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): October 28, 2024

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 **(Address of Principal Executive Offices)**		**02494** **(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 October 28, 2024, Candel Therapeutics, Inc. (the "Company") issued a press release reporting safety and tolerability data arising from the multiple injection cohort of the ongoing phase 1b clinical trial of CAN-3110 in recurrent high-grade glioma (rHGG) and describing early clinical data and biomarker analysis from the first six patients enrolled in this cohort. The Company presented the data at the 2024 International Oncolytic Virotherapy Conference Annual Meeting on October 28, 2024.

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 October 28, 2024, the Company announced that in the multiple injection cohort of the Company's ongoing phase 1b clinical trial of CAN-3110 in rHGG, investigators observed ongoing improved survival compared to historical controls, with 3 out of 6 patients with rHGG still alive more than one year (12.2, 13.0, and 18.7 months, respectively) after initiation of experimental treatment with repeated CAN-3110 injections. The data also showed discrepancies between imaging and histologic findings, suggesting radiologic pseudo-progression: there was a near absence of tumor cells alongside dense lymphocyte infiltrates in biopsies obtained after CAN-3110 administration, especially in patients with enhancement on post-treatment MRI scans.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated October 28, 2024
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: October 28, 2024

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

Exhibit 99.1

Candel Therapeutics Showcases Innovative Cancer Therapy Candidates at 16th Annual International Oncolytic Virus Conference (IOVC)

NEEDHAM, Mass., October 28, 2024 – 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 three presentations at the 16th Annual International Oncolytic Virus Conference (IOVC), taking place October 27-30, 2024, in Rotterdam, the Netherlands.

The presentations will showcase Candel's advancements in innovative viral immunotherapies, including new data from the ongoing phase 1b clinical trial of CAN-3110 in recurrent high-grade glioma (rHGG), a presentation on a new multimodal immunotherapy candidate from the enLIGHTEN™ Discovery Platform, and a Company overview, focused on Candel's broad clinical and preclinical pipeline.

In detail:

E. Antonio Chiocca, MD, PhD, Professor of Neurosurgery at Harvard Medical School, and recently appointed Executive Director of the Center for Tumors of the Nervous System (CTNS) and co-chair of the Executive Committee for Mass General Brigham (MGB) Cancer Center, will deliver an oral presentation titled "Oncolytic immunoactivation clinical trial in rHGG: Preliminary safety and feasibility from longitudinal Injections." The presentation will review safety and tolerability data from the multiple injection cohort of the ongoing phase 1b clinical trial of CAN-3110 in rHGG and will describe early clinical data and biomarker analysis from the first six patients enrolled in this cohort. The investigators observed 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. The data also show discrepancies between imaging and histologic findings, suggesting radiologic pseudo-progression: there was a near absence of tumor cells alongside dense lymphocyte infiltrates in biopsies obtained after CAN-3110 administration, especially in patients with enhancement on post-treatment MRI scans.

Qiuchen Guo, PhD, Discovery Scientist at Candel Therapeutics, will present a poster titled "A first-in-class multimodal immunotherapy for enhanced immune activation in the tumor microenvironment as a novel therapeutic strategy for solid tumors." The presentation will focus

on the latest asset from the enLIGHTEN™ Discovery Platform, a multimodal viral therapeutic candidate encoding IL-12 and IL-15. Data will include 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 regression in two different models.

“Targeting IL-12 and IL-15 has been the focus of many therapeutic approaches. However, progress has been hindered by limited local target engagement and systemic toxicity,” said Anne R. Diers, PhD, Senior Director of Research at Candel Therapeutics. “Leveraging the biological activity of the Alpha-201 programmable vector, we have successfully delivered these cytokines to the tumor microenviroment, inducing tumor oncolysis and enhancing antigen presentation, resulting in profound antitumoral activity without added toxicity in these *in vivo* models”.

Francesca Barone, MD, PhD, Chief Science Officer at Candel Therapeutics, will present a corporate overview of the company, titled “Off-the-shelf therapy, individualized anti-tumor response: Reprogramming the immune system by viral immunotherapy for the treatment of solid tumors.” This comprehensive review of Candel's pipeline will include updates on clinical and preclinical programs with a focus on Candel’s lead experimental medicine, CAN-2409.

“The in-depth analysis of paired biopsy samples and MRIs obtained from patients undergoing multiple injections of CAN-3110 confirmed and extended the findings observed after a single injection of this agent,” said Francesca Barone, MD, PhD. “These recent data from our ongoing phase 1b clinical trial show the ability of CAN-3110 to trigger profound activation of the immune system and tumor clearance associated with improved survival in this therapy-resistant population.”

“The breadth of the data presented during the 16th Annual IOVC underscores the transformative potential of Candel’s therapeutic approach,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “These presentations reflect the progress that the company has made in designing new therapies and translating groundbreaking discoveries into potential clinical candidates. We are excited by the encouraging overall survival data after CAN-3110 experimental treatment in recurrent glioblastoma, which suggests a long tail of survival, as previously observed with immunotherapies in other solid tumors.”

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. Its activity is designed to be conditional to the expression of Nestin in cancer cells. 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 U.S. Food and Drug Administration (FDA) Fast Track Designation and Orphan Drug Designation for the treatment of rHGG.

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 without inordinate concern of overlapping adverse events.

Currently, Candel is evaluating CAN-2409 in non-small cell lung cancer (NSCLC), borderline resectable pancreatic ductal adenocarcinoma (PDAC), and localized, non-metastatic prostate cancer in ongoing clinical trials. 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 is being conducted under a Special Protocol Assessment with the FDA. The FDA has also granted Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

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 Society for Immunotherapy of Cancer (SITC) 2023 Annual Meeting and the 2023 International Oncolytic Virus Conference, 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 American Association for Cancer Research (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 tertiary lymphoid structures (TLS), being developed as a novel therapeutic for solid tumors.

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 and is currently in ongoing clinical trials in NSCLC (phase 2), borderline resectable PDAC (phase 2), and localized, non-metastatic prostate cancer (phase 2b and phase 3). CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing investigator-sponsored 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: http://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 the Company's programs to treat difficult-to-treat cancers; and expectations regarding the potential benefits conferred by orphan drug designation and fast track designation. 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.

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

Media Contact:
Ben Shannon
Vice President
ICR Westwicke
CandelPR@westwicke.com

Ling AL, et al. Nature. 2023;623(7985):157-166.