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): February 25, 2025

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 February 25, 2025, Candel Therapeutics, Inc. (the "Company") issued a press release announcing positive final overall survival data from its randomized controlled phase 2 clinical trial of CAN-2409 in non-metastatic pancreatic cancer.

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 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 on Form 8-K, regardless of any general incorporation language in any such filing.

Item 8.01 Other Events.

On February 25, 2025, the Company announced positive final overall survival data from its randomized controlled phase 2 clinical trial of CAN-2409 in non-metastatic pancreatic cancer (as of a February 20, 2025 data cut-off):

- Prolonged and sustained survival was observed in this randomized controlled clinical trial after experimental treatment with CAN-2409 compared to the control group in patients with borderline resectable pancreatic ductal adenocarcinoma ("PDAC")
  - Estimated median overall survival after enrollment was 31.4 months in the CAN-2409 group (n=7) versus only 12.5 months in the control group (n=6).
  - Median survival post-progression was 21.2 months in patients who received CAN-2409 compared to 7.2 months in the control arm.
  - Importantly, three out of seven patients who received CAN-2409 were still alive at the time of data cut-off with a survival of 66.0, 63.6, and 35.8 months, respectively, after enrollment; survival from the time of diagnosis for these patients was 73.5, 68.8, and 41.3 months, respectively. Of these, the first patient had stage IV metastatic disease detected during surgery, the second had residual tumor present at the resection margin, and the third had adenocarcinoma with negative resection margins. In contrast, only one out of six patients randomized to standard of care ("SoC") chemotherapy arm remained alive at the data cut-off (61.2 months from enrollment and 65.5 months from diagnosis); histologic analysis at resection showed intraepithelial neoplasia (without evidence of residual invasive adenocarcinoma) in this patient, which is associated with improved prognosis.
  - Previous analysis at 24 months showed survival rates of 71.4% in patients treated with CAN-2409 compared to 16.7% in the control group.
- Previous analysis of blood and resected tumors showed consistent and robust activation of the immune response after experimental treatment with CAN-2409
  - In pancreatic tissue of patients treated with CAN-2409 plus prodrug, together with SoC (but not SoC alone), dense aggregates of CD8+ granzyme B+ cytotoxic tumor infiltrating lymphocytes, dendritic cells, and B cells were observed in the tumor microenvironment.
  - Increased levels of soluble granzymes B and H, along with pro-inflammatory cytokines, including IFN-γ, were detected in peripheral blood following CAN-2409 treatment, but not in the control arm, supporting CAN-2409's ability to drive a potent systemic anti-tumoral immune response.
- CAN-2409 continued to be associated with a favorable safety/tolerability profile
  - The addition of CAN-2409 regimen to SoC was generally well-tolerated, with no dose-limiting toxicities, including no cases of pancreatitis.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated February 25, 2025
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: February 25, 2025

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

Exhibit 99.1

Candel Therapeutics Announces Positive Final Survival Data from Randomized Controlled Phase 2 Clinical Trial of CAN-2409 in Non-Metastatic Pancreatic Cancer

- *Positive final survival data after additional follow-up showed notable improvement in estimated median overall survival of 31.4 months after experimental treatment with CAN-2409 versus only 12.5 months in the control group in patients with borderline resectable pancreatic ductal adenocarcinoma (PDAC).*
- *Three of seven patients treated with CAN-2409 were still alive with survival of 66.0, 63.6 and 35.8 months after enrollment, respectively. Survival from the time of diagnosis for these patients was 73.5, 68.8, and 41.3 months, respectively. Survival observed in these patients is well beyond the expected median overall survival for pancreatic cancer with standard of care, suggesting a long tail of survival.*
- *CAN-2409 safety profile was generally favorable in the phase 2 trial, further supporting the favorable safety profile to date associated with this investigational therapy across multiple indications.*
- *CAN-2409 previously received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of PDAC.*

NEEDHAM, Mass., February 25, 2025 (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 final overall survival data from the completed randomized controlled phase 2 clinical trial of CAN-2409 plus valacyclovir (prodrug), together with standard of care (SoC) chemoradiation, followed by resection, in patients with borderline resectable PDAC.

Final data of the randomized controlled clinical trial, updated with an additional nine months of follow-up, confirmed a durable improvement in survival for patients treated with CAN-2409 plus SoC therapy (n=7) compared to SoC alone (n=6). Notably, long-term survivors in the CAN-2409 arm, remaining alive at 66.0, 63.6, and 35.8-months post-enrollment experienced disease recurrence but, in contrast to patients in the control arm

with disease recurrence, responded to salvage chemotherapy and have experienced extended and ongoing post-progression survival at the time of the data cutoff (February 20, 2025), further highlighting the sustained benefit of CAN-2409 in this aggressive disease setting.

“Pancreatic cancer remains one of the most difficult to treat diseases,” said W. Garrett Nichols, MD, MS, Candel’s Chief Medical Officer. “Patients with borderline resectable PDAC often have undetectable metastases that are not cleared with current standard of care neoadjuvant chemoradiation and surgery. CAN-2409 is a first-in-class multimodal immunotherapy candidate designed for in situ vaccination against the patient’s tumor, which offers the potential to control this disease and to prolong survival, thus improving outcomes following this dismal prognosis.”

Data highlights:

- Prolonged and sustained survival was observed in this randomized controlled clinical trial after experimental treatment with CAN-2409 compared to the control group in patients with borderline resectable PDAC
    - Estimated median overall survival after enrollment was 31.4 months in the CAN-2409 group (n=7) versus only 12.5 months in the control group (n=6).
    - Median survival post-progression was 21.2 months in patients who received CAN-2409 compared to 7.2 months in the control arm.
    - Importantly, three out of seven patients who received CAN-2409 were still alive at the time of data cut-off with a survival of 66.0, 63.6, and 35.8 months, respectively, after enrollment; survival from the time of diagnosis for these patients was 73.5, 68.8, and 41.3 months, respectively. Of these, the first patient had stage IV metastatic disease detected during surgery, the second had residual tumor present at the resection margin, and the third had adenocarcinoma with negative resection margins. In contrast, only one out of six patients randomized to SoC chemotherapy arm remained alive at the data cut-off (61.2 months from enrollment and 65.5 months from diagnosis); histologic analysis at resection showed intraepithelial neoplasia (without evidence of residual invasive adenocarcinoma) in this patient, which is associated with improved prognosis.
    - Previous analysis at 24 months showed survival rates of 71.4% in patients treated with CAN-2409 compared to 16.7% in the control group.
- Previous analysis of blood and resected tumors showed consistent and robust activation of the immune response after experimental treatment with CAN-2409

- In pancreatic tissue of patients treated with CAN-2409 plus prodrug, together with SoC (but not SoC alone), dense aggregates of CD8+ granzyme B+ cytotoxic tumor infiltrating lymphocytes, dendritic cells, and B cells were observed in the tumor microenvironment.

- Increased levels of soluble granzymes B and H, along with pro-inflammatory cytokines, including IFN-γ, were detected in peripheral blood following CAN-2409 treatment, but not in the control arm, supporting CAN-2409's ability to drive a potent systemic anti-tumoral immune response.

- CAN-2409 continued to be associated with a favorable safety/tolerability profile

  - The addition of CAN-2409 regimen to SoC was generally well-tolerated, with no dose-limiting toxicities, including no cases of pancreatitis.

"The notable benefits observed with CAN-2409 in this clinical trial, including evidence of a long tail of survival, highlights the transformative potential of this biological multimodal immunotherapy in difficult to treat cancers", said Paul Peter Tak, MD, PhD, FMedSci, CEO and President of Candel. "Recently, the Company announced positive, statistically significant topline data for CAN-2409 based on a large, randomized, placebo-controlled clinical trial in localized prostate cancer. The data presented today support the potential of CAN-2409 across various solid tumors, by showing its potential to alter the balance between the pancreatic tumor and the anti-tumor immune response, even in patients with residual tumor, improving long-term survival in a subset of the patients. Based on these promising findings, the Company has decided to prepare for a larger, late-stage randomized controlled clinical trial of CAN-2409 in PDAC."

The FDA previously granted Fast Track Designation and Orphan Drug Designation to the Company for CAN-2409 in combination with valacyclovir for the treatment of patients with PDAC.

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 specific tumor and induce an individualized, systemic immune response against the tumor. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. 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. 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. More than 1,000 patients have been dosed with CAN-2409 with a favorable tolerability profile to date, supporting the potential for combination with other therapeutic strategies.

Currently, Candel is evaluating CAN-2409 in non-small cell lung cancer (NSCLC), PDAC, and localized, non-metastatic prostate cancer. In December 2024, Candel announced that CAN-2409 achieved its primary endpoint in a pivotal phase 3 clinical trial in men with intermediate-to-high-risk, localized prostate cancer, demonstrating statistically significant improvement in disease-free survival when added to SoC radiation therapy +/- androgen deprivation therapy. CAN-2409 plus prodrug has been granted Fast Track Designation by the FDA for the 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 localized prostate cancer. The FDA has also granted Orphan Drug Designation to CAN-2409 for the treatment of PDAC. Candel's pivotal phase 3 clinical trial in localized prostate cancer was conducted under a Special Protocol Assessment (SPA) agreed with the FDA.

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on developing off-the-shelf multimodal biological immunotherapies that elicit an individualized, systemic anti-tumor immune response to help patients fight cancer. Candel has established two clinical stage multimodal biological immunotherapy platforms based on novel, genetically modified adenovirus and HSV gene constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform. CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in recurrent high-grade glioma (rHGG). Finally, 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

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 current and future development programs; expectations regarding early biological readouts as predictor of clinical response; and expectations regarding the therapeutic benefit of the Company’s programs, including the ability of CAN-2409 to treat a broad range of solid tumors and improve disease-free survival, overall survival, and post-progression survival. 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; 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 Quarterly Report on Form 10-Q 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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