



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

Nov 13, 2025

- Presented new subgroup analyses from phase 3 clinical trial of CAN-2409 in localized prostate cancer at the American Society for Radiation Oncology (ASTRO) 2025 meeting, demonstrating improved prostate cancer-specific disease-free survival (DFS), independent of radiation therapy modality utilized
- Company plans to initiate pivotal phase 3 clinical trial of CAN-2409 in patients with metastatic, non-squamous, non-small cell lung cancer (NSCLC) and progressive disease, despite immune checkpoint inhibitor (ICI) treatment, in Q2 2026
- Announced encouraging updated survival data for patients enrolled in its phase 1b clinical trial of CAN-3110 (linosartemurev) in recurrent high-grade glioma (rHGG)
- Manuscript published in the scientific journal *Science Translational Medicine*, reporting the tissue response to CAN-3110 based on the analysis of serial tumor biopsies from two patients treated with multiple administrations of CAN-3110 in arm C of the phase 1b clinical trial
- Plan to submit a Biologics License Application (BLA) for CAN-2409 in intermediate-to-high-risk localized prostate cancer in Q4 2026
- Entered into a \$130 million term loan facility with Trinity Capital Inc. for a \$50 million drawn down at closing, with access to up to an additional \$80 million
- Cash and cash equivalents of \$87.0M, as of September 30, 2025, plus the upfront proceeds from the Trinity Capital debt facility, strengthens the Company's financial position to fund initiation of potentially registrational phase 3 trial of CAN-2409 in NSCLC and other planned operations into Q1 2027

NEEDHAM, Mass., Nov. 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 third quarter ended September 30, 2025, and provided a corporate update.

"This quarter we continued to make strong progress across our clinical pipeline," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and CEO of Candel. "We continue to work toward a planned BLA submission in Q4 2026. We presented additional supportive data from our positive phase 3 trial of CAN-2409 in newly diagnosed, localized prostate cancer during an oral presentation at the Association of Radiation Oncology (ASTRO) Annual Meeting, demonstrating that CAN-2409 improved prostate cancer-specific DFS, independent of the type of external beam radiation therapy used, extending the results presented during an oral presentation at the American Society of Clinical Oncology Annual Meeting. We also presented data during an invited lecture at the Annual Meeting of the Prostate Cancer Foundation. We continue to follow the patients enrolled in the phase 3 study for prostate cancer-specific outcomes and expect the first results after extended follow-up in Q2 2026. In addition, in collaboration with the U.S. Food and Drug Administration, we designed a supportive, mechanistic clinical trial of CAN-2409 in localized prostate cancer. We plan to release immunologic biomarker data from this study in Q3 2026. Furthermore, we reported encouraging survival data from our phase 1b clinical trial of CAN-3110 in patients with rHGG, most of whom had recurrent glioblastoma, supported by sophisticated brain biopsy analyses. Mature overall survival data for Arm C are expected in Q4 2026. Together, the data supports the design of a randomized controlled phase 2 clinical trial of CAN-3110 in recurrent glioblastoma. Finally, we strengthened our Research Advisory Board with the appointments of Dr. Carl H. June and Dr. Bali Pulendran, underscoring our continuous commitment to scientific excellence and to advancing immunotherapies that may meaningfully improve the lives of patients with devastating cancers."

Dr. Tak continued, "On the financial front, we were pleased to secure strategic, non-dilutive funding through a five-year, \$130 million term loan facility with Trinity Capital, Inc., which strengthens our balance sheet and positions us to advance our key priorities, including the initiation of a pivotal phase 3 clinical trial of CAN-2409 in NSCLC and the potential commercial launch of CAN-2409 in localized prostate cancer. We expect updated data on long-term survivors from our phase 2 study in NSCLC in Q1 2026 and anticipate initiation of the phase 3 study in Q2 2026. We look forward to sharing more details on our progress and strategic vision at our virtual Research and Development event in Q4 2025."

Third Quarter 2025 & Recent Highlights

- **CAN-2409 (aglatimagene besadenovec) – Prostate Cancer**
 - In an oral presentation at the 2025 ASTRO Annual Meeting, the Company presented subgroup analyses focused on the radiation regimen used during its positive phase 3 clinical trial of CAN-2409 in patients with intermediate-to-high-risk localized prostate cancer. Data were presented by Glen Gejerman, M.D., M.B.A., Co-Director of Urologic Oncology at Hackensack Meridian Health and one of the principal investigators of the study.

- CAN-2409 demonstrated statistically significant improvement in prostate cancer-specific DFS (Hazard Ratio (HR) 0.62; p=0.0046). Effects were observed with both moderate hypo-fractionated external beam radiation therapy (EBRT) (HR 0.52, CI 0.30 - 0.93, p=0.0236) and conventional EBRT (HR 0.76, CI 0.53 - 1.07, p=0.1131).
- CAN-2409 administration was safe across radiation therapy modalities, with both conventional radiation therapy (~78 Gy in 2 Gy fractions, ~72% of patients) and moderate hypofractionated radiation therapy (60 Gy in 3 Gy fractions, ~25% of patients), showing similar tolerability profiles. Grade ≥ 3 treatment related adverse events were similar in the CAN-2409 plus valacyclovir and placebo arms with both hypofractionated (1.6% vs. 1.9%) and standard EBRT (1.8% vs. 1.1%), respectively.
- The U.S. Food and Drug Administration (FDA) previously granted Fast Track Designation and Regenerative Medicine Advanced Therapy Designation to CAN-2409 for the treatment of prostate cancer; the phase 3 clinical trial of CAN-2409 in localized prostate cancer was conducted under a Special Protocol Assessment agreed to with the FDA.
- The Company is advancing its pre-BLA readiness, including through its Chemistry, Manufacturing, and Controls (CMC) activities, and preparation of clinical study reports and BLA modules.
- *CAN-2409 – Non-Small Cell Lung Cancer (NSCLC)*
 - Following a positive end-of-phase 2 meeting with the FDA in July 2025, the Company is preparing to initiate a pivotal phase 3 clinical trial of CAN-2409 in NSCLC in Q2 2026.
 - The FDA previously granted Fast Track Designation to CAN-2409 for the treatment of NSCLC.
- *CAN-2409 - Pancreatic Cancer*
 - The Company previously generated encouraging data based on a randomized controlled phase 2a clinical trial of CAN-2409 in borderline resectable pancreatic cancer (PDAC). The FDA previously granted Fast Track Designation and Orphan Drug Designation to CAN-2409 for the treatment of PDAC and the European Medicines Agency granted Orphan Designation for CAN-2409 for the treatment of pancreatic cancer in July 2025.
 - With Candel's top priorities focused on prostate cancer and NSCLC, the Company will pause the PDAC program, unless it is funded through external, non-dilutive funding.
- *CAN-3110 (linoserpaturev) - Recurrent High-Grade Glioma (rHGG)*
 - In October 2025, the Company reported encouraging updated survival data for all patients enrolled in its phase 1b clinical trial of CAN-3110 in rHGG:
 - Updated median overall survival (mOS) was 11.8 months (CI: 8.3–14.9) for arm A (n = 41) and 12.0 months (CI: 10.0–NA) for arm B (n = 9) after a single injection of CAN-3110, consistent with previously reported data for arms A and B. At the time of data cutoff (August 15, 2025), one patient from arm A and one patient from arm B were still alive after prolonged follow-up (59.2 and 42.4 months, respectively, after CAN-3110 administration). The FDA previously granted Fast Track Designation and Orphan Drug Designation to CAN-3110 in recurrent high-grade glioma based on an earlier data cut.
 - At data cutoff as of August 15, 2025, 9 patients in arm C had received multiple administrations of CAN-3110. At the 1×10⁸ PFU dose, 3 patients received 4 injections, 1 patient received 5 injections, and 2 patients received 6 injections. At the 1×10⁷ PFU dose, 1 patient received 4 injections, and 2 patients received 5 injections. Median follow-up was 8.9 months. Four out of 9 patients were alive at time of data cutoff (range 3.1-28.2 months after initiation of CAN-3110 treatment). Five patients had died, of which 3 died more than one year after initiation of CAN-3110 treatment (range 5.5-21.8 months).
 - Candel also announced the scientific publication, “*Serial Multiomics Uncovers Anti-Glioblastoma Responses Not Evident by Routine Clinical Analyses*,” in the journal *Science Translational Medicine*. Led by E. Antonio Chiocca, M.D., Ph.D., Executive Director of the Center for Tumors of the Nervous System at the Mass General Brigham Cancer Institute, as part of the multi-institutional Break Through Cancer Accelerating GBM Therapies Through Serial Biopsies TeamLab, the publication presents findings from the comprehensive analysis of 97 serial tumor biopsies collected from two patients treated with repeated administrations of CAN-3110 in arm C of the ongoing phase 1b clinical trial ([NCT03152318](https://clinicaltrials.gov/ct2/show/study/NCT03152318)).
 - Together, the encouraging data supports the Company's plans to design a randomized controlled phase 2 clinical trial of CAN-3110 in recurrent glioblastoma.
- *Recent Corporate Events*
 - The Company presented insights into the third preclinical candidate from its enLIGHTEN™ Discovery Platform in a mouse model of breast cancer, as well as additional data from the CAN-2409 program in NSCLC, through two

accepted poster presentations, along with an invited faculty presentation and panel discussion by Paul Peter Tak, M.D., Ph.D., FMedSci, Candel's President and CEO, showcasing the phase 3 clinical trial of CAN-2409 in newly diagnosed, localized prostate cancer at the Society for Immunotherapy of Cancer's (SITC) 40th Anniversary Annual Meeting.

- In October 2025, Candel entered into a \$130 million term loan facility with Trinity Capital Inc. (Nasdaq: TRIN). The loan facility consists of four tranches, with the first tranche of \$50 million drawn upon closing of the agreement. The second and third tranches totaling \$50 million in the aggregate are available to be drawn subject to the achievement of certain regulatory, clinical and operational milestones, subject to certain conditions precedent described in the agreement, and the fourth tranche of \$30 million is available at the lender's discretion. The loan facility has a five-year term with an interest-only period of 36 months, which is extendable for an additional 12 months upon the achievement of a certain commercial milestone. The loan facility contains customary representations, warranties, covenants, and events of default.
- In September 2025, the Company appointed Carl H. June, M.D., to its Research Advisory Board (RAB). Dr. June is an internationally recognized expert in cancer immunotherapy, and a pioneer in developing the first FDA-approved CAR-T cell therapy.
- In October 2025, the Company appointed Bali Pulendran, Ph.D., to its RAB. Dr. Pulendran is an internationally recognized expert in systems immunology and vaccinology, who has pioneered the use of systems' approaches to understand human immune responses.

Anticipated Milestones

- Candel will host a Virtual R&D Day on Friday, December 5, 2025.
- Updated mOS data and "long tail" of survival analysis from the phase 2a open-label clinical trial of CAN-2409 in patients with stage III/IV NSCLC who had progressed, despite ICI treatment ([NCT04495153](#)) is expected in Q1 2026.
- Updated data on prostate cancer-specific DFS, time to salvage anti-cancer therapy, and time to metastasis from the positive phase 3 clinical trial of CAN-2409 in patients with intermediate-to-high-risk localized prostate cancer after extended follow-up is expected in Q2 2026.
- The Company plans to initiate a pivotal phase 3 clinical trial of CAN-2409 in NSCLC in Q2 2026.
- Data on local and systemic biomarkers of immune activation from a mechanistic, supportive clinical trial of CAN-2409 in patients with localized prostate cancer, is expected in Q3 2026.
- The Company expects to present mature mOS data and an update on long-term survivors from arm C of its phase 1b clinical trial of CAN-3110 in patients with recurrent glioblastoma in Q4 2026.
- Submission of BLA for CAN-2409 in prostate cancer is expected in Q4 2026.

Financial Results for the Third Quarter Ended September 30, 2025

Research and Development Expenses: Research and development expenses were \$8.5 million for the third quarter of 2025 compared to \$5.4 million for the third quarter of 2024. The increase was primarily due to an increase in manufacturing and regulatory costs, in support of the Company's CAN-2409 programs, and an increase in employee-related expenses, as well as an increase in depreciation and loss on the disposal and sale of fixed assets. Research and development expenses included a non-cash stock compensation expense of \$0.5 million for the third quarter of 2025 compared to a non-cash stock compensation expense of \$0.6 million for the third quarter of 2024.

General and Administrative Expenses: General and administrative expenses were \$4.7 million for the third quarter of 2025, compared to \$3.3 million for the third quarter of 2024. The increase was primarily due to an increase in commercial readiness costs as well as an increase in employee-related expenses. General and administrative expenses included non-cash stock compensation expense of \$0.6 million for the third quarter of 2025 compared to \$0.5 million for the third quarter of 2024.

Net Loss: Net loss for the third quarter of 2025 was \$11.3 million compared to a net loss of \$10.6 million for the third quarter of 2024 and included net other income of \$1.9 million and net other expense of \$1.9 million, respectively. The change from net other expense in 2024 to net other income in 2025 was primarily related to the change in the fair value of the Company's warrant liability and an increase in interest income.

Cash Position: Cash and cash equivalents, as of September 30, 2025, were \$87.0 million compared to \$102.7 million as of December 31, 2024. Based on current operating plans, including the initiation of a potentially registrational phase 3 trial in NSCLC, the Company expects that its existing cash and cash equivalents, as of September 30, 2025, together with proceeds from the upfront tranche of the Trinity debt facility, will be sufficient to fund operations into Q1 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 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 in clinical trials with a favorable tolerability profile to date, supporting the potential for combination with standard of care, when indicated.

About CAN-3110

CAN-3110 (linoserpaturev) 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. In October 2023, the Company announced that *Nature* published results from the ongoing clinical trial where CAN-3110 was reported to be generally well tolerated with no dose-limiting toxicity. In the clinical trial, the investigators observed improved mOS compared to historical controls after a single CAN-3110 injection in this therapy-resistant condition.¹ The Company and academic collaborators are currently supported by the Break Through Cancer foundation.

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.

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 (aglatimagene besadenovec) is the lead product candidate from the adenovirus platform. The Company recently completed successful phase 2a clinical trials of CAN-2409 in non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), and a pivotal, placebo-controlled, phase 3 clinical trial of CAN-2409 in localized prostate cancer, conducted under a Special Protocol Assessment agreed with the FDA. The FDA also granted Fast Track Designation and Regenerative Medicine Advanced Therapy 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 Designation and Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

CAN-3110 (linoserpaturev) is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in recurrent high-grade glioma, evaluating the effects of repeat CAN-3110 injections. Initial results were published in [Nature](#) and [Science Translational Medicine](#) 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; the impact of the Company's existing and any future indebtedness on its ability to operate its business; the Company's ability to access any future tranches under its debt facility and to comply with all of its obligations thereunder; 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 September 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.

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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)
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 8,461	\$ 5,416	\$ 19,468	\$ 14,497
General and administrative	4,746	3,341	13,046	10,733
Total operating expenses	<u>13,207</u>	<u>8,757</u>	<u>32,514</u>	<u>25,230</u>
Loss from operations	<u>(13,207)</u>	<u>(8,757)</u>	<u>(32,514)</u>	<u>(25,230)</u>
Other income (expense):				
Interest income	953	236	2,813	796
Interest expense	(161)	(487)	(703)	(1,700)
Change in fair value of warrant liability	1,146	(1,638)	21,718	(14,970)
Total other income (expense), net	<u>1,938</u>	<u>(1,889)</u>	<u>23,828</u>	<u>(15,874)</u>
Net loss and comprehensive loss	<u>\$ (11,269)</u>	<u>\$ (10,646)</u>	<u>\$ (8,686)</u>	<u>\$ (41,104)</u>
Net loss per share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.33)</u>	<u>\$ (0.17)</u>	<u>\$ (1.35)</u>
Weighted-average common shares outstanding, basic and diluted	<u>54,894,347</u>	<u>32,013,569</u>	<u>52,305,013</u>	<u>30,369,129</u>

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

	SEPTEMBER 30, 2025 (Unaudited)	DECEMBER 31, 2024
Cash and cash equivalents	\$ 86,963	\$ 102,654
Working capital (1)	79,205	66,275
Total assets	93,598	106,866
Warrant liability	—	21,718
Total other liabilities	13,474	18,821
Accumulated deficit	(200,891)	(192,205)
Total stockholders' equity	\$ 80,124	\$ 66,327

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