Candel Therapeutics Reports First Quarter 2025 Financial Results and Recent Corporate Highlights

May 13, 2025

- *Announced accepted oral presentation of positive phase 3 randomized placebo controlled clinical trial results of CAN-2409 (aglatimagene besadenovec) in localized prostate cancer at the 2025* American Society of Clinical Oncology *(ASCO) Annual Meeting*
- *Preparations on track for Biologics License Application (BLA) for CAN-2409 in intermediate-to-high-risk localized prostate cancer, with submission expected in Q4 2026*
- *Recently announced both prolonged median overall survival (mOS) and a long tail of survival in an open label phase 2a clinical trial of CAN-2409 in advanced non-small cell lung cancer (NSCLC) patients, non-responsive to immune checkpoint inhibitor (ICI) treatment, particularly those patients with non-squamous histology*
- *Recently announced notable improvement in mOS after experimental treatment with CAN-2409 compared to the control group based on a randomized controlled phase 2a clinical trial of CAN-2409 in borderline resectable pancreatic adenocarcinoma (PDAC)*
- *Recent publication in Neuro-Oncology of encouraging clinical and immunological biomarker data based on a phase 1b clinical trial of the combination of CAN-2409 and nivolumab plus standard of care in newly diagnosed high-grade glioma*
- *On track to report biomarker and initial survival data from ongoing phase 1b clinical trial evaluating repeat doses of CAN-3110 in patients with recurrent high-grade glioma (rHGG), expected in Q4 2025*

NEEDHAM, Mass., May 13, 2025 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing multimodal biological immunotherapies to help patients fight cancer, announced today financial results for the first quarter ended March 31, 2025, and provided a corporate update.

“During the quarter, we continued our strong momentum of compelling clinical evidence, reinforcing our promising pipeline of pan solid tumor immunotherapies,” said Paul Peter Tak, MD PhD FMedSci, President and CEO of Candel. “Our primary focus for 2025 remains on working toward CAN-2409’s BLA submission for prostate cancer, which we believe represents a very significant unmet medical need and opportunity for value creation. In this indication, we observed the ability of CAN-2409 to reduce the risk of prostate cancer recurrence compared to standard of care, through meeting the primary endpoint agreed with the FDA under a Special Protocol Assessment in a phase 3 clinical trial. We are now focusing on executing strategic preparations for potential commercialization, to ensure that, if approved, CAN-2409 is immediately available to patients with localized prostate cancer.”

Dr. Tak continued, “CAN-2409, Candel’s most advanced multimodal biological immunotherapy candidate, continues to demonstrate meaningful overall survival benefits in patients with advanced NSCLC, non-responsive to immune checkpoint inhibitors, as well as in patients with borderline resectable PDAC. The totality of data showing notable extension of survival based on both phase 2a clinical trials in NSCLC and PDAC, respectively, suggests that CAN-2409 has the potential to represent a transformative treatment option for patients with difficult-to-treat solid tumors. The FDA Fast Track Designation for each indication further validates the potential of this novel approach to address significant unmet medical needs in oncology.”

First Quarter 2025 & Recent Highlights

- *CAN-2409 – Prostate Cancer*
  - Positive phase 3 results from the CAN-2409 clinical trial in intermediate-to-high risk localized prostate cancer have been selected for an oral presentation at the upcoming 2025 ASCO Annual Meeting, taking place May 30 to June 3, 2025, in Chicago, IL.
  - This phase 3 study was conducted under a Special Protocol Assessment (SPA) agreed with the U.S. Food and Drug Administration (FDA), meaning that certain data generated from this study could be sufficient for the Company to seek regulatory approval for CAN-2409 in this indication.
  - The Company continues to work toward a Q4 2026 BLA submission for prostate cancer, following the positive topline data from its multicenter, randomized, placebo-controlled phase 3 clinical trial evaluating CAN-2409 in intermediate-to-high-risk localized prostate cancer patients.
  - The FDA previously granted Fast Track Designation for CAN-2409 for the treatment of localized primary prostate cancer.
- *CAN-2409 - Pancreatic Cancer*

- Positive final survival data from the randomized controlled phase 2a clinical trial of CAN-2409 in borderline resectable PDAC demonstrated notable improvement in overall survival compared to standard of care. Patients who had received experimental treatment with CAN-2409 and chemoradiotherapy achieved a mOS of 31.4 months versus 12.5 months observed in the control arm treated with chemoradiotherapy.
- Notably, three long-term survivors in the CAN-2409 arm remained alive at 66.0, 63.6, and 35.8-months post-treatment, whereas only one patient from the control arm was still alive at the time of data cut-off (February 20, 2025). Patients in the CAN-2409 arm were stable at the time of last follow up with minimal maintenance therapy and, despite previous recurrence, experienced extended and ongoing post-progression survival, further highlighting the sustained benefit of CAN-2409, even in metastatic disease.
- The FDA previously granted Orphan Drug Designation and Fast Track Designation for CAN-2409 in borderline resectable PDAC.

- *CAN-2409 – Non-Small Cell Lung Cancer*
  - In March, the Company reported final survival data from its phase 2a clinical trial of CAN-2409 in patients with stage III/IV NSCLC, inadequately responding to ICI treatment.
  - In patients with an inadequate response to ICI treatment (Cohort 1+2, n=46), mOS was 24.5 months.
  - In patients with progressive disease, despite ICI treatment (Cohort 2, n=41), mOS was 21.5 months, which is markedly longer than the 9.8–11.8 months of survival reported in published literature[1,2] in the same patient population receiving standard of care of docetaxel chemotherapy.
  - 37% of patients with progressive disease at enrollment were still alive > 24 months after CAN-2409 treatment at the time of the March 3, 2025 data cut, suggesting a long tail of survival. 14/15 patients with overall survival > 24 months and 9/9 patients with overall survival > 30 months had non-squamous NSCLC.
  - In patients with non-squamous NSCLC and progressive disease despite ICI (cohort 2, n=33), observed mOS was 25.4 months after CAN-2409 treatment.
  - A decrease in the size of uninjected tumors was observed in 69% of patients with multiple lesions (n=35), indicating that a local injection is associated with a systemic anti-tumor immune response.
  - CAN-2409 maintained its generally favorable safety and tolerability profile throughout the extended follow-up period.
  - The FDA previously granted Fast Track Designation for CAN-2409 for the treatment of NSCLC.
- *Recent Corporate Events*
  - In March 2025, the Company entered a strategic, commercial collaboration with IDEA Pharma, a Division of SAI MedPartners (IDEA). Under this agreement, IDEA will provide strategic commercial input throughout the development and commercialization process for Candel's lead asset, CAN-2409. Through this collaboration, Candel will gain access to a dedicated team of experts with extensive experience in oncology commercialization and go-to-market strategy optimization.
  - In March 2025, the Company appointed Elizabeth M. Jaffee, M.D., to its Research Advisory Board (RAB). Dr. Jaffee, an internationally recognized expert in cancer immunology and pancreatic cancer, brings her extensive expertise to the RAB, which is important in light of the Company's focus on borderline resectable pancreatic cancer.
- Publication
  - Manuscript published in the March 2025 online edition of *Neuro-Oncology*, reporting results of a phase 1b clinical trial exploring safety and tolerability of the combination of CAN-2409 plus prodrug (valacyclovir) and nivolumab, in addition to standard of care (neurosurgery, radiotherapy, and temozolomide), in patients with newly diagnosed rHGG.

Anticipated Milestones

- Clinical and biomarker activity data from an ongoing phase 1b clinical trial evaluating repeat doses of CAN-3110 in patients with rHGG expected in Q4 2025.
- Submission of BLA for CAN-2409 in prostate cancer expected in Q4 2026.

Financial Results for the First Quarter Ended March 31, 2025

Research and Development Expenses: Research and development expenses were $4.0 million for the first quarter of 2025 compared to $4.1 million for the first quarter of 2024. The decrease was primarily due to a decrease in employee-related expenses, partially offset by an increase in manufacturing costs, in support of the Company's CAN-2409 programs. Research and development expenses included a non-cash stock compensation expense of ($0.1) million for the first quarter of 2025, as compared to a non-cash stock compensation expense of $0.6 million for the first quarter of 2024.

General and Administrative Expenses: General and administrative expenses were $4.1 million for the first quarter of 2025, compared to $3.8 million for the first quarter of 2024. The increase was primarily due to higher professional and consulting fees. General and administrative expenses included non-cash stock compensation expense of $0.4 million for the first quarter of 2025, as compared to a non-cash stock compensation expense of $0.5 million for the first quarter of 2024.

Net Income/Loss: Net income for the first quarter of 2025 was $7.4 million compared to a net loss of $8.2 million for the first quarter of 2024 and included net other income of $15.5 million and net other expense of $0.3 million, respectively. The increase in net income was primarily related to the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents, as of March 31, 2025, were $92.2 million, as compared to $102.7 million as of December 31, 2024. Based on current plans and assumptions, the Company expects that its existing cash and cash equivalents will be sufficient to fund its current operating plan into the first quarter of 2027.

About CAN-2409

CAN-2409 (aglatimagene besadenovec), 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 specific tumor and induce an individualized, systemic immune response against the tumor. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. 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. Because of its versatility, CAN-2409 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 ICI have previously been shown in several preclinical and clinical settings. More than 1,000 patients have been dosed with CAN-2409 with a favorable tolerability profile to date, supporting the potential for combination with other therapeutic strategies.

Currently, Candel is evaluating CAN-2409 in NSCLC and borderline resectable PDAC and has recently completed a successful phase 3 clinical trial in localized prostate cancer. CAN-2409 plus prodrug (valacyclovir) has been granted Fast Track Designation by the FDA for the treatment of PDAC, stage III/IV NSCLC in patients who are resistant to first line PD-(L)1 inhibitor therapy and who do not have activating molecular driver mutations or have progressed on directed molecular therapy, and localized primary prostate cancer. Candel's pivotal phase 3 clinical trial in prostate cancer was conducted under a SPA agreed with the FDA. The FDA has also granted Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

About CAN-3110

CAN-3110 is a first-in-class, replication-competent herpes simplex virus-1 (HSV-1) next-generation oncolytic viral, immunotherapy candidate designed for dual activity for oncolysis and immune activation in a single therapeutic. CAN-3110 is being evaluated in a phase 1b clinical trial in patients with rHGG. In October 2023, the Company announced that *Nature* published results from this ongoing clinical trial. CAN-3110 was well tolerated with no dose-limiting toxicity reported. In the clinical trial, the investigators observed improved median overall survival compared to historical controls after a single CAN-3110 injection in this therapy-resistant condition.[3] The Company and academic collaborators are currently evaluating the effects of repeat CAN-3110 injections in rHGG, supported by the Break Through Cancer foundation. CAN-3110 has previously received FDA Fast Track Designation and Orphan Drug Designation for the treatment of rHGG.

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. In 2022, the Company announced a discovery partnership with the University of Pennsylvania Center for Cellular Immunotherapies to create new viral immunotherapies that could enhance the efficacy of chimeric antigen receptor T cell (CAR-T) therapy in solid tumors. During the 2023 Society for Immunotherapy of Cancer Annual Meeting and the 2023 International Oncolytic Virotherapy Conference (IOVC) Meeting, Candel presented encouraging data on the first candidate from this platform, Alpha 201-macro-1, which was designed to interfere with the CD47/SIRP1α pathway, in mouse models of breast cancer and lung cancer. During the 2024 American Association for Cancer Research Annual Meeting, Candel presented preclinical data, unveiling the second candidate from the enLIGHTEN™ Discovery Platform, a first-in-class multimodal immunotherapy candidate to induce tertiary lymphoid structures, being developed as a novel therapeutic for solid tumors. Candel also presented data on a multimodal viral therapeutic candidate encoding IL-12 and IL-15 at the 2024 IOVC meeting.

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 HSV gene constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform and recently completed successful phase 2a clinical trials in NSCLC and PDAC, and a pivotal phase 3 clinical trial in localized prostate cancer. 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; 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; 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 March 31, 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 Paz-Ares LG et al. J Clin Oncol 2024;42:2860-2872
2 Ahn MJ et al. J Clin Onc 2024;43:260-272
3 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)
(Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2025	2024
Operating expenses:		
Research and development	$ 4,016	$ 4,102
General and administrative	4,114	3,800
Total operating expenses	8,130	7,902
Loss from operations	(8,130)	(7,902)

Other income (expense):		
Interest income	934	320
Interest expense	(306)	(646)
Change in fair value of warrant liability	14,881	7
Total other income (expense), net	15,509	(319)
Net income (loss) and comprehensive income (loss)	$ 7,379	$ (8,221)
Net income (loss) per share, basic	$ 0.15	$ (0.28)
Weighted-average common shares outstanding, basic	50,482,278	29,197,537
Net income (loss) per share, diluted	$ 0.13	$ (0.28)
Weighted-average common shares outstanding, diluted	54,765,842	29,197,537

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

	MARCH 31, 2025 (Unaudited)	DECEMBER 31, 2024
Cash and cash equivalents	$ 92,165	$ 102,654
Working capital (1)	73,079	66,275
Total assets	95,905	106,866
Warrant liability	6,837	21,718
Total other liabilities	14,393	18,821
Accumulated deficit	(184,826)	(192,205)
Total stockholders' equity	$ 74,675	$ 66,327

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