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

August 13, 2024

- *Announced positive survival data from the phase 2 randomized controlled clinical trial of CAN-2409 in borderline resectable pancreatic cancer*
- *Presented positive topline overall survival data from the phase 2 clinical trial of CAN-2409 in non-small cell lung cancer (NSCLC) at 2024 American Society of Clinical Oncology (ASCO) Annual Meeting*
- *Received orphan drug designation from the U.S. Food and Drug Administration (FDA) for both CAN-2409 and CAN-3110, for the treatment of pancreatic cancer and recurrent high-grade glioma (rHGG), respectively*
- *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*
- *The Company expects that its existing cash and cash equivalents will be sufficient to fund its current operating plan into Q1 2025*

NEEDHAM, Mass., Aug. 13, 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 second quarter ended June 30, 2024, and provided a corporate update.

“The second quarter of 2024 represented a pivotal period for Candel, characterized by robust clinical advancements and key regulatory successes, that further validate our innovative approach to cancer immunotherapy,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “Our encouraging overall survival phase 2 data for CAN-2409 highlights the potential of our lead candidate to address a significant unmet need for non-small cell lung cancer patients, who are non-responsive to immune checkpoint inhibitor treatment, and for patients with borderline resectable pancreatic cancer. In addition, the FDA granting orphan drug designation for CAN-3110 in recurrent high-grade glioma underscores the promise of this first-in-class, novel asset developed for difficult-to-treat cancers.”

Dr. Tak continued, “Our inclusion in the Russell 3000 Index also marks a significant milestone in Candel’s growth and offers an opportunity to increase our recognition within the investment community. These achievements, coupled with a successful R&D event at ASCO, have set a strong foundation as we approach several key readouts in the latter half of 2024.”

Second Quarter 2024 & Recent Highlights

- Program Updates
  - *CAN-2409 – Pancreatic Cancer*
    - In early April, announced positive updated survival data from the phase 2 randomized controlled clinical trial of CAN-2409 plus valacyclovir (prodrug), together with standard of care (SoC) chemoradiation, in borderline resectable pancreatic ductal adenocarcinoma (PDAC).
    - Data showed notable improvements in estimated median overall survival (mOS) of 28.8 months after experimental treatment with CAN-2409 versus 12.5 months in control group.
    - At 24 months, survival rate was 71.4% in CAN-2409 treated patients after chemoradiation and prior to surgery versus 16.7% in the control group. At 36 months, estimated survival was 47.6% in the CAN-2409 group after chemoradiation and prior to surgery versus 16.7% in the control group.
    - No new safety signals were observed, providing further support that multiple injections of CAN-2409 have been generally well-tolerated to date, with no dose-limiting toxicities and no cases of pancreatitis reported.
    - Analysis of resected tumors showed the formation of dense aggregates of immune cells, including CD8+, cytotoxic tumor infiltrating lymphocytes and dendritic cells, within the tumor microenvironment after CAN-2409 administration, confirming the activation of a robust antitumoral immune response.
    - Received orphan drug designation from the FDA for CAN-2409 for the treatment of pancreatic cancer.
  - *CAN-2409 – Non-Small Cell Lung Cancer*
    - Presented topline overall survival data from the phase 2 clinical trial of CAN-2409 plus valacyclovir in combination with continued immune checkpoint inhibitor (ICI) therapy in patients with stage III/IV NSCLC inadequately responding to ICI therapy at the 2024 ASCO Annual Meeting.
    - Data showed mOS of 20.6 months in patients with progressive disease despite ICI treatment compared to

published results of less than 12 months with SoC docetaxel-based chemotherapy in similar patient populations.[1]

- CAN-2409 treatment resulted in activation of the systemic immune response after two administrations of CAN-2409, including increased numbers of circulating cytotoxic and memory T cells associated with subsequent prolonged survival.
- As of the April 1, 2024 data cut-off date, CAN-2409 treatment in NSCLC continued to exhibit a favorable safety and tolerability profile.

- *CAN-3110 – Recurrent High-Grade Glioma*
  - Received orphan drug designation from the FDA for CAN-3110 for the treatment of rHGG.
  - Presented a Trial-in-Progress poster at the 2024 ASCO Annual Meeting on the ongoing phase 1b clinical trial exploring multiple doses of CAN-3110 in patients with rHGG.
- *enLIGHTEN ™Discovery Platform*
  - Presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting unveiling the second candidate from the enLIGHTEN™ Discovery Platform, a first-in-class multimodal immunotherapy candidate to induce tertiary lymphoid structures (TLS), being developed as a novel therapeutic for solid tumors.

- Corporate Updates
  - Hosted successful NSCLC Research and Development panel during the 2024 ASCO Annual Meeting, featuring prominent scientific and medical thought leaders discussing the topline overall survival data from the phase 2 clinical trial of CAN-2409 in NSCLC.
  - Announced inclusion in the Russell 3000 Index, effective July 1, 2024, as part of FTSE Russell's annual reconstitution of its U.S. equity indexes.

Anticipated Milestones

- Updated phase 1b data (Arm C) for CAN-3110 in rHGG expected in H2 2024.
- 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 Second Quarter Ended June 30, 2024

Research and Development Expenses: Research and development expenses were $5.0 million for the second quarter of 2024 compared to $5.9 million for the second quarter of 2023. The decrease was primarily due to lower clinical development costs driven by a reduction in regulatory, manufacturing and clinical trial costs for CAN-2409 programs and lower payroll-related expenses following the corporate restructuring in the fourth quarter of 2023. These decreases were partially offset by increased stock-based compensation expense. Research and development expenses included non-cash stock compensation expense of $1.3 million for the second quarter of 2024 compared to $0.3 million for the second quarter of 2023.

General and Administrative Expenses: General and administrative expenses were $3.6 million for both the second quarter of 2024 and the second quarter of 2023. There was a small decrease, primarily due to lower insurance costs and recruiting costs. These decreases were partially offset by increased professional and consulting fees. General and administrative expenses included non-cash stock compensation expense of $0.6 million for the second quarter of 2024 compared to $0.4 million for the second quarter of 2023.

Net Loss: Net loss for the second quarter of 2024 was $22.2 million, compared to a net loss of $9.6 million for the second quarter of 2023, and included other expense, net of $13.7 million and $35,000, respectively, primarily due to the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents, as of June 30, 2024, were $21.5 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 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 2 and phase 3). CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing investigator-sponsored 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 who are non-responsive to immune checkpoint inhibitor therapy and of patients with borderline resectable pancreatic cancer; the ability of CAN-3110 to treat difficult-to-treat cancers; 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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 4,979	$ 5,934	$ 9,081	$ 11,403
General and administrative	3,592	3,645	7,392	7,809
Total operating expenses	8,571	9,579	16,473	19,212
Loss from operations	(8,571)	(9,579)	(16,473)	(19,212)
Other income (expense):				
Grant income	—	12	—	24
Interest income	240	453	560	1,164
Interest expense	(567)	(644)	(1,213)	(1,253)
Change in fair value of warrant liability	(13,339)	144	(13,332)	868
Total other income (expense), net	(13,666)	(35)	(13,985)	803
Net loss and comprehensive loss	$ (22,237)	$ (9,614)	$ (30,458)	$ (18,409)
Net loss per share, basic and diluted	$ (0.74)	$ (0.33)	$ (1.03)	$ (0.64)
Weighted-average common shares outstanding, basic and diluted	29,878,210	28,919,810	29,537,874	28,919,810

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

	JUNE 30, 2024 (Unaudited)	DECEMBER 31, 2023
Cash and cash equivalents	$ 21,454	$ 35,413
Working capital (1)	8,739	22,613
Total assets	26,485	41,201
Warrant liability	14,248	916
Total other liabilities	22,209	27,540
Accumulated deficit	(167,486)	(137,028)
Total stockholders equity (deficit)	$ (9,972)	$ 12,745

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