that CG Oncology Owes No Future Royalties or Other Payments to ANI Pharmaceuticals**: On July 29th, the Company announced that a jury in the Superior Court of the State of Delaware unanimously found in favor of CG Oncology on all claims in a March 2024 lawsuit brought by ANI Pharmaceuticals, Inc. (ANI). The jury unanimously rejected all of ANI's claims for unjust enrichment damages after Judge Sheldon K. Rennie, on July 16, 2025, had ruled in favor of CG Oncology that, as a matter of law, ANI was not entitled to any royalties on future sales of cretostimogene grenadenorepvec. As a result, CG Oncology will not owe ANI a future royalty of 5% on commercial sales of cretostimogene, no damages have been awarded to ANI, and there are no further payments due to ANI under the 2010 agreement between ANI and CG Oncology. The Company will

continue to vigorously defend any post-trial motions and appeals brought by ANI.

Anticipated Upcoming Milestones

- PIVOT-006 (intermediate-risk NMIBC): Phase 3 enrollment completion in 3Q'25
- Initiation of BLA submission in 4Q'25 for cretostimogene monotherapy in 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): Topline data from the Phase 3 clinical trial of cretostimogene monotherapy in 4Q'25
- CORE-008 Cohort A (HR BCG-naïve NMIBC with CIS +/- Ta/T1): Topline data from the Phase 2 clinical trial of cretostimogene monotherapy in 4Q'25
- CORE-008 Cohort CX (HR BCG-exposed NMIBC): Topline data from the Phase 2 clinical trial of the combination of cretostimogene with gemcitabine in 1H’26

Second Quarter 2025 Financial Highlights

- **Cash Position**: Cash and cash equivalents and marketable securities as of June 30, 2025, were $661.1 million, compared with $688.4 million as of March 31, 2025. Based on current operating plans, the Company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund operations into the first half of 2028.
- **Research and Development (R&D) Expenses**: R&D expenses for the three months ended June 30, 2025 were $31.3 million compared with $18.5 million for the three months ended June 30, 2024. The increase was primarily due to an increase in clinical trial expenses and an increase in compensation costs due to increased headcount.
- **General and Administrative (G&A) Expenses**: G&A expenses for the three months ended June 30, 2025 were $17.4 million compared with $7.5 million for the three months ended June 30, 2024. The increase was primarily attributed to an increase in personnel-related expenses, including compensation costs from increased headcount and an increase in legal expenses.
- **Net Loss**: Net loss was $41.4 million, or ($0.54) per share, for the three months ended June 30, 2025, compared to a net loss of $18.9 million, or ($0.28) per share, for the three months ended June 30, 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 400 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 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 best-in-disease durability and tolerability data. 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, as supplemented in Part II, Item 1A, “Risk Factors” of our quarterly report on Form 10-Q for the quarter ended June 30, 2025, 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,	
	2025	2024	2025	2024
Revenues				
License and collaboration revenue	$ —	$ 111	$ 52	$ 640
Operating expenses				
Research and development	31,331	18,470	58,799	35,680
General and administrative	17,410	7,494	32,198	13,282
Total operating expenses	48,741	25,964	90,997	48,962
Loss from operations	(48,741)	(25,853)	(90,945)	(48,322)
Other income (expense), net:				
Interest income, net	7,319	6,943	15,066	12,487
Other expense (income), net	(4)	8	1	(1)
Total other income, net	7,315	6,951	15,067	12,486
Net loss and comprehensive loss	$ (41,426)	$ (18,902)	$ (75,878)	$ (35,836)
Net loss per share, basic and diluted	$ (0.54)	$ (0.28)	$ (1.00)	$ (0.63)
Weighted average shares of common stock outstanding, basic and diluted	76,226,829	66,649,443	76,207,333	56,857,104

CG ONCOLOGY, INC.

Consolidated Balance Sheet Data
(In thousands)

	June 30, 2025 (unaudited)	December 31, 2024
Cash, cash equivalents, and marketable securities	$ 661,052	$ 741,998
Total assets	701,445	754,797
Total liabilities	31,087	21,420
Total stockholders' equity	670,358	733,377