Candel Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Recent Corporate Highlights

March 13, 2025

- *Recently announced positive data from pivotal randomized, placebo-controlled phase 3 clinical trial of CAN-2409 in intermediate-to-high risk, localized prostate cancer*
- *Recently announced positive final data from randomized controlled phase 2a clinical trial of CAN-2409 in borderline resectable pancreatic ductal adenocarcinoma*
- *On track to report biomarker and final overall survival data from open label phase 2a clinical trial per protocol analysis in non-small cell lung cancer (NSCLC) patients who received two administrations of CAN-2409, expected in Q1 2025*
- *On track to report biomarker and initial survival data from ongoing phase 1b trial evaluating multiple doses of CAN-3110 in patients with recurrent high-grade glioma (rHGG), expected in Q4 2025*
- *Preparations for Biologics License Application (BLA) for CAN-2409 in prostate cancer underway, with submission expected in Q4 2026*

NEEDHAM, Mass., March 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 fourth quarter and year ended December 31, 2024, and provided a corporate update.

“Last year was transformational for Candel, driven by our team’s incredible focus and execution of the Company’s key priorities,” said Paul Peter Tak, MD PhD FMedSci, President and CEO of Candel. “We delivered positive data across our platforms, including pivotal topline phase 3 data for CAN-2409 in intermediate-to-high-risk localized prostate cancer in December, which we believe shows the potential of CAN-2409, if approved, to redefine the current standard of care for patients with prostate cancer.”

Dr. Tak continued, “We enter 2025 well-resourced with a clear direction and mandate. Our primary focus for the year is working toward readiness to submit CAN-2409’s BLA for prostate cancer, a key opportunity to address a very significant unmet need and opportunity for value creation. In addition, we continue to explore the efficacy of CAN-2409 in other indications, as evidenced by our recently disclosed positive final overall survival data for CAN-2409 in a randomized controlled phase 2a trial in borderline resectable pancreatic cancer. This result has triggered enabling work, which will include scientific advisory boards and engagement with the FDA, to get ready for a larger, late-stage, randomized clinical trial in this indication in the future. In addition, we anticipate final overall survival and biomarker data from our open label phase 2a clinical trial of CAN-2409 in therapy-resistant non-small cell lung cancer patients in the very near future. This study may also trigger similar enabling work. In Q4 2025, we will also provide a clinical and biomarker update from our ongoing phase 1b clinical trial evaluating multiple doses of CAN-3110 in patients with recurrent high-grade glioma. Finally, we have also made significant progress with our preclinical programs, leveraging the enLIGHTEN™ Discovery Platform.”

Fourth Quarter 2024 & Recent Highlights

- *CAN-2409 - Pancreatic Cancer*
  - Positive final survival data from the randomized controlled phase 2a clinical trial of CAN-2409 in borderline resectable pancreatic ductal adenocarcinoma (PDAC), demonstrating notable improvement in overall survival. Patients who had received experimental treatment with CAN-2409 and standard of care achieved a median overall survival of 31.4 months versus only 12.5 months observed in the control arm treated with standard of care.
  - Notably, long-term survivors in the CAN-2409 arm remained alive at 66.0, 63.6, and 35.8-months post-enrollment, whereas only one patient from the control arm was still alive at the time of data cut-off (February 20, 2025). Patients in the experimental 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 U.S. Food and Drug Administration (FDA) previously granted orphan drug designation and fast track designation for CAN-2409 in borderline resectable PDAC.
- *CAN-2409 – Prostate Cancer*
  - In December 2024, the Company reported 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 study met its primary endpoint by demonstrating statistically significant improvement in disease-free survival (DFS) in patients who received CAN-2409 plus valacyclovir (prodrug) combined with standard of care external beam

radiation therapy (n=496) compared to standard of care alone (n=249) within the intent to treat population.

- The data showed a 30% reduction in the risk for prostate cancer recurrence or death due to any cause for the CAN-2409 treatment arm compared to placebo control arm (p=0.0155), and 80.4% pathological complete responses in 2-year post-treatment biopsies after CAN-2409 administration compared to 63.6% in the control arm (p=0.0015). The safety profile of CAN-2409 was generally consistent with previous studies, with no new safety signals identified.

- This study was conducted under a Special Protocol Assessment (SPA) agreed with the FDA, meaning that safety and efficacy data generated from this study could be sufficient for the Company to seek regulatory approval for CAN-2409 in this indication.

- The FDA previously granted fast track designation for CAN-2409 for the treatment of localized primary prostate cancer.

- *CAN-3110 – Recurrent High-Grade Glioma*
  - Presented updated clinical and biomarker activity data from cohort C of a phase 1b clinical trial during the 6th Annual International Oncolytic Virotherapy Conference (IOVC) in October 2024. The Principal Investigator reported ongoing improved survival compared to historical controls, with 3 out of 6 patients still alive after more than one year (12.2, 13.0 and 18.7 months, respectively) after initiation of experimental treatment with repeated administrations of CAN-3110.

  - The FDA granted fast track designation and orphan drug designation to CAN-3110 for the treatment of rHGG in February and May 2024, respectively.

- *CAN-3110 – Melanoma*
  - Presented preclinical results on the therapeutic potential of CAN-3110 in the Ras-Raf pathway altered melanoma model at the Society for Immunotherapy of Cancer (SITC) 2024 Annual Meeting. CAN-3110 exhibited potent, tumor-specific cytotoxicity in human and murine melanoma cell lines with varied CDKN2A pathway alterations and Nestin expression. *In vivo* mouse studies showed dose-dependent inhibition of tumor growth, with regression observed in a subset (3 of 8) of tumor bearing animals treated with a high dose of CAN-3110. CAN-3110 treatment was well-tolerated in melanoma preclinical mouse models based on body weight and histopathological analysis following intra-tumoral administration.

- *enLIGHTEN ™Discovery Platform*
  - Presented data on a new multimodal viral therapeutic candidate encoding IL-12 and IL-15 during IOVC 2024. Data showed the ability of the asset to induce expansion and activation of natural killer and CD8+ T cell populations, resulting in significant tumor growth inhibition and tumor regression in two different models.

- *Recent Corporate Events*
  - In December 2024, the Company completed an underwritten public offering of 12,000,001 shares of its common stock (inclusive of the exercise of the underwriters' option to purchase additional shares in full) at a price to the public of $6.00 per share, and pre-funded warrants to purchase up to 3,333,333 shares of its common stock at a price to the public of $5.99 per warrant with an exercise price of $0.01 per pre-funded warrant, resulting in net proceeds of approximately $85.9 million. The offering closed on December 16, 2024.

Anticipated Milestones

- Final overall survival data from phase 2a clinical trial evaluating CAN-2409 in patients with NSCLC and an inadequate response to immune checkpoint inhibitors, expected in Q1 2025.

- Biomarker and initial overall survival data from ongoing phase 1b clinical trial evaluating multiple doses of CAN-3110 in patients with rHGG, expected in Q4 2025.

Financial Results for the Year and Fourth Quarter Ended December 31, 2024

Research and Development Expenses: Research and development expenses were $4.8 million for the fourth quarter of 2024 compared to $7.3 million for the fourth quarter of 2023, and $19.3 million for the full year 2024 compared to $24.5 million for the full year 2023. The decrease was primarily due to lower regulatory, manufacturing and clinical trial costs in support of the Company's CAN-2409 programs and lower payroll-related expenses following the corporate restructuring in the fourth quarter of 2023. Research and development expenses included a non-cash stock compensation expense of $0.8 million and $3.3 million for the fourth quarter and full year of 2024, respectively, as compared to a non-cash stock compensation expense of $0.5 million and $1.3 million for the fourth quarter and full year of 2023.

General and Administrative Expenses: General and administrative expenses were $3.3 million for the fourth quarter of 2024 compared to $3.1 million for the fourth quarter of 2023, and $14.1 million for the full year 2024 compared to $13.9 million for the full year 2023. The increase was primarily due to higher professional and consulting fees, which were partially offset by decreased payroll-related expenses following the corporate restructuring in the fourth quarter of 2023. General and administrative expenses included non-cash stock compensation expense of $0.4 million and $2.0 million for the fourth quarter and full year of 2024, respectively, as compared to a non-cash stock compensation expense of $0.5 million and $1.7 million for the fourth quarter and full year of 2023.

Net Loss: Net loss for the fourth quarter of 2024 was $14.1 million compared to a net loss of $11.1 million for the fourth quarter of 2023, and included net other expense of $5.9 million and $0.8 million, respectively, related primarily to the change in the fair value of the Company's warrant liability. Net loss for the full year 2024 was $55.2 million compared to a net loss of $37.9 million for the full year 2023 and included net other expense of $21.8 million and net other income of $0.5 million, respectively. The change from net other income in 2023 to net other expense in 2024 primarily related to the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents as of December 31, 2024 were $102.7 million, as compared to $35.4 million as of December 31, 2023. 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, 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 un-injected distant metastases for broad anti-tumor activity, based on in situ vaccination 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 immune checkpoint inhibitors 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, in ongoing clinical trials, 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) oncolytic viral immunotherapy candidate designed with 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.[1] The Company and academic collaborators are currently evaluating the effects of multiple 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 herpes simplex virus (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 SITC 2023 Annual Meeting and the 2023 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 AACR Annual Meeting 2024, 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 presented data at the 2024 IOVC meeting. The presentation focused on a multimodal viral therapeutic candidate encoding IL-12 and IL-15, the latest asset from the platform.

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 is currently in an ongoing phase 2a clinical trial in NSCLC and recently completed phase 2a and phase 3 clinical trials in pancreatic cancer and localized prostate cancer, respectively. 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 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 filed with the SEC and 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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 4,817	$ 7,258	$ 19,314	$ 24,506
General and administrative	3,324	3,060	14,057	13,885
Total operating expenses	8,141	10,318	33,371	38,391
Loss from operations	(8,141)	(10,318)	(33,371)	(38,391)
Other income (expense):				
Grant income	—	(36)	—	—
Interest income	290	415	1,086	2,081
Interest expense	(390)	(673)	(2,090)	(2,595)
Change in fair value of warrant liability	(5,832)	(483)	(20,802)	966
Total other income (expense), net	(5,932)	(777)	(21,806)	452
Net loss and comprehensive loss	$ (14,073)	$ (11,095)	$ (55,177)	$ (37,939)
Net loss per share, basic and diluted	$ (0.40)	$ (0.38)	$ (1.74)	$ (1.31)
Weighted-average common shares outstanding, basic and diluted	35,564,528	28,981,222	31,675,076	28,935,289

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

	DECEMBER 31, 2024	DECEMBER 31, 2023
Cash and cash equivalents	$ 102,654	$ 35,413
Working capital (1)	66,275	22,613
Total assets	106,866	41,201
Warrant liability	21,718	916
Total other liabilities	18,821	27,540
Accumulated deficit	(192,205)	(137,028)
Total stockholders' equity	$ 66,327	$ 12,745

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