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 25, 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 April 25, 2024, Candel Therapeutics, Inc. (the "Company"), announced that it will present two poster presentations at the 2024 American Society of Clinical Oncology Annual Meeting taking place May 31 to June 4, 2024, in Chicago, IL. The first presentation will feature data from the ongoing phase 1 clinical trial of CAN-3110 in patients with recurrent high-grade glioma. The presentation will focus on patients recruited in cohort C, treated with multiple injections of CAN-3110 (up to six), demonstrating that this approach is both feasible and well tolerated. The second presentation will show topline overall survival data from the phase 2 clinical trial of CAN-2409 plus valacyclovir, in combination with continued immune checkpoint inhibitor treatment in patients with non-resectable, stage III/IV non-small cell lung cancer who have an inadequate response to front line anti-PD(L)1 therapy.

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 25, 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: April 25, 2024

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

Exhibit 99.1

Candel Therapeutics Announces Upcoming Presentations at the 2024 ASCO Annual Meeting

NEEDHAM, Mass., April 25, 2024 (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 two abstracts were accepted for presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting taking place May 31 to June 4, 2024, in Chicago, IL. The first presentation will feature data from the ongoing phase 1 clinical trial of CAN-3110 in patients with recurrent high-grade glioma. The presentation will focus on patients recruited in cohort C, treated with multiple injections of CAN-3110 (up to six), demonstrating that this approach is both feasible and well tolerated. The second presentation will show topline overall survival data from the phase 2 clinical trial of CAN-2409 plus valacyclovir, in combination with continued immune checkpoint inhibitor (ICI) treatment in patients with non-resectable, stage III/IV non-small cell lung cancer (NSCLC) who have an inadequate response to front line anti-PD(L)1 therapy.

Details are as follows:

CAN-3110 – Recurrent High-Grade Glioma

- **Trials-in-Progress Poster Presentation Title:** Longitudinal stereotactic injections of oncolytic immunoactivating rQNestin34.5v.2 (CAN-3110) with concomitant biopsies for “-omic” analyses in recurrent glioblastoma (GBM).
- **Presenter:** David A. Reardon, MD, Professor of Medicine at Harvard Medical School; Clinical Director, Center for Neuro-Oncology at Dana Farber Cancer Institute
- **Session Title:** Poster Session – Central Nervous System Tumors
- **Session Date/Time:** Saturday, June 1, 2024; 9:00 AM - 12:00 PM CT
- **Location:** Hall A, McCormick Place Convention Center, Chicago, IL

CAN-2409 – Non-Small Cell Lung Cancer

- **Poster Presentation Title:** Overall survival after treatment with CAN- 2409, plus valacyclovir in combination with continued ICI in patients with stage III/IV NSCLC with inadequate response to ICI.
- **Presenter:** Charu Aggarwal, MD, MPH, Associate Professor for Lung Cancer Excellence, Perelman School of Medicine, University of Pennsylvania
- **Session Title:** Poster Session – Lung Cancer – Non-Small Cell Metastatic
- **Session Date/Time:** Monday, June 3, 2024; 1:30 PM - 4:30 PM CT
- **Location:** Hall A, McCormick Place Convention Center, Chicago, IL

Full abstracts will be released by ASCO on Thursday, May 23, 2024, at 5:00 PM ET. Details from the presentations will be available following the events on the Candel website at https://www.candeltx.com/media/.

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 tumor and induce an individualized, systemic anti-tumor immune response. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells, resulting in the release of a wide variety of cancer antigens. At the same time, the adenoviral serotype 5 capsid protein has the potential to elicit a pro-inflammatory response in the tumor microenvironment. 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. As a result, CAN-2409 is an off-the-shelf drug candidate designed to result in an individualized anti-tumor immune response with the potential to treat a broad range of solid tumors. Encouraging monotherapy activity, as well as combination therapy activity with Standard of Care (SoC) radiotherapy, surgery, chemotherapy, and ICI, have previously been shown in several preclinical and clinical settings. Furthermore, to date, more than 1,000 patients have been dosed with CAN-2409 with a favorable tolerability profile supporting the potential for combination with other therapeutic strategies without inordinate concern of overlapping adverse events.

Currently, Candel is evaluating the effects of treatment with CAN-2409 in NSCLC, borderline resectable pancreatic ductal adenocarcinoma (PDAC), and localized, non-metastatic prostate cancer. CAN-2409 has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for 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 treatment of localized, primary prostate cancer in combination with radiotherapy to

improve the local control rate, decrease recurrence and improve disease-free survival. Candel's pivotal phase 3 clinical trial in prostate cancer is being conducted under a Special Protocol Assessment by 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. 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 recurrent HGG (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 and CAN-3110 plus prodrug was associated with improved survival. Positive HSV-1 serology was a predictor of response and was associated with improved survival. Increased infiltrating immune cells in the tumor microenvironment and expansion of the T cell repertoire after treatment were also associated with improved survival. In the clinical trial, the investigators observed a nearly doubling of the expected median overall survival after a single CAN-3110 injection compared to historical reports of less than 6 to 9 months in this therapy-resistant condition. By comparison, survival in the anti-HSV1 positive patients treated with CAN-3110 was more than 14 months. The Company and academic collaborators are currently evaluating the effects of multiple CAN-3110 injections in rHGG, supported by the Break Through Cancer Foundation.

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 development programs, including the timing and availability of additional data; and expectations regarding the therapeutic benefit of the Company's programs, 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 Annual Report on Form 10-K 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 of the hereof date and should not be relied upon as representing its views as of any subsequent date.

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