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 4, 2024

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 4, 2024, Candel Therapeutics, Inc. (the "Company") issued a press release announcing positive interim data from its randomized 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 April 4, 2024, the Company announced positive interim data from its randomized phase 2 clinical trial of CAN-2409 in non-metastatic pancreatic cancer (as of a March 29, 2024 data cut-off):

- Prolonged and sustained survival was observed after experimental treatment with CAN-2409 in patients with borderline resectable pancreatic ductal adenocarcinoma ("PDAC") (n=13)
  - Estimated median overall survival was 28.8 months in the CAN-2409 group versus only 12.5 months in the control group.
  - At 24 months, a survival rate of 71.4% was observed in CAN-2409 treated patients, after standard of care ("SoC") chemoradiation and prior to surgery, versus only 16.7% in the control group. At 36 months, a survival rate of 47.6% was estimated in patients who received CAN-2409, together with SoC chemoradiation prior to surgery, versus only 16.7% in the control group.
  - Importantly, 4 out of 7 patients who received CAN-2409 were still alive at the time of data cut-off, with 2 patients surviving more than 50.0 months from enrollment. Only 1 out of 6 patients, randomized to control SoC chemotherapy, remained alive at data cut-off (alive at 50.6 months).
- 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 positive cytotoxic tumor infiltrating lymphocytes, dendritic cells, and B cells were observed in the tumor microenvironment.
  - Increased levels of soluble granzymes B and H, as well as pro-inflammatory cytokines, including IFN-γ, were observed in peripheral blood after CAN-2409 administration, but not after SoC.
- CAN-2409 continued to be associated with a favorable safety/tolerability profile
  - 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 April 4, 2024
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: April 4, 2024

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 Interim Data from Randomized Phase 2 Clinical Trial of CAN-2409 in Non-Metastatic Pancreatic Cancer

- *Updated positive interim data showed notable improvements in estimated median overall survival of 28.8 months after experimental treatment with CAN-2409 versus only 12.5 months in control group in borderline resectable pancreatic ductal adenorcarcinoma (PDAC)*
- *At 24 months, survival rate was 71.4% in CAN-2409 treated patients versus only 16.7% in the control group after chemoradiation. At 36 months, estimated survival was 47.6% in the CAN-2409 group versus 16.7% in the control group*
- *No new safety signals were observed, providing further support that multiple injections of CAN-2409 were generally well tolerated, with no dose-limiting toxicities and no cases of pancreatitis*
- *Previous analysis of resected tumors showed dense aggregates of immune cells, including CD8+, cytotoxic tumor infiltrating lymphocytes, and dendritic cells, in PDAC tissue after CAN-2409 administration, confirming activation of a robust antitumoral immune response*

NEEDHAM, Mass., April 4, 2024 (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 updated interim survival data from the ongoing randomized phase 2 clinical trial of CAN-2409 plus valacyclovir (prodrug), together with standard of care (SoC) chemoradiation, followed by resection for borderline resectable pancreatic ductal adenocarcinoma (PDAC). Survival data were updated with eight months of further follow-up since the first analysis presented at the 2023 Society for Immunotherapy (SITC) Annual Meeting. Based on the data presented at SITC, the U.S. Food and Drug

Administration (FDA) granted Fast Track Designation to the Company for CAN-2409 in combination with valacyclovir for the treatment of patients with PDAC in December 2023.

“Given frequent recurrence and short survival with SoC chemotherapy for non-metastatic PDAC, effective new treatment options are urgently needed,” said Garrett Nichols, MD, MS, Chief Medical Officer of Candel. “We are very encouraged by the improved survival associated with CAN-2409, which has been shown to be durable after prolonged follow-up based on the updated data shown in this randomized clinical trial. CAN-2409 was generally well tolerated without significant additional local or systemic toxicity when added to SoC chemoradiation.”

Data Highlights as of a March 29, 2024 Data Cut-off, Include:

- Prolonged and sustained survival was observed after experimental treatment with CAN-2409 in patients with borderline resectable PDAC (n=13)
    - Estimated median overall survival was 28.8 months in the CAN-2409 group versus only 12.5 months in the control group.
    - At 24 months, a survival rate of 71.4% was observed in CAN-2409 treated patients, after SoC chemoradiation and prior to surgery, versus only 16.7% in the control group. At 36 months, a survival rate of 47.6% was estimated in patients who received CAN-2409, together with SoC chemoradiation prior to surgery, versus only 16.7% in the control group.
    - Importantly, 4 out of 7 patients who received CAN-2409 were still alive at the time of data cut-off, with 2 patients surviving more than 50.0 months from enrollment. Only 1 out of 6 patients, randomized to control SoC chemotherapy, remained alive at data cut-off (alive at 50.6 months).
- 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 positive cytotoxic tumor infiltrating lymphocytes, dendritic cells, and B cells were observed in the tumor microenvironment.
    - Increased levels of soluble granzymes B and H, as well as pro-inflammatory cytokines, including IFN-γ, were observed in peripheral blood after CAN-2409 administration, but not after SoC.
- CAN-2409 continued to be associated with a favorable safety/tolerability profile

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

“The failure of conventional immunotherapy to improve outcomes in pancreatic cancer is attributed to the highly immunosuppressive tumor microenvironment, which is largely devoid of immune cells,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “The immunological changes induced by CAN-2409, evident in the pancreatic tissue and the peripheral blood after administration, suggest that CAN-2409 is able to change the balance between the tumor and the patient’s anti-tumor immune response, which can convert progressive cancer into a chronic disease associated with improved survival.”

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 herpes simplex virus (HSV) gene constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform and is currently in ongoing clinical trials in non-small cell lung cancer (NSCLC) (phase 2), borderline resectable PDAC (phase 2), and localized, non-metastatic prostate cancer (phase 2 and phase 3). CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing investigator-sponsored phase 1 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

About the Phase 2 Clinical Trial of CAN-2409 in Non-Metastatic Pancreatic Cancer

This randomized, open-label phase 2 clinical trial is designed to evaluate the safety, preliminary efficacy, and biologic activity of a 2-3 injection regimen of CAN-2409 plus prodrug (valacyclovir or acyclovir) in patients with borderline resectable PDAC who are being treated with neoadjuvant chemoradiation prior to resection. After a protocol amendment in 2022, when enrollment of patients with locally advanced PDAC was discontinued, the clinical trial was designed to exclusively focused on borderline resectable disease. The clinical trial remains active but is not currently unrolling new patients. In a previously completed phase 1b clinical trial, a highly significant increase in the number of CD8+ tumor infiltration lymphocytes was demonstrated at the site of the tumor after CAN-2409 treatment.

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 disease. 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. Furthermore, to date, 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 without inordinate concern of overlapping adverse events.

Currently, Candel is evaluating the effects of treatment with CAN-2409 in NSCLC, borderline resectable PDAC, and localized, non-metastatic prostate cancer in ongoing clinical trials. CAN-2409, plus prodrug (valacyclovir), has been granted Fast Track Designation by the FDA for treatment of PDAC or 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. The Company's pivotal phase 3 clinical trial in prostate cancer is being conducted under a Special Protocol Assessment by FDA.

About Pancreatic Ductal Adenocarcinoma (PDAC)

Pancreatic cancer is a highly lethal malignancy, and is the fourth leading cause of cancer-related death in the United States among both men and women. Based on the National Cancer Institute, Surveillance, Epidemiology and End Results (SEER) database, pancreatic cancer is expected to account for 3.3% of all new cancer cases with an estimated 64,050 new cases and estimated 50,550 deaths in 2023. Effective therapeutics for pancreatic cancer, including PDAC, which accounts for 90% of all pancreatic carcinomas, are urgently needed.

Surgical resection offers the only chance of cure, thus a major therapeutic goal for subjects with non-metastatic disease is to achieve complete tumor resection. Surgical treatment (pancreaticoduodenectomy, also known as the Whipple procedure) or total or distal pancreatectomy (depending on tumor location) is generally the recommended treatment for patients diagnosed with resectable cancer; the addition of adjuvant chemotherapy has been shown to only slightly improve survival rates (20 to 23 months).[2] To this end, there has been increasing use of neoadjuvant chemotherapy and chemoradiation regimens for subjects with borderline resectable pancreatic ductal adenocarcinoma. Neoadjuvant regimens are intended to debulk the tumor, thereby increasing the proportion of patients who may become eligible for surgical resection and achieve complete resection (i.e., resection with negative margins, designated 'R0

resection'). Unfortunately, even when an R0 resection is initially achieved, cures remain elusive as most patients experience disease recurrence due to residual micrometastatic disease. In a recent meta-analysis of 20 studies representing 283 patients with borderline resectable PDAC, neoadjuvant FOLFIRINOX with or without radiotherapy, median overall survival was only 22.2 months (95% CI, 18.8 to 25.6 months).

Immunotherapy with PD-1 antibodies with or without CTLA-4 antibodies has been uniformly unsuccessful in patients with PDAC due to the dense stroma that surrounds PDAC tissue and the absence of tumor infiltrating lymphocytes.

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, including the timing and availability of additional data, key data readout milestones, and expectations regarding the therapeutic benefit of the Company's programs, including the potential for its programs to extend patient 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; the Company's ability to continue as a going concern; expectations regarding the therapeutics 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 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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