



CG Oncology Reports 2024 Year End Financial Results and Provides Business Updates

Mar 28, 2025

- Cretostimogene Monotherapy Demonstrated Sustained, Durable Complete Responses in High-Risk Bacillus Calmette Guérin (BCG)-Unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC) -
- Initiated CORE-008 Clinical Trial of Cretostimogene Monotherapy in High-Risk BCG-Naïve (Cohort A) and BCG-Exposed (Cohort B) NMIBC -
- Late-Breaking Clinical and First Translational Data from BOND-003 Cohort C Presented at the 40th Annual European Association of Urology Congress -
- Completed Oversubscribed \$238 Million Follow-on Public Equity Offering that Extends Expected Runway into the First Half of 2028 -

IRVINE, Calif., March 28, 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 fourth quarter and year ended December 31, 2024, and provided business updates.

"We made substantial progress in the fourth quarter of 2024, with our announcement at SUO of topline data from the Phase 3 BOND-003 Cohort C trial, as well as a successful follow-on equity offering to expand our clinical development programs and support our commercial readiness activities," said Arthur Kuan, Chairman & Chief Executive Officer at CG Oncology. "Looking ahead, further readouts are expected from our BOND-003 trial and the anticipated initiation of our Biologics License Application (BLA) submission, as well as the announcement of topline data from CORE-008 Cohort A expected before year-end."

Corporate Highlights

- **Cretostimogene Monotherapy Demonstrated 74.5% Complete Response Rate at Any Time in High-Risk (HR) BCG-Unresponsive NMIBC with carcinoma in situ (CIS) with or without Ta/T1 disease.** On December 5th at the Society of Urologic Oncology (SUO) 25th Annual Meeting, the Company presented groundbreaking data from Cohort C of the Phase 3 BOND-003 clinical trial that showed 74.5% of patients (82 out of 110, 95% confidence interval (CI), 65.4-82.4%) with HR-NMIBC unresponsive to BCG achieved a complete response (CR) at any time, after receiving treatment with cretostimogene as a single agent. The median duration of response (DoR) has not been reached but exceeds 27 months as of the data cutoff of September 30, 2024.
- **Updated Clinical Results from BOND-003 Cohort C Raised CR Rate at Any Time to 75.5%.** On March 24th at the 40th Annual European Association of Urology (EAU) Congress, the Company reported that 83 out of 110 patients (75.5%) achieved a CR at any time, with 30 complete responders having reached 24-month timepoint and beyond. The median DoR has not been reached but exceeds 28 months as of the data cutoff of January 20, 2025.

Also at the EAU Congress, new translational data showed the level of cretostimogene peaked immediately after instillation, which was sustained locally for 4-5 days. Furthermore, intravesical delivery of cretostimogene reduces anti-drug antibody neutralization, thereby preserving therapeutic efficacy. There was no systemic exposure, with cretostimogene levels remaining below the limit of detection, providing evidence that post cretostimogene treatment close contact precautions are not needed.

- **Initiated CORE-008 clinical trial of cretostimogene in HR NMIBC.** In October, the Company initiated CORE-008 Cohort A clinical trial of cretostimogene in high-risk NMIBC which are naïve to BCG treatment, including patients with CIS and with or without Ta/T1 disease and patients with only Ta/T1 disease. In March 2025, this study was expanded into the BCG-exposed population (Cohort B).
- **Published in *Nature Medicine* Phase 1b study results evaluating cretostimogene in combination with nivolumab in muscle-invasive bladder cancer.** Encouraging data adds to the body of evidence supporting potential use of cretostimogene as a backbone bladder-sparing therapeutic for bladder cancer.
- **Completed oversubscribed follow-on public equity offering with full exercise of**

underwriters' option. Raised \$238 million gross proceeds to CG Oncology that extends expected runway into the first half of 2028.

Anticipated Milestones

- Initiation of BLA submission for cretostimogene monotherapy in HR BCG-unresponsive NMIBC with CIS with or without Ta/T1 disease anticipated in the second half of 2025.
- BOND-003 Cohort C (HR BCG-unresponsive NMIBC with CIS and with or without Ta/T1 disease): Final data from the Phase 3 clinical trial of cretostimogene monotherapy to be presented at the 120th American Urological Association Annual Meeting.
- 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 anticipated in the second half of 2025.
- CORE-008 Cohort A (HR BCG-naïve NMIBC): Topline data from the Phase 2 clinical trial of cretostimogene monotherapy anticipated in the second half of 2025.
- CORE-008 Cohort B (HR BCG-exposed NMIBC) and CX (HR BCG-exposed NMIBC): Initiation anticipated in the first half of 2025.

Fourth Quarter and Year End Financial Highlights

- **Cash Position:** Cash and cash equivalents and marketable securities as of December 31, 2024, were \$742.0 million, compared with \$540.7 million as of September 30, 2024. 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 were \$26.8 million for the fourth quarter of 2024, as compared to \$16.3 million for the prior year period. The increase was primarily due to an increase in clinical trial expenses, including CMC costs, an increase in compensation costs due to increased headcount, and higher facilities and other related costs. For the full year 2024, R&D expenses were \$82.1 million, which compares to \$45.8 million for the full year 2023.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$11.7 million for the fourth quarter of 2024, as compared to \$3.0 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 insurance and marketing-related costs. For the full year 2024, G&A expenses were \$33.7 million, which compares to \$9.9 million for the full year 2023.
- **Net Loss:** Net loss attributable to common stockholders was \$31.8 million, or (\$0.46) per share, for the fourth quarter of 2024, as compared to \$22.5 million, or (\$4.36) per share, for the prior year period. For the full year 2024, net loss attributable to common stockholders was \$88.0 million, or (\$1.41) per share, as compared to \$67.8 million, or (\$15.65) per share, for the full year 2023.

About Cretostimogene Grenadenorepvec

Cretostimogene is an investigational, intravesically delivered oncolytic immunotherapy that has been studied in a clinical development program, which includes more than 250 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.

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; and the timing and likelihood of regulatory filings and approvals for cretostimogene. 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 Balance Sheets (In thousands, except share and per share amounts)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 257,068	\$ 8,266
Marketable securities	484,930	179,408
Prepaid expenses and other current assets	11,431	6,358
Accounts receivable - other	781	92
Total current assets	<u>754,210</u>	<u>194,124</u>
Property and equipment, net	272	69
Operating lease right-of-use assets	221	422
Other assets	94	19
Deferred offering costs	—	4,667
Total assets	<u>\$ 754,797</u>	<u>\$ 199,301</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 6,517	\$ 3,242
Success fee liability, current portion	—	352
Operating lease liabilities, current portion	186	217
Accrued expenses and other current liabilities	14,665	10,443
Total current liabilities	<u>21,368</u>	<u>14,254</u>
Success fee liability, non-current	—	13
Operating lease liabilities, net of current portion	<u>52</u>	<u>244</u>
Total liabilities	<u>21,420</u>	<u>14,511</u>
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock:		
Redeemable convertible preferred stock, \$0.0001 par value per share; zero and 337,928,674 shares authorized, issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; liquidation value of \$0 and \$307.890 as of December 31, 2024 and December 31, 2023, respectively	-	307,890
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value per share; 700,000,000 and 493,530,000 shares authorized as of December 31, 2024 and December 31, 2023, respectively; 76,154,783 and 5,222,283 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	8	—
Additional paid-in capital	951,350	6,842
Accumulated deficit	<u>(217,981)</u>	<u>(129,942)</u>

Total stockholders' equity (deficit)	733,377	(123,100)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 754,797</u>	<u>\$ 199,301</u>

CG Oncology, Inc.

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

	<u>Year Ended December 31,</u>	
	<u>2024</u>	<u>2023</u>
Revenues		
License and collaboration revenue	\$ 1,139	\$ 204
Operating expenses		
Research and development	82,102	45,752
General and administrative	33,703	9,901
Total operating expenses	<u>115,805</u>	<u>55,653</u>
Loss from operations	(114,666)	(55,449)
Other income (expense), net:		
Interest income, net	26,624	6,904
Other income (expense), net	3	(62)
Total other income, net	<u>26,627</u>	<u>6,842</u>
Net loss and comprehensive loss	<u>\$ (88,039)</u>	<u>\$ (48,607)</u>
Deemed dividend on redeemable convertible preferred stock issuances	—	(410)
Cumulative redeemable convertible preferred stock dividends	—	(18,781)
Net loss attributable to common stockholders	<u>\$ (88,039)</u>	<u>\$ (67,798)</u>
Net loss per share, basic and diluted	<u>\$ (1.41)</u>	<u>\$ (15.65)</u>
Weighted average shares of common stock outstanding, basic and diluted	<u>62,496,725</u>	<u>4,330,933</u>