# 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 18, 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 18, 2022, Candel Therapeutics, Inc., announced the release of data from a phase 1 clinical trial evaluating a herpes simplex virus replication-competent viral immunotherapy, CAN-3110, in patients with recurrent 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 18, 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 18, 2022

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

# Candel Therapeutics Announces Oral Presentation of Updated Data from its Phase 1 Clinical Trial of CAN-3110 in 41 Patients with Recurrent High-Grade Glioma at the Society for Neuro-Oncology 27th Annual Meeting

- *CAN-3110 designed to limit replication and promote anti-tumor response to tumor cells while protecting healthy tissue*
- *No dose-limiting toxicities observed in 41 patients with recurrent high-grade glioma (rHGG)*
- *Median overall survival was 11.6 months after a single injection of CAN-3110 in patients with rHGG; one patient achieved a complete response lasting more than one year*
- *CAN-3110 observed to activate lymphocyte-depleted tumor microenvironment in rHGG, with changes in T cell receptor repertoire associated with survival*

**NEEDHAM, Mass., November 18, 2022 (GLOBE NEWSWIRE) --** Candel Therapeutics, Inc. (“Candel” or “the Company”) (Nasdaq: CADL), a clinical stage biopharmaceutical company developing novel viral immunotherapies, today announced presentation of updated data from a phase 1 clinical trial of CAN-3110 in patients with recurrent high-grade glioma (rHGG). An overview of this data will be presented in-person at the Society for Neuro-Oncology (SNO) 27th Annual Meeting (SNO) today starting at 5:30 pm ET in Tampa, Florida.

Data will be reported from 41 patients who were administered CAN-3110, with 40 patients having received a single injection and one patient having received two injections. There were no dose-limiting toxicities. The median overall survival was 11.6 months. In-depth biomarker analyses show a statistically significant expansion of activated CD4+ and CD8+ T cells effector cells in multiple tumor lesions following a single injection of CAN-3110. Diversity of the T cell receptor repertoire after CAN-3110 administration was reported to be associated with overall survival. Next, the Company will examine whether multiple injections of CAN-3110 over time could lead to further improvement in overall survival (NCT03152318, clinicaltrials.gov).
“Patients with high-grade glioma whose cancer has recurred following initial standard of care treatments face a daunting challenge, with most succumbing to their disease within months due to a lack of effective therapies,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel Therapeutics. “We believe CAN-3110 is the first HSV-based viral

immunotherapy candidate designed to leverage the ICP34.5 gene, which plays a key role in the viral anti-host response. The absence of observed dose-limiting toxicities in 41 patients and a median overall survival rate of one year provides clinical validation for this unique construct. This trial has clearly shown that a single injection of CAN-3110 can convert the highly immunosuppressive tumor microenvironment in recurrent high-grade glioma into a 'hot' tumor. We are now determining if multiple injections of CAN-3110 can fundamentally transform this universally fatal brain cancer."

CAN-3110 is unique in that it is designed to express a copy of the viral ICP34.5 gene, which is critical for viral replication and anti-host responses, under the transcriptional control of the tumor specific Nestin promoter. This approach is intended to restrict viral replication and virulence to the tumor cells, protecting healthy tissues while maintaining its anti-tumor responses.

Details on the presentation at SNO are as follows:

**Oral Presentation Title:** Enriched TCR/BCR VDJ rearrangements correlate with MRI and survival outcomes in patients with recurrent high-grade glioma treated with CAN-3110

- **Presenter:** Alexander Ling, PhD, Postdoctoral Research Fellow, Brigham and Women's Hospital Investigator for Candel Therapeutics
- **Abstract Session:** Clinical Trials I
- **Session Date and Time:** Friday, November 18, 2022, from 5:30 pm – 5:35 pm ET
- **Location:** Ballroom B, Tampa Convention Center, Tampa, FL

For more information on the clinical trial please visit: https://clinicaltrials.gov/ct2/show/NCT03152318

**About CAN-3110**

CAN-3110 is a herpes simplex virus (HSV) replication-competent viral immunotherapy candidate engineered to enhance selective killing of malignant cells while sparing healthy normal neighboring cells. CAN-3110 has been shown to selectively express ICP34.5, a key gene in HSV replication, in tumor cells that overexpress Nestin, a cytoskeletal protein. Nestin is highly expressed in glioma cells and other tumor tissue, but is absent in the healthy adult brain. The effects of multiple doses of CAN-3110 in recurrent glioblastoma are currently being evaluated in an ongoing phase 1 clinical trial.

**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.

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