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): November 11, 2022

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 8.01 Other Events.

On November 11, 2022, Candel Therapeutics, Inc. announced the release of data from a phase 1 clinical trial of viral immunotherapy with CAN-2409 + valacyclovir in combination with nivolumab and standard of care in newly diagnosed high-grade glioma.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated November 11, 2022
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: November 14, 2022

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

Candel Therapeutics Announces Late-Breaking Oral Presentation at SITC Annual Meeting with Data on CAN-2409 in Combination with Nivolumab in a Phase 1 Mechanistic Clinical Trial in Patients with High-Grade Glioma

- *Combination of nivolumab and CAN-2409 delivered during neurosurgery was generally well tolerated with no significant added toxicity compared to standard of care*
- *Systemic immune activation was observed in peripheral blood following administration of CAN-2409/valacyclovir prior to nivolumab treatment*
- *Median overall survival (mOS) for patients with methylated MGMT promoter was 30.6 months for those undergoing gross total resection (GTR) and 12.6 months for those undergoing sub-total resection (STR). For patients with unmethylated MGMT promotor, mOS was 13.2 months and 15.9 months, respectively.*

NEEDHAM, Mass., November 11, 2022 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Nasdaq: CADL), a clinical stage biopharmaceutical company developing novel viral immunotherapies, today announced presentation of late-breaking data from a phase 1 mechanistic clinical trial of CAN-2409, Candel's lead viral immunotherapy in development, in combination with nivolumab and standard of care treatment in patients with high-grade glioma. Data were presented at the 37th Annual Meeting of Society for Immunotherapy of Cancer (SITC) today in Boston.

In the trial involving 35 evaluable patients, extensive biomarker analyses demonstrated that the combination of CAN-2409 and nivolumab resulted in a statistically significant expansion of activated tumor-fighting CD4+ and CD8+ T cells effector cells as well as decreased markers of exhaustion on effector cells. Proteomic analysis by OLINK revealed an increase in pro-inflammatory cytokines, including interferon-gamma, the chemokines CXCL9/10 and CXCL11, MCP-1, MCP-3, and granzyme A. Systemic immune activation was observed after the single administration of CAN-2409, prior to initiation of nivolumab (week 3 post treatment). Median overall survival (mOS) for patients with methylated MGMT promoter was 30.6 months for those who underwent gross total resection (GTR) (n=10) and 12.6 months for those who underwent

sub-total resection (STR) (n=5). mOS for patients with unmethylated MGMT was 13.2 months (GTR) (n=16) and 15.9 months (STR) (n=4), respectively.

“We are encouraged to see strong systemic immune activation after a single administration of CAN-2409 to the resection bed during neurosurgical removal of the tumor combined with nivolumab treatment in one of the most treatment-resistant cancers, high-grade glioma, which is characterized by a highly immunosuppressive microenvironment,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel Therapeutics. “The data support the potential therapeutic synergies between CAN-2409 in combination with immune checkpoint inhibitors across various solid tumors.”
Details on the oral presentation at SITC are as follows:
Oral Presentation Title: First efficacy and multi-omic analysis data from phase 1 clinical trial of oncolytic viral immunotherapy with CAN-2409 + valacyclovir in combination with nivolumab and standard of care in newly diagnosed high-grade glioma

- **Presenter:** Patrick Y. Wen, MD, Director, Cancer for Neuro-Oncology, Dana-Farber Cancer Institute; Professor, Neurology, Harvard Medical School; Principal Investigator for Candel Therapeutics
- **Abstract Session:** Late-Breaking 204
- **Session Date and Time:** Friday, November 11, 2022, at 11:25 am ET
- **Location:** Hall B2, Omni Boston Hotel, Boston, MA or Virtual

For more information on the clinical trial please visit: https://www.clinicaltrials.gov/ct2/show/NCT03576612?term=candel&draw=3

About CAN-2409

CAN-2409, Candel’s most advanced viral immunotherapy candidate, is a replication-defective adenovirus that delivers 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 creates the optimal conditions to induce a 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. 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, CAN-2409 presents a favorable tolerability profile; more than 950 patients have been dosed to date, supporting the potential for combination with other therapeutic strategies without inordinate concern of overlapping adverse events. Currently,

Candel is also 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.

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on helping patients fight cancer with viral immunotherapies. 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 viral immunotherapy platforms based on novel, genetically modified adenovirus and HSV 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 the first 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 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 Registration Statement on Form S-1, the Company's Quarterly Report on Form 10-Q filed on November 10, 2022, 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.

Media Contact
Cassidy McClain
Account Director
Evoke Canale
Cassidy.McClain@evokegroup.com
(619) 694-6291

Investor Contact
Sylvia Wheeler
Principal
Wheelhouse Life Science Advisors
swheeler@wheelhouselsa.com