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): December 6, 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 December 6, 2022, Candel Therapeutics, Inc. (the "Company"), hosted a virtual Research and Development (R&D) Day. The event provided an extensive overview of the Company's viral immunotherapy approach and oncology-focused pipeline, with new data presented from its phase 2 clinical trial of CAN-2409 in combination with anti-PD-1 agents in patients with stage III/IV non-small cell lung cancer, as well as an update on its phase 3 clinical trial of CAN-2409 in 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 December 6, 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: December 6, 2022

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

Candel Therapeutics R&D Day Presentations Spotlight its Advanced Pipeline and Capabilities to Develop Novel Viral Immunotherapies for Patients with Cancer

- *Updated data from the phase 2 clinical trial of CAN-2409 in non-small cell lung cancer showing disease control rate of 77 percent in patients entering the study with progressive disease, translating into preliminary evidence of improved progression-free survival*
- *Highlighted effects of a single injection of CAN-3110 in recurrent high-grade glioma (HGG) demonstrating a median overall survival (mOS) of 11.6 months*
- *Due to promising clinical activity, portfolio decision made to prioritize CAN-3110 in HGG and not to pursue phase 3 clinical trial of CAN-2409 in HGG*
- *Provided scientific rationale of partnership with University of Pennsylvania, leveraging Candel's enLIGHTEN™ Discovery Platform to create novel viral immunotherapies to enhance CAR-T cell therapies in solid tumors*
- *Candel's Research Advisory Board Members Drs. James P. Allison, Roy Herbst, and Padmanee Sharma shared their perspectives on the promise of viral immunotherapy for solid tumors*

NEEDHAM, Mass., December 6, 2022 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. ("Candel" or "the Company") (Nasdaq: CADL), a clinical stage biopharmaceutical company developing novel viral immunotherapies, today held its Research and Development Day to provide an extensive overview of the Company's unique viral immunotherapy platforms and to review updated clinical data from its oncology-focused pipeline.

"We are proud to present data and a growing body of evidence from our clinical stage pipeline," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. "The totality of clinical data demonstrates that CAN-2409 and CAN-3110 are active investigational viral immunotherapies with robust biomarker evidence of local and systemic immune responses. We look forward to advancing our product candidates through the next phase of clinical development towards registration and beyond to bring important treatment options to patients in need."

Candel provided updates on a broad range of its programs. Highlights included:

Phase 2 clinical trial of CAN-2409 in non-small cell lung cancer

- Robust evidence of local and systemic anti-tumor activity in patients with inadequate response to immune checkpoint inhibitors
  - Disease control rate of 77 percent (20/26) in patients entering trial with disease progression (cohort 2)
  - Sustained and ongoing clinical responses greater than 1 year
  - CAN-2409 favorably changed the trajectory of tumor progression
  - Decreased tumor size of RECIST target lesions in most patients
  - Reduced uninjected tumor size in 14/21 patients (67 percent)
  - Overall response rate of 13 percent (4/30) across cohorts 1 and 2
  - Durable disease stabilization translating into encouraging preliminary evidence of progression-free survival

- Consistent induction of local and systemic cytotoxic T cell response
  - Increased infiltration of CD8+ T cells in the tumor microenvironment
  - Systemic expansion of effector T cells and increase in soluble granzyme B levels in peripheral blood

- Favorable safety/tolerability profile
  - Only two administrations with relatively simple procedure
  - Most treatment-related adverse events were grade 1/2

- Next clinical data update expected in 2H 2023

Phase 1 clinical trial of CAN-3110 in recurrent HGG

- Treatment is well tolerated, with no dose limiting toxicity observed
- 11.6 month mOS in recurrent HGG with a single dose
- Evidence of persistent herpes simplex virus (HSV)-1 antigen and HSV-1 replication consistent with mechanism of action
- Robust evidence of immune activation
- Now evaluating the effects of multiple doses of CAN-3110 supported by Break Through Cancer foundation

Phase 1 clinical trial of CAN-2409 in combination with nivolumab in HGG

- Data suggest combination is well tolerated, with no dose-limiting toxicity and no added toxicity to standard of care (SoC)
- mOS in evaluable patients appeared comparable to historical SoC

- Biomarker analysis indicates the ability to activate a systemic immune response with a single administration of CAN-2409 in patients with HGG

Reaffirmed guidance of phase 2 and 3 clinical trials of CAN-2409 in prostate cancer

- Phase 3 clinical trial in localized intermediate/high-risk prostate cancer expected to read out in Q4 2024 (event-driven endpoint)
- Phase 2 clinical trial in active surveillance, localized prostate cancer expected to read out in Q4 2023 (event-driven endpoint)

enLIGHTEN Discovery Platform launched

- Novel discovery engine to generate viral immunotherapies by design
- Discovery partnership with University of Pennsylvania to explore the effects of investigational viral immunotherapy in combination with CAR-T cells in solid tumor models
- Data-driven, human-based, novel platform enabling future discovery partnerships

Corporate highlights

- Diverse pipeline of viral immunotherapies with proof of concept in multiple difficult-to-treat solid tumors
- Strong scientific support from high-profile Research Advisory Board
- Cash and cash equivalents of $77.2M as of September 30, 2022 with runway into Q1 2024

The recorded webcast is accessible under “Events and Presentations” on the Investors page of the Company’s website at https://ir.candeltx.com/news-and-events/events-and-presentations or by clicking here. A replay of the event will be available for up to a year.

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 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.

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