UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 13, 2025

CANDEL THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40629**	**52-2214851**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
117 Kendrick St., Suite 450 Needham, MA		**02494**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 916-5445

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	**CADL**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

The information contained in Item 8.01 of this Current Report on Form 8-K, to the extent required, is incorporated into this Item 2.02 by reference.

Item 7.01 Regulation FD Disclosure.

On January 13, 2025, Candel Therapeutics, Inc. (the "Company") issued a press release providing a corporate update, which highlighted the strong pipeline momentum from 2024 and upcoming key value drivers for 2025 and announced its unaudited cash position at December 31, 2024 of $102.9 million.

A copy of the full press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K are furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report on Form 8-K, regardless of any general incorporation language in any such filing.

Item 8.01 Other Events.

On January 13, 2025, the Company announced that its unaudited cash position at December 31, 2024 was $102.9 million. This amount is unaudited and preliminary and is subject to the completion of financial closing procedures. As a result, this amount may differ materially from the amount that will be reflected in the Company's financial statements as of and for the year ended December 31, 2024.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated January 13, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Candel Therapeutics, Inc.

Date: January 13, 2025

By: /s/ Paul Peter Tak
Paul Peter Tak, M.D., Ph.D., FMedSci
President and Chief Executive Officer

Exhibit 99.1

Candel Therapeutics Provides Corporate Update and Highlights Strong Pipeline Momentum and Key Value Drivers for 2025

- *On track to report updated overall survival data for CAN-2409 from phase 2a clinical trials in pancreatic ductal adenocarcinoma (PDAC) and non-small cell lung cancer (NSCLC), expected in Q1 2025*
- *Preparations for Biologics License Application (BLA) for CAN-2409 in prostate cancer underway, with submission expected in Q4 2026*
- *The Company intends to present phase 3 clinical trial data from CAN-2409 in prostate cancer at upcoming scientific conferences*
- *On track to report overall survival data in patients with recurrent high-grade glioma (rHGG) from ongoing phase 1b trial evaluating multiple doses of CAN-3110, expected in Q4 2025*
- *The Company expects that its cash and cash equivalents of approximately $103M (unaudited) as of December 31, 2024, will be sufficient to fund its current operating plan into Q1 of 2027*

NEEDHAM, Mass., January 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, today highlighted recent successes across the Company's viral immunotherapy portfolio and provided an update on the Company's cash position and upcoming 2025 milestones.

"I am incredibly proud of the Candel team for their successful execution of our 2024 priorities," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. "We demonstrated substantial clinical activity for our investigational medicines and delivered strong results across our pipeline, including positive and pivotal topline phase 3 data for CAN-2409 in intermediate-to-high risk localized prostate cancer, positive topline overall survival data from the phase 2a randomized controlled clinical trial of CAN-2409 in borderline resectable PDAC, as well as topline overall survival data from the open label phase 2a clinical trial of CAN-2409 in patients with stage III/IV NSCLC. We have also reported initial clinical and biomarker activity after repeated injection of CAN-3110 in the ongoing phase 1b clinical trial in rHGG and encouraging data demonstrating

CAN-3110's potential in a second indication, in a model of melanoma. In 2024, we also presented data on two novel experimental assets generated using Candel's enLIGHTEN™ Discovery Platform. During the 2024 American Association of Cancer Research (AACR) Annual Meeting, we reported preclinical data for the first-in-class, tertiary lymphoid structure (TLS) inducer viral immunotherapy, and during the 2024 International Oncolytic Virotherapy Conference (IOVC), we presented data on a multimodal immunotherapy that delivers interleukin-12 (IL-12) and interleukin-15 (IL-15) to the tumor microenvironment."

Dr. Tak continued, "We are entering 2025 with clear momentum. Our primary focus will be achieving BLA readiness for CAN-2409 in prostate cancer. If approved, we believe that CAN-2409 has the potential to become a first-line treatment, as an addition to radiation therapy to reduce the risk of recurrence of prostate cancer, and to redefine the current standard-of-care for prostate cancer patients. In the upcoming months we look forward to collaborating closely with the FDA to ensure alignment in preparation for our BLA submission which, if approved, would enable us to deliver this much-needed therapy to patients."

2024 Accomplishments

- *CAN-2409 – Prostate Cancer*
    - In December, the Company reported positive topline data from its multicenter phase 3 clinical trial evaluating CAN-2409 in intermediate-to-high-risk localized prostate cancer patients. The study met its primary endpoint by demonstrating statistically significant improvement in disease-free survival (DFS) in patients who received CAN-2409 plus valacyclovir (prodrug) combined with standard of care (SoC) external beam radiation therapy (n=496) compared to standard of care alone (n=249) in the intent to treat population.
    - The data showed a 30% reduction in the risk for prostate cancer recurrence or death due to any cause for the CAN-2409 treatment arm compared to placebo control arm (p=0.0155), and 80.4% pathological complete responses in 2-year post-treatment biopsies after CAN-2409 administration compared to 63.6% in the control arm (p=0.0015). The safety profile of CAN-2409 was generally consistent with previous studies, with no new safety signals identified.
    - This study was conducted under a Special Protocol Assessment (SPA) with U.S. Food and Drug Administration (FDA) agreement on key aspects of study design, meaning that safety and efficacy data generated from the study could be sufficient for the Company to seek regulatory approval for CAN-2409 in this indication.

- FDA previously granted Fast Track Designation for CAN-2409 for the treatment of prostate cancer.

- *CAN-2409 - Pancreatic Cancer*
  - In April 2024, the Company announced positive updated survival data, from the phase 2a randomized controlled clinical trial of CAN-2409 plus valacyclovir (prodrug), together with SoC chemoradiation, in borderline resectable PDAC (n=13). The 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, the survival rate was 71.4% in CAN-2409-treated patients versus 16.7% in the control group. At 36 months, estimated survival was 47.6% in the CAN-2409 group versus 16.7% in the control group.
  - FDA previously granted Fast Track Designation for CAN-2409 in borderline resectable PDAC.
  - FDA granted Orphan Drug Designation for CAN-2409 in borderline resectable PDAC in April 2024.
- *CAN-2409 – Non-Small Cell Lung Cancer*
  - At the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, the Company presented topline overall survival data from the phase 2a 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. The data (as of April 1, 2024) showed mOS of 20.6 months in patients with progressive disease (n=41) despite ICI treatment compared to published results of less than 12 months with SoC docetaxel-based chemotherapy in similar patient populations.
  - As of the data cut-off date, CAN-2409 treatment in NSCLC continued to exhibit a favorable safety and tolerability profile.
  - FDA previously granted Fast Track Designation for CAN-2409 for the treatment of NSCLC.
- *CAN-3110 – Recurrent High-Grade Glioma*
  - 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.
  - Presented updated clinical and biomarker activity data at the IOVC in October 2024. 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

- FDA granted Orphan Drug Designation for CAN-3110 for treatment of rHGG in May 2024.
- FDA granted Fast Track Designation for CAN-3110 for the treatment of rHGG in February 2024.

- *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 (SITC) 2024 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. The therapy was well-tolerated in preclinical mouse models based on body weight and histopathological analysis following intra-tumoral administration.
- *enLIGHTEN™ Discovery Platform*
  - Presented data on a new multimodal viral therapeutic candidate encoding IL-12 and IL-15 at the 2024 IOVC. 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 tumor regression in two different models.
  - Presented data at the AACR 2024 Annual Meeting describing a first-in-class, multimodal immunotherapy candidate for the induction of tertiary lymphoid structures, being developed as a novel therapeutic strategy for solid tumors. Delivery of two unique payload combinations, predicted in silico using the enLIGHTEN™ Advanced Analytics suite, was shown to induce TLS formation, inhibit tumor growth, and improve response to ICI therapy in preclinical models of cancer.

2025 Anticipated Milestones and Key Catalysts

- *CAN-2409 – Pancreatic Cancer*
  - Updated overall survival data from phase 2a clinical trial, expected in Q1 2025
  - Preparations underway for potential phase 2b, randomized clinical trial
- *CAN-2409 – Non-Small Cell Lung Cancer*
  - Updated overall survival data from phase 2a clinical trial, expected in Q1 2025

    - Preparations underway for potential phase 2b, randomized clinical trial
- *CAN-2409 – Prostate Cancer*
    - Presentation of the phase 3 clinical trial data at upcoming scientific conference
    - Publication of the phase 3 clinical trial data in a scientific journal
    - BLA submission on track for Q4 2026
- *CAN-3110 – Recurrent High-Grade Glioma*
    - Overall survival data from ongoing phase 1b clinical trial evaluating multiple doses, expected in Q4 2025

Cash Position

Cash and cash equivalents, as of December 31, 2024, were $102.9 million (unaudited), as compared to $35.4 million (audited) as of December 31, 2023. Based on current plans and assumptions, the Company expects that its existing cash and cash equivalents will support the preparation and submission of a BLA for CAN-2409 in prostate cancer, as well as fund its current operating plan into Q1 2027.

About CAN-2409

CAN-2409, 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 specific tumor and induce an individualized, systemic immune response against the tumor. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. 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 vaccination against a variety of tumor antigens. Because of its versatility, 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 other therapeutic strategies.

Currently, Candel is evaluating CAN-2409 in NSCLC, and borderline resectable PDAC, in ongoing clinical trials, and has recently completed phase 2b and phase 3 clinical trials in localized, non-metastatic prostate cancer. CAN-2409 plus prodrug (valacyclovir) has been granted Fast Track Designation by the FDA for the treatment of PDAC, stage III/IV NSCLC in patients who are resistant to first line PD-(L)1 inhibitor therapy and who do not have activating molecular driver mutations or have progressed on directed molecular therapy and localized primary prostate cancer. Candel's pivotal phase 3 clinical trial in

prostate cancer was conducted under a Special Protocol Assessment agreed with the FDA. The FDA has also granted Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

About CAN-3110

CAN-3110 is a first-in-class, replication-competent herpes simplex virus-1 (HSV-1) oncolytic viral immunotherapy candidate designed with 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.[1] The Company and academic collaborators are currently evaluating the effects of multiple 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 the enLIGHTEN™ Discovery Platform

The enLIGHTEN™ Discovery Platform is a systematic, iterative herpes simplex virus (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. In 2022, the Company announced a discovery partnership with the University of Pennsylvania Center for Cellular Immunotherapies to create new viral immunotherapies that could enhance the efficacy of chimeric antigen receptor T cell (CAR-T) therapy in solid tumors. During the SITC 2023 Annual Meeting and the 2023 IOVC meeting, Candel presented encouraging data on the first candidate from this platform, Alpha 201-macro-1, which was designed to interfere with the CD47/SIRP1α pathway, in mouse models of breast cancer and lung cancer. During the AACR Annual Meeting 2024, Candel presented preclinical data, unveiling the second candidate from the enLIGHTEN™ Discovery Platform, a first-in-class multimodal immunotherapy candidate to induce TLS, being developed as a novel therapeutic for solid tumors. Candel presented data at the 2024 IOVC meeting. The presentation focused on a multimodal viral therapeutic candidate encoding IL-12 and IL-15, the latest asset from the platform.

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 HSV gene constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform and is currently in ongoing clinical trials in NSCLC (phase 2) and borderline resectable PDAC (phase 2) and recently completed phase 2b and phase 3 clinical trials in localized, non-metastatic prostate cancer. 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 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 intermediate-to-high-risk localized prostate cancer, NSCLC, and pancreatic cancer and the ability of CAN-3110 to treat rHGG and melanoma; the ability of our enLIGHTEN™ 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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[1] Ling AL, et al. Nature. 2023;623(7985):157-166.