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

Aug 14, 2025

- *Presented positive results from the phase 3 randomized, placebo-controlled clinical trial of CAN-2409 (aglatimagene besadenovec) in localized prostate cancer, during an oral presentation at the 2025 Annual Meeting of the* American Society of Clinical Oncology *(ASCO)*
- *Received FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for CAN-2409 for the treatment of prostate cancer*
- *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*
- *Received Orphan Designation for CAN-2409 for the treatment of pancreatic cancer from the European Medicines Agency (EMA)*
- *Cash and cash equivalents of $100.7 million, as of June 30, 2025, will be sufficient to fund operations into Q1 2027*

NEEDHAM, Mass., Aug. 14, 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 second quarter ended June 30, 2025, and provided a corporate update.

“This quarter marked several pivotal achievements for Candel, highlighted by the FDA RMAT Designation for CAN-2409, and being selected for an oral presentation at ASCO, reflecting the strength of the data based on our pivotal phase 3 clinical trial in localized prostate cancer,” said Paul Peter Tak, M.D. Ph.D. FMedSci, President and CEO of Candel. “Further, the addition of Dr. Maha Radhakrishnan to our Board of Directors, as well as the appointment of Charles Schoch as Chief Financial Officer, further strengthens our organization as we accelerate our pre-commercialization activities and advance toward BLA submission, anticipated in Q4 2026.”

Dr. Tak continued, “The positive results from our clinical trials in prostate cancer, pancreatic cancer, and non-small cell lung cancer reinforce the therapeutic potential of CAN-2409 as a novel therapy. With the proceeds from our recent registered direct offering being utilized to support pre-commercialization and launch readiness activities, and with multiple regulatory designations, we believe we are well-positioned to execute on our near-term milestones and advance toward our goal of bringing this important treatment option to patients with prostate cancer.”

Second Quarter 2025 & Recent Highlights

- *CAN-2409 – Prostate Cancer*
  - In an oral presentation at the 2025 ASCO Annual Meeting on June 3, 2025, in Chicago, IL, the Company reported phase 3 results from the CAN-2409 clinical trial in intermediate-to-high risk localized prostate cancer. The primary endpoint, agreed with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA), was met, with a statistically significant improvement of 30% in disease-free survival among CAN-2409 recipients (HR 0.70, p=0.0155) when compared to placebo, both in combination with standard-of-care external beam radiation therapy. This data was supported by secondary endpoints.
  - On June 3, 2025, Candel hosted a conference call featuring perspectives from leading prostate cancer specialists, John E. Sylvester, M.D., Atlantic Urology Clinics, Myrtle Beach, South Carolina, and Ronald F. Tutrone, Jr., M.D., FACS, CPI, National Medical Director of Clinical Research, United Urology Group, Towson, Maryland. Both physicians were principal investigators on the trial. The call replay can be accessed here.
  - This phase 3 study was conducted under a SPA agreed with the 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 is advancing its pre-BLA readiness, including through Chemistry, Manufacturing, and Controls (CMC) activities and documentation, and preparation of clinical study reports.
  - In May, the Company received RMAT Designation from the FDA for CAN-2409 for the treatment of newly diagnosed, localized prostate cancer in patients with intermediate-to-high-risk disease. The FDA previously granted Fast Track Designation for CAN-2409 for the treatment of localized primary prostate cancer.
  - The Company continues to work toward a BLA submission for CAN-2409 in prostate cancer in Q4 2026.

- *CAN-2409 – Non-Small Cell Lung Cancer (NSCLC)*
  - In March, the Company reported positive overall 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 (Cohorts 1+2, n=46), median overall survival (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.

- *CAN-2409 - Pancreatic Cancer*
  - In February 2025, the Company reported positive overall survival data from the randomized, controlled, phase 2a clinical trial of CAN-2409 in borderline resectable pancreatic ductal adenocarcinoma (PDAC).
  - 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 out of seven patients in the CAN-2409 arm were long-term survivors and remained alive at 66.0, 63.6, and 35.8 months post-treatment, whereas only one out of six patients 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.
  - The EMA granted Orphan Designation for CAN-2409 for the treatment of pancreatic cancer in July 2025.

- *Recent Corporate Events*
  - In June 2025, the Company completed a registered direct offering, of approximately 3.2 million shares of its common stock, to a select group of existing healthcare-focused institutional investors, executive officers, and directors of the Company, at a price per share of $4.67, resulting in gross proceeds of approximately $15 million, before deducting offering expenses payable by the Company.
  - In June 2025, the Company appointed Charles Schoch as Chief Financial Officer (CFO). Mr. Schoch previously served as interim CFO of Candel. He will continue to be instrumental as the Company advances its clinical pipeline and prepares for BLA submission of CAN-2409 in localized prostate cancer, anticipated in Q4 2026.
  - In June 2025, the Company appointed Maha Radhakrishnan, M.D., to its Board of Directors. Dr. Radhakrishnan has significant expertise in product development and commercialization.

Anticipated Milestones

- Additional clinical and biomarker activity data from an ongoing phase 1b clinical trial evaluating repeat doses of CAN-3110 in patients with recurrent high-grade glioma (rHGG), is expected in Q4 2025.
- Candel plans to host a virtual Research and Development event in Q4 2025.
- Submission of BLA for CAN-2409 in prostate cancer expected in Q4 2026.

Financial Results for the Second Quarter Ended June 30, 2025

Research and Development Expenses: Research and development expenses were $7.0 million for the second quarter of 2025 compared to $5.0 million for the second quarter of 2024. The increase was primarily due to an increase in manufacturing costs in support of the Company's CAN-2409 programs, partially offset by a decrease in employee-related expenses, which was driven primarily from a reduction in stock-based compensation expense. Research and development expenses included a non-cash stock compensation expense of $0.4 million for the second quarter of 2025 compared to a non-cash stock compensation expense of $1.3 million for the second quarter of 2024.

General and Administrative Expenses: General and administrative expenses were $4.2 million for the second quarter of 2025, compared to $3.6 million for the second quarter of 2024. The increase was primarily due to an increase in commercial readiness costs as well as higher professional and consulting fees. General and administrative expenses included non-cash stock compensation expense of $0.6 million for both the second quarter of 2025 and the second quarter of 2024.

Net Loss: Net loss for the second quarter of 2025 was $4.8 million compared to a net loss of $22.2 million for the second quarter of 2024 and included net other income of $6.4 million and net other expense of $13.7 million, respectively. The decrease in net loss was primarily related to the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents, as of June 30, 2025, were $100.7 million 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 operations into Q1 2027, including the Company's expected submission of the BLA for CAN-2409 in intermediate-to-high-risk prostate cancer to the FDA in Q4 2026.

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 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. 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 standard of care, when indicated.

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 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.

The Company recently completed successful phase 2a clinical trials of CAN-2409 in NSCLC and PDAC, and a pivotal, placebo-controlled, phase 3 clinical trial of CAN-2409 in localized prostate cancer, conducted under a SPA agreed with the FDA. The FDA also granted RMAT Designation to CAN-2409 for the treatment of newly diagnosed localized prostate cancer in patients with intermediate-to-high-risk disease, Fast Track Designation in NSCLC and prostate cancer, and both Fast Track and Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in rHGG. Initial results were published in Nature and CAN-3110 received Fast Track Designation and Orphan Drug Designation from the FDA. 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; 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 June 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.

Investor Contact
Theodore Jenkins
Vice President, Investor Relations and Business Development
Candel Therapeutics, Inc.
tjenkins@candeltx.com

Media Contact
Ben Shannon
Vice President
ICR Healthcare
CandelPR@icrhealthcare.com

---

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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 6,991	$ 4,979	$ 11,007	$ 9,081
General and administrative	4,186	3,592	8,300	7,392
Total operating expenses	11,177	8,571	19,307	16,473
Loss from operations	(11,177)	(8,571)	(19,307)	(16,473)
Other income (expense):				
Interest income	926	240	1,860	560
Interest expense	(236)	(567)	(542)	(1,213)
Change in fair value of warrant liability	5,691	(13,339)	20,572	(13,332)
Total other income (expense), net	6,381	(13,666)	21,890	(13,985)
Net income (loss) and comprehensive income (loss)	$ (4,796)	$ (22,237)	$ 2,583	$ (30,458)
Net income (loss) per share, basic	$ (0.09)	$ (0.74)	$ 0.05	$ (1.03)
Weighted-average common shares outstanding, basic	51,489,929	29,878,210	50,988,887	29,537,874
Net income (loss) per share, diluted	$ (0.09)	$ (0.74)	$ 0.05	$ (1.03)
Weighted-average common shares outstanding, diluted	51,489,929	29,878,210	53,369,582	29,537,874

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

	JUNE 30, 2025 (Unaudited)	DECEMBER 31, 2024
Cash and cash equivalents	$ 100,687	$ 102,654
Working capital (1)	88,893	66,275
Total assets	105,968	106,866
Warrant liability	1,146	21,718
Total other liabilities	14,612	18,821
Accumulated deficit	(189,622)	(192,205)
Total stockholders' equity	$ 90,210	$ 66,327

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