Candel Therapeutics Reports Third Quarter 2024 Financial Results and Recent Corporate Highlights

November 14, 2024

- *On track for topline disease-free survival data from the phase 3 randomized controlled clinical trial of CAN-2409 in localized intermediate/high risk prostate cancer, expected in Q4 2024*
- *On track for topline progression-free survival data from the phase 2b randomized controlled clinical trial of CAN-2409 in the active surveillance population with localized low/intermediate risk prostate cancer, expected in Q4 2024*
- *Presented preclinical data on therapeutic potential of CAN-3110 in melanoma at the SITC 2024 Annual Meeting*
- *The Company expects that its existing cash and cash equivalents will be sufficient to fund its current operating plan to the end of Q1 2025*

NEEDHAM, Mass., Nov. 14, 2024 (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, today reported financial results for the third quarter ended September 30, 2024, and provided a corporate update.

"We remain on track for phase 2b and phase 3 topline data in non-metastatic, localized prostate cancer for CAN-2409 in the fourth quarter of 2024, and hope we will deliver the data and regulatory approvals to enable a paradigm shift in how these patients will be treated in the future. We continue to advance our clinical and pre-clinical candidates, while leveraging our robust enLIGHTEN™ Discovery Platform to identify new and innovative assets that may be impactful in cancer immunotherapy," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. "We are encouraged by the first clinical and biomarker activity data after repeated injection of CAN-3110 from our ongoing phase 1b clinical trial of CAN-3110 in recurrent high-grade glioma, which suggests a long tail of survival. We are also excited about the data that supports potential expansion of CAN-3110 from recurrent high-grade glioma into melanoma, where we observed antitumor activity in pre-clinical models."

Dr. Tak continued, "As to the future, we are also looking forward to reporting updated overall survival data from both our ongoing CAN-2409 phase 2 NSCLC and pancreatic cancer clinical trials in Q1 2025."

Third Quarter 2024 & Recent Highlights

- *CAN-3110 – Recurrent High-Grade Glioma*
  - Received orphan drug designation from the U.S. Food and Drug Administration (FDA) for CAN-3110 for the treatment of recurrent high-grade glioma (rHGG).
  - Presented a Trial-in-Progress poster at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting on the ongoing phase 1b clinical trial exploring multiple doses of CAN-3110 in patients with rHGG.
  - Presented clinical and biomarker activity data from the ongoing phase 1b clinical trial at the 16th Annual International Oncolytic Virotherapy Conference (IOVC).
  - In the oral presentation, the investigators 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 CAN-3110 injections.
  - The data also show discrepancies between imaging and histologic findings, suggesting radiologic pseudo-progression: there was a near absence of tumor cells alongside dense lymphocyte infiltrates in biopsies obtained after CAN-3110 administration, especially in patients with enhancement on post-treatment magnetic resonance imaging (MRI) scans.
- *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's 39th 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 tumors treated with a high dose of CAN-3110.

- Cytotoxic activity in melanoma-bearing mice was associated with systemic immune activation, including increased activation and proliferation of circulating T cells.

- Findings mirror those from rHGG patients treated with CAN-3110 reported last year in *Nature*. The therapy was well-tolerated in preclinical models based on body weight and histopathological analysis following intratumoral administration.

- *enLIGHTEN ™Discovery Platform*
  - Presented poster titled "A first-in-class multimodal immunotherapy for enhanced immune activation in the tumor microenvironment as a novel therapeutic strategy for solid tumors" at IOVC.

  - The presentation focused on the latest asset from the enLIGHTEN™ Discovery Platform, a multimodal viral therapeutic candidate encoding IL-12 and IL-15. 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 regression in two different models.

Anticipated Milestones

- Phase 2b topline data for CAN-2409 in *low-to-intermediate-risk*, localized, non-metastatic prostate cancer expected in Q4 2024.

- Phase 3 topline disease-free survival data for CAN-2409 in localized *intermediate/high-risk* prostate cancer expected in Q4 2024.

Financial Results for Third Quarter Ended September 30, 2024

Research and Development Expenses: Research and development expenses were $5.4 million for the third quarter of 2024 compared to $5.8 million for the third quarter of 2023. The decrease was primarily due to lower payroll-related expenses following the corporate restructuring in the fourth quarter of 2023 and a decrease in depreciation, impairment, and loss on the sale of fixed assets. These decreases were partially offset by clinical development costs driven by increased manufacturing costs for CAN-2409 programs. Research and development expenses included non-cash stock compensation expense of $0.6 million for the third quarter of 2024 compared to $0.3 million for the third quarter of 2023.

General and Administrative Expenses: General and administrative expenses were $3.3 million for the third quarter of 2024 compared to $3.0 million for the third quarter of 2023. The increase was primarily due to increased professional and consulting fees. The increase was partially offset by lower insurance costs. General and administrative expenses included non-cash stock compensation expense of $0.5 million for the third quarter of 2024 compared to $0.4 million for the third quarter of 2023.

Net Loss: Net loss for the third quarter of 2024 was $10.6 million, compared to a net loss of $8.4 million for the third quarter of 2023, and included other expense, net of $1.9 million for the third quarter of 2024 and other income, net of $0.4 million for the third quarter of 2023, primarily due to the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents, as of September 30, 2024, were $16.6 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 to the end of the first quarter of 2025.

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. CAN-2409 is the lead product candidate from the adenovirus platform and is currently in ongoing clinical trials in non-small cell lung cancer (NSCLC) (phase 2), borderline resectable pancreatic ductal adenocarcinoma (PDAC) (phase 2), and localized, non-metastatic prostate cancer (phase 2b and phase 3). CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in recurrent high-grade glioma (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 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 programs, including the ability of CAN-2409 to improve overall survival of patients with NSCLC and pancreatic cancer and the ability of CAN-3110 to treat rHGG; the ability of our enLIGHTEN^{TM} Discovery Platform to identify new candidates with the potential to alter the lives of patients living with difficult to treat, solid tumors; expectations regarding the potential benefits conferred by orphan drug designation and fast track designation; 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; the Company's ability to continue as a going concern; expectations regarding the therapeutic benefit of the Company's programs; that final data from the Company's pre-clinical 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 Quarterly Report on Form 10-Q 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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Candel Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 5,416	$ 5,845	$ 14,497	$ 17,248
General and administrative	3,341	3,016	10,733	10,825
Total operating expenses	8,757	8,861	25,230	28,073
Loss from operations	(8,757)	(8,861)	(25,230)	(28,073)
Other income (expense):				
Grant income	—	12	—	36
Interest income	236	502	796	1,666
Interest expense	(487)	(669)	(1,700)	(1,922)
Change in fair value of warrant liability	(1,638)	581	(14,970)	1,449
Total other income (expense), net	(1,889)	426	(15,874)	1,229
Net loss and comprehensive loss	$ (10,646)	$ (8,435)	$ (41,104)	$ (26,844)
Net loss per share, basic and diluted	$ (0.33)	$ (0.29)	$ (1.35)	$ (0.93)
Weighted-average common shares outstanding, basic and diluted	32,013,569	28,919,810	30,369,129	28,919,810

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

	SEPTEMBER 30, 2024 (Unaudited)	DECEMBER 31, 2023
Cash and cash equivalents	$ 16,558	$ 35,413
Working capital (1)	2,817	22,613
Total assets	21,517	41,201
Warrant liability	15,886	916
Total other liabilities	20,888	27,540
Accumulated deficit	(178,132)	(137,028)

Total stockholders equity (deficit)	$	(15,257)	$	12,745

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