Candel Therapeutics Reports First Quarter 2026 Financial Results and Recent Corporate Highlights

May 14, 2026

- *Company plans to submit a Biologics License Application (BLA) for aglatimagene besadenovec (aglatimagene or CAN-2409) in localized, intermediate- to high-risk prostate cancer in Q4 2026*
- *Announced purpose-built commercial partnership with EVERSANA® to support potential U.S. launch of aglatimagene in localized prostate cancer*
- *Company reported extended survival tail observed in trial of aglatimagene in advanced non-small cell lung cancer (NSCLC) patients with inadequate response to immune checkpoint inhibitors (ICI)*
- *Company to report extended follow-up data from the positive phase 3 clinical trial of aglatimagene in patients with localized, intermediate- to high-risk prostate cancer at the American Urological Association (AUA) 2026 Annual Meeting Plenary Program in May 2026*
- *Company plans to initiate a pivotal phase 3 clinical trial of aglatimagene in patients with progressive, metastatic, NSCLC despite ICI treatment, in Q2 2026*
- *Cash and cash equivalents of $194.8 million, as of March 31, 2026, are expected to be sufficient to fund the Company's current operating plan into Q1 2028, which includes activities to support the potential commercial launch of aglatimagene in 2027*

NEEDHAM, Mass., May 14, 2026 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical-stage biopharmaceutical company focused on developing multimodal immunotherapies to improve outcomes for patients with cancer, today announced financial results for the first quarter ended March 31, 2026, and provided a corporate update.

"The quarter was marked by strong execution across our lead clinical programs, commercial readiness efforts, and further strengthening of our balance sheet," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and CEO of Candel. "Our primary focus remains on preparing for our planned BLA submission in Q4 2026 for aglatimagene in localized, intermediate- to high-risk prostate cancer. In parallel, we continue to follow patients from our phase 3 localized prostate cancer trial, with extended follow up data to be presented in a plenary oral presentation in May 2026 at AUA and additional biomarker data to be announced in Q3 2026. We are also encouraged by the persistent survival tail observed after extended follow-up from our phase 2a NSCLC trial and look forward to the planned initiation of a pivotal NSCLC phase 3 trial in June 2026."

Dr. Tak continued, "On the commercial readiness front, we are encouraged by our progress in building a differentiated, partnership-driven model that leverages the expertise of world-class organizations EVERSANA® and IDEA Pharma. We believe this approach can enhance speed, flexibility, and scalability, positioning Candel for a successful and timely commercial launch of aglatimagene, if approved, for patients with localized prostate cancer."

First Quarter 2026 & Recent Highlights

- *Aglatimagene besadenovec (CAN-2409) – Prostate Cancer*
  - The Company continues to advance its pre-BLA readiness initiative, including its Chemistry, Manufacturing, and Controls (CMC) activities, and preparation of clinical study reports and BLA modules.
  - The Company will report follow-up clinical data from its phase 3 trial of aglatimagene in prostate cancer in an oral presentation at the American Urological Association (AUA) 2026 Annual Meeting Plenary Program being held in Washington D.C. from May 15-18, 2026. In Q3 2026, the Company expects to present additional biomarker data.
  - The Company plans to conduct process validation with its Contract Development and Manufacturing Organization in Q2 2026 to enable its anticipated submission of a BLA in Q4 2026. Clinical material from the new process has been manufactured and filled into vials. Candel intends to use this material in the pivotal phase 3 clinical trial in NSCLC.
  - The U.S. Food and Drug Administration (FDA) previously granted Fast Track Designation and Regenerative Medicine Advanced Therapy Designation to aglatimagene for the treatment of localized prostate cancer. The phase 3 clinical trial of aglatimagene in localized prostate cancer was conducted under a Special Protocol Assessment with respect to certain aspects of the study design, agreed with the FDA.
- *Aglatimagene besadenovec (CAN-2409) – Non-Small Cell Lung Cancer (NSCLC)*
  - The Company reported an additional 12 months of extended follow-up from its clinical trial of aglatimagene plus valacyclovir in combination with continued ICI therapy in patients with advanced NSCLC, who had an inadequate response to prior ICI treatment. The reported data included:

- Extended long-term survival observed after an additional year of follow-up in an ongoing phase 2a clinical trial, with 50% of the 46 patients with advanced NSCLC treated per-protocol with aglatimagene surviving beyond 24 months, despite prior inadequate response to ICI and multiple adverse baseline prognostic factors.
- Among the patients surviving beyond 24 months and with PD-L1 status available, 85% (17/20) had baseline PD-L1 tumor proportion scores (TPS) below 50% (a population typically less responsive to ICI), supporting the potential of aglatimagene to upregulate PD-L1 in the tumor microenvironment and convert non-responders to ICI into responders.
- Median overall survival (mOS) was 25.4 months in the evaluable patients with inadequate response to ICI in cohorts 1 and 2 (per-protocol population), 21.5 months among evaluable patients exhibiting progressive disease at baseline despite prior ICI therapy (cohort 2), and 25.4 months in the subgroup of patients with non-squamous histology within cohort 2, supporting the rationale for a precision medicine-based design for the phase 3 pivotal trial planned for initiation in June 2026.
- Post-treatment tumor biopsies demonstrated an increase in pro-inflammatory gene expression, which was significantly associated with long-term survival, supporting activation of inflammatory pathways within the tumor microenvironment following aglatimagene treatment.
- Expansion of T-cell receptor (TCR) repertoire diversity was observed after treatment both within the tumor and in peripheral blood, consistent with broad activation of anti-tumor immunity through enhanced exposure of tumor antigens following aglatimagene therapy.
- 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 aglatimagene in NSCLC in June 2026.
- The FDA previously granted Fast Track Designation to aglatimagene for the treatment of NSCLC.

- *Linoserpaturev (CAN-3110) - Recurrent High-Grade Glioma (rHGG)*
  - In February 2026, at the 7th Annual Glioblastoma Drug Development Summit, the Company shared insights from its herpes simplex virus (HSV)-based platform and its linoserpaturev program through workshop presentations and panel discussions focused on advancing biomarker-driven clinical development in glioblastoma.
  - The Company submitted an IND for linoserpaturev to advance the ongoing development of this asset in rHGG in Q4 2025 and received clearance to proceed from the FDA in Q1 2026.
  - The FDA previously granted Fast Track Designation and Orphan Drug Designation to linoserpaturev in rHGG.
- *Recent Corporate Events*
  - In April 2026, the Company announced a commercialization agreement with EVERSANA® to support the potential U.S. launch of aglatimagene in localized prostate cancer. EVERSANA® joins IDEA Pharma, a division of SAI MedPartners, who has been providing path-to-market strategies and strategic positioning for aglatimagene. This operating model gives Candel immediate access to leading commercial capabilities, while maintaining financial flexibility, capital efficiency, and scientific focus that has driven the Company's progress to date.
  - On February 23, 2026, Candel issued and sold 18,348,624 shares of common stock at a price to the public of $5.45 per share for aggregate gross proceeds of approximately $100 million, which will be used to complete critical launch readiness, medical affairs, pre-commercialization, and commercial activities for aglatimagene in early, localized prostate cancer, ongoing development costs related to the phase 3 trial of aglatimagene in NSCLC, and for general corporate purposes.
  - On February 19, 2026, Candel announced a $100 million royalty funding agreement with funds managed by RTW Investments, LP (RTW), subject to FDA approval of aglatimagene in localized, intermediate- to high-risk, prostate cancer. Under the terms of the agreement, RTW will receive a tiered single digit percentage of annual net sales of aglatimagene in the U.S., subject to a cap. Funds will strengthen the Company's balance sheet for potential U.S. commercial launch of aglatimagene in intermediate- to high-risk localized prostate cancer.

Anticipated Milestones

- Updated extended follow-up data from the positive phase 3 clinical trial of aglatimagene in patients with localized, intermediate- to high-risk localized prostate cancer, will be reported in an oral presentation at the AUA 2026 Annual Meeting Plenary Program being held in Washington D.C. from May 15-18, 2026.
- The Company plans to initiate a pivotal phase 3 clinical trial of aglatimagene in patients with metastatic, non-squamous, NSCLC, and progressive disease despite ICI treatment in June 2026.
- Biomarker data related to the effects of aglatimagene 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 linoserpaturev in patients with rHGG in Q4 2026.
- Submission of BLA for aglatimagene in prostate cancer is planned for Q4 2026.

Financial Results for the First Quarter Ended March 31, 2026

Research and Development Expenses: Research and development expenses were $9.8 million for the first quarter of 2026 compared to $4.0 million for the first quarter of 2025. The increase was primarily due to higher clinical trial and manufacturing costs, in support of the Company's aglatimagene programs, and an increase in employee-related expenses. Research and development expenses included a non-cash stock compensation expense of $0.6 million for the first quarter of 2026, as compared to a non-cash stock compensation expense of ($0.1) million for the first quarter of 2025.

General and Administrative Expenses: General and administrative expenses were $6.4 million for the first quarter of 2026, compared to $4.1 million for the first quarter of 2025. The increase was primarily due to higher commercial readiness costs and an increase in employee-related expenses. General and administrative expenses included non-cash stock compensation expense of $0.8 million for the first quarter of 2026, as compared to a non-cash stock compensation expense of $0.4 million for the first quarter of 2025.

Net Income/Loss: Net loss for the first quarter of 2026 was $8.9 million compared to net income of $7.4 million for the first quarter of 2025 and included net other income of $7.4 million and $15.5 million, respectively. The decrease in net other income was primarily related to the change in the fair value of the Company's warrant liabilities.

Cash Position: Cash and cash equivalents, as of March 31, 2026, were $194.8 million compared to $119.7 million as of December 31, 2025. Based on current operating plans, the Company expects that its existing cash and cash equivalents, as of March 31, 2026, will be sufficient to fund operations into Q1 2028.

About aglatimagene besadenovec (CAN-2409)

Aglatimagene, 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 proteins promote 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. Aglatimagene 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 aglatimagene in clinical trials with a favorable tolerability profile to date, supporting the potential for use with standard of care, when indicated. Aglatimagene is currently not approved by the FDA or any other regulatory authority for any use.

About linoserpaturev (CAN-3110)

Linoserpaturev is a first-in-class, replication-competent, next-generation oncolytic herpes simplex virus-1 (HSV-1) 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 linoserpaturev was reported to be generally well tolerated with no dose-limiting toxicity. In the clinical trial, the investigators observed improved median overall survival compared to historical controls after a single linoserpaturev injection in this therapy-resistant condition[1]. The Company and academic collaborators are currently supported by the Break Through Cancer foundation to evaluate the effects of repeated linoserpaturev injections in patients with recurrent glioblastoma in an expansion cohort from the phase 1b clinical trial. In October 2025, *Science Translational Medicine* presented findings from the comprehensive analysis of 97 serial tumor biopsies collected from two patients treated with repeated administrations of linoserpaturev in arm C. Linoserpaturev previously received Fast Track Designation and Orphan Drug Designation for the treatment of rHGG from the U.S. Food and Drug Administration (FDA).

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. Aglatimagene besadenovec (aglatimagene or CAN-2409) is the lead product candidate from the adenovirus platform. The Company recently completed successful phase 2a clinical trials of aglatimagene in non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), and a pivotal, placebo-controlled, phase 3 clinical trial of aglatimagene 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 aglatimagene for the treatment of newly diagnosed localized prostate cancer in patients with intermediate- to high-risk disease, Fast Track Designation in NSCLC, and both Fast Track Designation and Orphan Drug Designation to aglatimagene for the treatment of PDAC.

Linoserpaturev (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 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; expectations regarding the royalty funding agreement with RTW and the intended and potential benefits thereof; expectations regarding the Company's ability to prepare and implement commercialization plans for aglatimagene in partnership with EVERSANA and IDEA and the potential benefits and duration of such partnerships; 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 March 31, 2026, 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 MARCH 31,	
	2026	**2025**
Operating expenses:		
Research and development	$ 9,840	$ 4,016
General and administrative	6,444	4,114
Total operating expenses	16,284	8,130
Loss from operations	(16,284)	(8,130)
Other income (expense):		
Grant income	22	—
Interest income	1,322	934
Interest expense	(1,564)	(306)
Change in fair value of warrant liabilities	7,643	14,881
Total other income, net	7,423	15,509
Net income (loss) and comprehensive income (loss)	$ (8,861)	$ 7,379
Net income (loss) per share, basic	$ (0.14)	$ 0.15
Weighted-average common shares outstanding, basic	62,361,897	50,482,278

Net income (loss) per share, diluted	$ (0.14)	$ 0.13
Weighted-average common shares outstanding, diluted	62,361,897	54,765,842

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

	MARCH 31, 2026 (Unaudited)	DECEMBER 31, 2025
Cash and cash equivalents	$ 194,834	$ 119,731
Working capital (1)	190,701	112,392
Total assets	201,920	125,195
Warrant liabilities	7,955	15,598
Total other liabilities	55,936	57,675
Accumulated deficit	(239,248)	(230,387)
Total stockholders' equity	$ 138,029	$ 51,922

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