Candel Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Recent Corporate Highlights

Mar 12, 2026

- *Company plans to initiate a pivotal phase 3 clinical trial of aglatimagene besadenovec (aglatimagene or CAN-2409) in patients with progressive, metastatic, non-squamous, non-small cell lung cancer (NSCLC) despite immune checkpoint inhibitor (ICI) treatment, in Q2 2026*
- *Company plans to submit a Biologics License Application (BLA) for aglatimagene in localized, intermediate-to high-risk prostate cancer in Q4 2026*
- *Company announced investigational new drug (IND) clearance for linoserpaturev (CAN-3110) in recurrent high-grade glioma (rHGG) to support enabling work for a potential future randomized controlled phase 2 dose regimen finding study.*
- *Entered into a $130 million term loan facility with Trinity Capital Inc. (Trinity Capital) with $50 million drawn down at closing, and access of up to an additional $80 million*
- *Cash and cash equivalents of $119.7 million, as of December 31, 2025, together with $93.5 million in net proceeds from the February 2026 follow-on equity offering, strengthens the Company's financial position and is sufficient to fund the current operating plan into Q1 2028, which includes activities to support the potential commercial launch of aglatimagene in 2027*

NEEDHAM, Mass., March 12, 2026 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical-stage biopharmaceutical company focused on developing multimodal immunotherapies to help patients fight cancer, today announced financial results for the fourth quarter and full year ended December 31, 2025, and provided a corporate update.

"During the quarter we made meaningful progress across our clinical pipeline and pre-commercial readiness, entering 2026 with strong momentum and a robust set of potential value-driving catalysts," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and CEO of Candel. "For aglatimagene in localized, intermediate-to high-risk prostate cancer, we continue to work toward a planned BLA submission in Q4 2026. We continue to follow the patients in our phase 3 study for prostate cancer-specific outcomes and expect to share results after extended follow-up in Q2 2026. We also expect to share additional biomarker data from our prostate program in Q3 2026. We plan to initiate a pivotal phase 3 clinical trial of aglatimagene in NSCLC despite ICI treatment in Q2 2026. In a phase 1b clinical trial of linoserpaturev in patients with rHGG, we reported encouraging survival data, supported by sophisticated serial brain biopsy analyses, and we expect to announce mature overall survival data for Arm C in Q4 2026. We submitted an IND for linoserpaturev in Q4 2025 to advance the development of this asset in rHGG and received clearance from the U.S. Food and Drug Administration in Q1 2026."

Dr. Tak continued, "We were pleased to strengthen the Company's financial position with the additional strategic funding from the term loan facility with Trinity Capital, the institutionally focused follow-on equity offering in February 2026, and our royalty financing agreement with funds managed by RTW Investments, LP. This further strengthens our balance sheet, brings new institutional investors into the Company, and positions us to advance our key priorities, including the initiation of a pivotal phase 3 clinical trial of aglatimagene in NSCLC and preparation for a potential commercial launch of aglatimagene in localized prostate cancer."

Fourth Quarter 2025 & Recent Highlights

- *Aglatimagene besadenovec (CAN-2409) – Prostate Cancer*
    - The Company continues to advance its pre-BLA readiness initiative, including its Chemistry, Manufacturing, and Controls (CMC) activities, and preparation of clinical study reports and BLA modules.
    - The Company will present follow-up clinical data from its phase 3 trial of aglatimagene in prostate cancer in Q2 2026 and novel biomarker data in Q3 2026.
    - The Company's control manufacturer plans to conduct process validation in Q2 2026 to potentially enable filing of a BLA in Q4 2026. The Company's control manufacturer has manufactured four large-scale batches to date. Clinical material from the new process has been manufactured and filled. Candel intends to use this material in the pivotal phase 3 clinical trial in NSCLC.
    - The U.S. Food and Drug Administration (FDA) previously granted Fast Track Designation and Regenerative Medicine Advanced Therapy Designation to aglatimagene for the treatment of localized prostate cancer. The phase 3 clinical trial of aglatimagene in localized prostate cancer was conducted under a Special Protocol Assessment with respect to the study design, agreed with the FDA.

- *Aglatimagene besadenovec (CAN-2409) – Non-Small Cell Lung Cancer (NSCLC)*
    - Following a positive end-of-phase 2 meeting with the FDA in July 2025, the Company is preparing to initiate a pivotal phase 3 clinical trial of aglatimagene in NSCLC in Q2 2026.
    - The FDA previously granted Fast Track Designation to aglatimagene for the treatment of NSCLC.
- *Aglatimagene besadenovec (CAN-2409) – Pancreatic Cancer*
    - The Company previously generated encouraging data based on a randomized controlled phase 2a clinical trial of aglatimagene in borderline resectable pancreatic cancer (PDAC).
    - The FDA previously granted Fast Track Designation and Orphan Drug Designation to aglatimagene for the treatment of PDAC, and the European Medicines Agency granted Orphan Designation for aglatimagene for the treatment of pancreatic cancer in July 2025.
    - With Candel's top priorities focused on prostate cancer and NSCLC, the Company has paused the PDAC program.
- *Linoserpaturev (CAN-3110) - Recurrent High-Grade Glioma (rHGG)*
    - In February 2026, at the 7th Annual Glioblastoma Drug Development Summit, the Company shared insights from its herpes simplex virus (HSV)-based platform and its linoserpaturev program through workshop presentations and panel discussions focused on advancing biomarker-driven clinical development in glioblastoma.
    - The Company submitted an IND for linoserpaturev to advance the development of this asset in rHGG in Q4 2025 and received clearance from the FDA in Q1 2026.
    - The FDA previously granted Fast Track Designation and Orphan Drug Designation to linoserpaturev in rHGG.
- *Recent Corporate Events*
    - On February 23, 2026, Candel issued and sold 18,348,624 shares of common stock at a price to the public of $5.45 per share for aggregate gross proceeds of approximately $100 million, which will be used to complete critical launch readiness, medical affairs, pre-commercialization, and commercial activities for aglatimagene in early, localized prostate cancer, ongoing development costs related to the phase 3 trial of aglatimagene in NSCLC, and for general corporate purposes.
    - On February 19, 2026, Candel announced a $100 million royalty funding agreement with funds managed by RTW Investments, LP (RTW), subject to FDA approval of aglatimagene in localized, intermediate-to high-risk, prostate cancer. Under the terms of the agreement, RTW will receive a tiered single digit percentage of annual net sales of aglatimagene in the U.S., subject to a cap. Funds will strengthen the Company's balance sheet for potential U.S. commercial launch of aglatimagene in intermediate- to high-risk localized prostate cancer.
    - On December 5, 2025, Candel hosted a virtual Research and Development (R&D) Event, which included presentations and panel discussions from its executive leadership, clinical investigators, scientific advisors, and key collaborators. The event provided an extensive overview of Candel's viral immunotherapy approach and oncology focused pipeline. Click here to view the event.

Anticipated Milestones

- Updated mOS data and potential long tail of survival from the phase 2a open-label clinical trial of aglatimagene in patients with stage III/IV NSCLC who had progressed despite ICI treatment (NCT04495153) is expected in Q1 2026.
- Updated extended follow-up data on prostate cancer-specific disease-free survival, time to salvage anti-cancer therapy, and time to metastasis from the positive phase 3 clinical trial of aglatimagene in patients with localized, intermediate- to high-risk prostate cancer is expected in Q2 2026.
- The Company plans to initiate a pivotal phase 3 clinical trial of aglatimagene in patients with metastatic, non-squamous, NSCLC and progressive disease despite ICI treatment in Q2 2026.
- Biomarker data related to the effects of aglatimagene in patients with localized prostate cancer is expected in Q3 2026.
- The Company expects to present mature mOS data and an update on long-term survivors from arm C of its phase 1b clinical trial of linoserpaturev in patients with rHGG in Q4 2026.
- Submission of BLA for aglatimagene in prostate cancer is planned for Q4 2026.

Financial Results for the Fourth Quarter and Full Year Ended December 31, 2025

Research and Development Expenses: Research and development expenses were $11.0 million for the fourth quarter of 2025 compared to $4.8 million for the fourth quarter of 2024, and $30.5 million for the full year 2025 compared to $19.3 million for the full year 2024. The increase was primarily due to higher manufacturing, clinical trial and regulatory costs, in support of the Company's aglatimagene programs, and an increase in employee-related expenses. Research and development expenses included a non-cash stock compensation expense of $0.7 million and $1.5 million for the fourth quarter and full year of 2025, respectively, as compared to a non-cash stock compensation expense of $0.8 million and $3.3 million for the fourth quarter and full year of 2024, respectively.

General and Administrative Expenses: General and administrative expenses were $4.7 million for the fourth quarter of 2025, compared to $3.3 million for the fourth quarter of 2024, and $17.8 million for the full year 2025 compared to $14.1 million for the full year 2024. The increase was primarily due to an increase in commercial readiness costs and employee-related expenses, as well as higher professional and consulting fees. General and administrative expenses included non-cash stock compensation expense of $0.6 million and $2.3 million for the fourth quarter and full year of 2025, respectively, as compared to a non-cash stock compensation expense of $0.4 million and $2.0 million for the fourth quarter and full year of 2024, respectively.

Net Loss: Net loss for the fourth quarter of 2025 was $29.5 million compared to a net loss of $14.1 million for the fourth quarter of 2024 and included net other expense of $13.7 million and net other expense of $5.9 million, respectively. Net loss for the full year 2025 was $38.2 million compared to a net loss of $55.2 million for the full year 2024 and included net other income of $10.1 million and net other expense of $21.8 million, respectively. The change from net other expense in 2024, to net other income in 2025, is primarily related to the change in the fair value of the Company's warrant liabilities.

Cash Position: Cash and cash equivalents, as of December 31, 2025, were $119.7 million compared to $102.7 million as of December 31, 2024. Based on current operating plans, the Company expects that its existing cash and cash equivalents, as of December 31, 2025, together with proceeds from the follow-on equity offering in February 2026, will be sufficient to fund operations into Q1 2028.

About aglatimagene besadenovec (CAN-2409)

Aglatimagene, Candel's most advanced multimodal biological immunotherapy candidate, is an investigational, off-the-shelf, replication-defective adenovirus designed to deliver the herpes simplex virus thymidine kinase (HSV-tk) gene to a patient's tumor. After intratumoral administration, HSV-tk enzyme activity results in conversion of prodrug (valacyclovir) into deoxyribonucleic acid (DNA)-incorporating nucleotide analogs, leading to immunogenic cell death in cells exhibiting DNA damage and proliferating cells, with subsequent release of a variety of tumor (neo)antigens in the tumor microenvironment. At the same time, the adenoviral serotype 5 capsid protein promotes inflammation through the induction of expression of pro-inflammatory cytokines, chemokines, and adhesion molecules. Together, this regimen is designed to induce an individualized and specific CD8+ T cell-mediated response against the injected tumor and uninjected distant metastases for broad anti-tumor activity, based on in situ immunization against a variety of tumor antigens. Aglatimagene has the potential to treat a broad range of solid tumors. Encouraging monotherapy activity as well as combination activity with standard of care radiotherapy, surgery, chemotherapy, and immune checkpoint inhibitors have previously been shown in several preclinical and clinical settings. More than 1,000 patients have been dosed with aglatimagene in clinical trials with a favorable tolerability profile to date, supporting the potential for combination with standard of care, when indicated.

About linoserpaturev (CAN-3110)

Linoserpaturev is a first-in-class, replication-competent, next-generation oncolytic herpes simplex virus-1 (HSV-1) immunotherapy candidate designed for dual activity for oncolysis and immune activation in a single therapeutic. In October 2023, the Company announced that *Nature* published results from the ongoing clinical trial where linoserpaturev was reported to be generally well tolerated with no dose-limiting toxicity. In the clinical trial, the investigators observed improved median overall survival compared to historical controls after a single linoserpaturev injection in this therapy-resistant condition.[1] The Company and academic collaborators are currently supported by the Break Through Cancer foundation to evaluate the effects of repeated linoserpaturev injections in patients with recurrent glioblastoma in an expansion cohort from the phase 1b clinical trial. In October 2025, *Science Translational Medicine* presented findings from the comprehensive analysis of 97 serial tumor biopsies collected from two patients treated with repeated administrations of linoserpaturev in arm C. Linoserpaturev previously received Fast Track Designation and Orphan Drug Designation for the treatment of rHGG from the U.S. Food and Drug Administration (FDA).

About the enLIGHTEN™ Discovery Platform

The enLIGHTEN™ Discovery Platform is a systematic, iterative HSV-based discovery platform leveraging human biology and advanced analytics to create new multimodal biological immunotherapies for solid tumors. The enLIGHTEN™ Discovery Platform has been designed to deconvolute the characteristics of the tumor microenvironment related to clinical outcomes. These characteristics are rapidly translated into optimized multi-gene payloads of tumor modulators that can be delivered to the tumor microenvironment for specific indications, disease stages, and rationally designed therapeutic combinations.

About Candel Therapeutics

Candel is a clinical-stage biopharmaceutical company focused on developing off-the-shelf multimodal biological immunotherapies that elicit an individualized, systemic anti-tumor immune response to help patients fight cancer. Candel has established two clinical-stage multimodal biological immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex

virus (HSV) gene constructs, respectively. Aglatimagene besadenovec (CAN-2409 or aglatimagene) is the lead product candidate from the adenovirus platform. The Company recently completed successful phase 2a clinical trials of aglatimagene in non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), and a pivotal, placebo-controlled, phase 3 clinical trial of aglatimagene in localized prostate cancer, conducted under a Special Protocol Assessment agreed with the FDA. The FDA also granted Fast Track Designation and Regenerative Medicine Advanced Therapy Designation to aglatimagene for the treatment of newly diagnosed localized prostate cancer in patients with intermediate- to high-risk disease, Fast Track Designation in NSCLC, and both Fast Track Designation and Orphan Drug Designation for the treatment of PDAC.

Linoserpaturev (CAN-3110) is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in rHGG. Finally, Candel's enLIGHTEN™ Discovery Platform is a systematic, iterative HSV-based discovery platform leveraging human biology and advanced analytics to create new viral immunotherapies for solid tumors.

For more information about Candel, visit: www.candeltx.com.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding the timing and advancement of current and future development programs, including the timing and availability of additional data and key data readout milestones and presentations; expectations regarding the submission of the BLA for CAN-2409 in intermediate-to-high-risk localized prostate cancer; expectations regarding early biological readouts as predictor of clinical response; expectations regarding the therapeutic benefit of the Company's platforms, including the ability of its platforms to improve overall survival and/or disease-free survival of patients living with difficult-to-treat solid tumors; expectations regarding the potential benefits conferred by regulatory designations; expectations regarding the royalty funding agreement with RTW and the intended and potential benefits thereof; and expectations regarding cash runway and expenditures. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the timing and advancement of development programs; expectations regarding the therapeutic benefit of the Company's programs; that final data from the Company's preclinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; the Company's ability to efficiently discover and develop product candidates; the Company's ability to obtain and maintain regulatory approval of product candidates; the Company's ability to maintain its intellectual property; the implementation of the Company's business model, including strategic plans for the Company's business and product candidates; the impact of the Company's existing and any future indebtedness on its ability to operate its business; the Company's ability to access any future tranches under its debt facility and to comply with all of its obligations thereunder; and other risks identified in the Company's filings with the U.S. Securities and Exchange Commission (SEC), including the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, each as filed with the SEC and any subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the Company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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1 Ling AL, et al. Nature. 2023;623(7985):157-166

Candel Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 11,028	$ 4,817	$ 30,496	$ 19,314
General and administrative	4,724	3,324	17,770	14,057
Total operating expenses	15,752	8,141	48,266	33,371
Loss from operations	(15,752)	(8,141)	(48,266)	(33,371)
Other income (expense):				
Grant income	89	—	89	—
Interest income	1,102	290	3,915	1,086
Interest expense	(1,416)	(390)	(2,119)	(2,090)
Change in fair value of warrant liabilities	(13,519)	(5,832)	8,199	(20,802)
Total other income (expense), net	(13,744)	(5,932)	10,084	(21,806)
Net loss and comprehensive loss	$ (29,496)	$ (14,073)	$ (38,182)	$ (55,177)
Net loss per share, basic and diluted	$ (0.54)	$ (0.40)	$ (0.72)	$ (1.74)
Weighted-average common shares outstanding, basic and diluted	54,898,223	35,564,528	52,958,644	31,675,076

Candel Therapeutics, Inc.
Consolidated Balance Sheet Data
(in thousands)

	DECEMBER 31, 2025	DECEMBER 31, 2024
Cash and cash equivalents	$ 119,731	$ 102,654
Working capital[(1)]	112,392	66,275
Total assets	125,195	106,866
Warrant liabilities	15,598	21,718
Total other liabilities	57,675	18,821
Accumulated deficit	(230,387)	(192,205)
Total stockholders' equity	$ 51,922	$ 66,327

(1) Working capital is calculated as current assets less current liabilities