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): April 23, 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, Massachusetts**	**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 7.01 Regulation FD Disclosure.

On April 23, 2025, Candel Therapeutics, Inc. (the "Company") announced that an abstract was accepted for an oral presentation at the 2025 American Society of Clinical Oncology Annual Meeting taking place May 30 to June 3, 2025, in Chicago, IL. The oral presentation will feature data from the Company's phase 3 clinical trial of CAN-2409 in patients with intermediate-to-high risk localized prostate cancer.

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 shall not be deemed to be "filed" for the purpose 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated April 23, 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: April 23, 2025

By: /s/ Paul Peter Tak

Paul Peter Tak, M.D., Ph.D., FMedSci
President and Chief Executive Officer

Exhibit 99.1

Candel Therapeutics Announces Oral Presentation of Positive Phase 3 CAN-2409 Results in Localized Prostate Cancer at ASCO 2025

NEEDHAM, Mass., April 23, 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 announced that an abstract was accepted for an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting taking place May 30 to June 3, 2025, in Chicago, IL. The oral presentation will feature data from the Company's phase 3 clinical trial of CAN-2409 in patients with intermediate-to-high risk localized prostate cancer.

Details are as follows:

CAN-2409 – Localized Prostate Cancer

- **Abstract Title:** Phase 3, randomized, placebo-controlled clinical trial of CAN-2409+prodrug in combination with standard-of-care external beam radiation therapy (EBRT) for newly diagnosed localized prostate cancer
- **Presenter:** Theodore DeWeese, M.D. *, the Francis Watt Baker, M.D., and Lenox D. Baker Jr., M.D., Dean of the Medical Faculty and CEO, Johns Hopkins Medicine
- **Session Title:** Oral Abstract Session – Genitourinary Cancer – Prostate, Testicular, and Penile
- **Session Date/Time:** Tuesday, June 3, 2025; 9:45 AM - 12:45 PM CT
- **Location:** Hall A, McCormick Place Convention Center, Chicago, IL

Full abstracts will be released by ASCO on Thursday, May 22, 2025, at 5:00 PM ET. Details from the presentations will be available following the event on the Candel website at Candel Media.

* Dr. DeWeese has no relationship with Candel, other than serving as the national principal investigator for Candel's phase 3 clinical trial of CAN-2409 in patients with intermediate-to-high risk localized prostate cancer. He has never received reimbursements, consulting fees, or EAB fees from Candel, and he has no shares of common stock, options to purchase common stock or other stake in Candel.

About CAN-2409

CAN-2409, Candel's most advanced multimodal biological immunotherapy candidate, is an investigational, off-the-shelf, replication-defective adenovirus engineered 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 nucleotide analogue 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 immunization against a variety of the patient's own 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 (SoC) 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 reported to date, supporting the potential for combination with other therapeutic strategies.

Candel's clinical development program for CAN-2409 includes completed positive phase 2a clinical trials in both non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), as well as a positive pivotal randomized, placebo-controlled phase 3 clinical trial of CAN-2409 in localized, non-metastatic prostate cancer. In December 2024, Candel announced that CAN-2409 achieved its primary endpoint in this phase 3 clinical trial in men with intermediate-to-high-risk, localized prostate cancer, demonstrating statistically significant and clinically meaningful improvement in disease-free survival when added to SoC radiation therapy +/- androgen deprivation therapy.

In the Company's randomized controlled phase 2a clinical trial of CAN-2409 in borderline resectable PDAC, positive survival data showed notable improvement with an estimated median overall survival of 31.4 months after experimental treatment with CAN-2409 plus SoC versus 12.5 months in the control group in patients with PDAC who only received SoC. Median survival post-progression was 21.2 months in patients who received CAN-2409 compared to 6.4 months in the control arm. The final survival data from the phase 2a clinical trial of CAN-2409, in patients with stage III/IV NSCLC, showed an mOS of 24.5 months in 46 evaluable patients receiving 2 courses of CAN-2409 (per protocol

population; cohort 1 and 2) and 21.5 months in evaluable patients from cohort 2 (n=41) that had progressive disease at baseline, despite Immune Checkpoint Inhibitor treatment. CAN-2409 plus prodrug has been granted Fast Track Designation by the U.S. Food and Drug Administration (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 prostate cancer. The FDA has also granted Orphan Drug Designation to CAN-2409 for the treatment of PDAC. Candel's pivotal phase 3 clinical trial in newly diagnosed, localized prostate cancer was conducted under a Special Protocol Assessment agreed with the 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. CAN-2409 is the lead product candidate from the adenovirus platform. CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in recurrent high-grade glioma (rHGG). In October 2023, the Company announced that *Nature* published initial results from this ongoing clinical trial: CAN-3110 was well tolerated and the investigators observed nearly two-fold increase in median overall survival compared to historical controls after a single CAN-3110 injection in this therapy-resistant condition.[1] 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 early biological readouts as predictor of clinical response; and expectations regarding the therapeutic benefit of the Company's programs, including the ability of CAN-2409 to treat localized prostate cancer and improve disease-free survival, overall survival, and post-progression survival. 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 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 Annual Report on Form 10-K 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.