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 17, 2023

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 7.01 Regulation FD Disclosure.

On April 17, 2023, Candel Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has granted fast track designation for CAN-2409 + valacyclovir in combination with pembrolizumab in order to improve survival or delay progression in patients with Stage III (not candidates for curative intent) or Stage IV non-small cell lung cancer, 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.

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.

That 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, 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 17, 2023
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 thereunto duly authorized.

Candel Therapeutics, Inc.

Date: April 17, 2023

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

Candel Therapeutics Receives FDA Fast Track Designation for CAN-2409 in Non-Small Cell Lung Cancer

- *Fast track designation has the potential to facilitate the development and expedite the U.S. FDA review of CAN-2409 plus valacyclovir and anti-PD1 antibodies in patients with stage III/IV non-small cell lung cancer who are resistant to first line PD-(L)1 inhibitor therapy and who do not have molecular driver mutations*

NEEDHAM, Mass., April 17, 2023 (GLOBE NEWSWIRE) — Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing and commercializing viral immunotherapies to help patients fight cancer, today announced that the U.S. Food and Drug Administration (FDA) granted fast track designation for its lead asset CAN-2409, an investigational viral immunotherapy, plus valacyclovir in combination with pembrolizumab in order to improve survival or delay progression in patients with stage III/IV non-small cell lung cancer (NSCLC) 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. Fast track designation is a process designed to facilitate the development and expedite the review of medicines to treat serious conditions and fulfill an unmet medical need. An investigational medicine that receives fast track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, eligibility for accelerated approval and priority review.

"We are pleased with the FDA's decision to grant fast track designation for CAN-2409, which reinforces our belief that our investigational medicine has meaningful potential to treat those living with late-stage lung cancer," said Paul Peter Tak, MD, PhD, FMedSci, President and CEO of Candel. "Despite progress made in recent years, there remains a significant unmet need for patients with lung cancer who have an inadequate response to standard of care immune checkpoint inhibitors. Fast track designation is intended to bring promising medicines to patients sooner and the receipt of this designation by the FDA reinforces our belief that CAN-2409 has the potential to improve outcomes for patients who lack other treatment options."

CAN-2409 is an investigational viral immunotherapy designed to stimulate an individualized, systemic immune response to the patient's specific tumor. CAN-2409

plus valacyclovir in combination with continued PD-1/PD-L1 agents is being evaluated in an ongoing, open-label phase 2 clinical trial (NCT04495153) in patients with late-stage NSCLC.

During its R&D Day in December 2022, the Company reported data from 26 patients with NSCLC in its ongoing phase 2 clinical trial demonstrating evidence of local and systemic anti-tumor activity and showed a disease control rate of 77 percent (20/26) in patients entering the trial with disease progression despite previous immune checkpoint inhibitor treatment. Importantly, CAN-2409 demonstrated a favorable change in the trajectory of tumor growth in all patients for whom pre-enrollment scans were available as of October 21, 2022.

The Company expects to present updated clinical data from its phase 2 clinical trial in the third quarter of 2023.

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on developing and commercializing viral immunotherapies that elicit a systemic anti-tumor immune response to help patients fight cancer. Candel's engineered viruses are designed to induce immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens while creating a pro-inflammatory microenvironment at the site of injection. Candel has established two clinical stage viral 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 CAN-3110 is the lead product candidate from the HSV platform. 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.

About CAN-2409

CAN-2409, Candel's most advanced viral immunotherapy candidate, is a replication-defective adenovirus that is designed to deliver the herpes simplex virus thymidine kinase (HSV-tk) gene to cancer cells. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. The intra-tumoral administration results in the release of tumor-specific neoantigens in the microenvironment. At the same time, the adenoviral serotype 5 capsid protein elicits a strong pro-inflammatory signal in the tumor microenvironment. This is designed to create the optimal conditions to induce an individualized and specific CD8+ T cell mediated response against the injected tumor and uninjected distant metastases for broad anti-tumor activity. 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. Furthermore, more than 950 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 the effects of treatment with CAN-2409 in non-small cell lung cancer, pancreatic cancer, and localized, non-metastatic prostate cancer in ongoing clinical trials. The FDA granted fast track designation for CAN-2409 plus valacyclovir in combination with pembrolizumab in order to improve survival or delay progression in patients with stage III/IV non-small cell lung cancer 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.

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, include key data readout milestones; expectations regarding the therapeutic benefit of its programs; 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; 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, and strategic plans for the Company’s business and product candidates, and other risks identified in the Company’s SEC filings, 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 representing its views as of any subsequent date.

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