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): May 14, 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 2.02 Results of Operations and Financial Condition.

On May 14, 2024, Candel Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2024. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is furnished herewith and shall not be deemed "filed" for 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated May 14, 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: May 14, 2024

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

Exhibit 99.1

Candel Therapeutics Reports First Quarter 2024 Financial Results and Recent Corporate Highlights

- *Announced positive survival data from ongoing randomized phase 2 clinical trial of CAN-2409 in borderline resectable pancreatic cancer*
- *Phase 2 topline overall survival data for CAN-2409 in non-small cell lung cancer (NSCLC), to be presented at ASCO on June 3, 2024*
- *On track for topline disease-free survival data from CAN-2409 phase 3 clinical trial in localized intermediate/high risk prostate cancer, expected in Q4 2024*

NEEDHAM, Mass., May 14, 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 reported financial results for the first quarter ended March 31, 2024, and provided a corporate update.

“It was a catalyst-rich first quarter for Candel, marked by significant advances across both our clinical and preclinical programs,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “Notably, as our clinical data mature with long-term follow up, we are beginning to observe highly differentiated results in long-term survival of patients treated with our viral immunotherapies. An example of these clinical results was recently shared in an update of the phase 2 randomized clinical trial of CAN-2409 in patients with borderline resectable pancreatic cancer, where a notable improvement in overall survival, in patients treated with CAN-2409 plus standard of care chemoradiation, was demonstrated compared to chemoradiation alone. The FDA granted CAN-2409 both Fast Track Designation and Orphan Drug Designation for treatment of patients with pancreatic ductal adenocarcinoma to improve median overall survival and treatment of pancreatic cancer, respectively, providing steady momentum to advance this promising investigational treatment for patients with significant unmet medical need.”

Dr. Tak continued, “We are also excited to announce that topline overall survival data from our phase 2 clinical trial of CAN-2409 in patients with stage III/IV non-small cell lung cancer and an inadequate response to immune checkpoint inhibitors will be presented at the upcoming ASCO meeting in Chicago on Monday, June 3, 2024.”

“In addition to our advances in the clinic, we have made great progress with our enLIGHTEN™ Discovery Platform. In April 2024, we presented our second drug

candidate from this platform, a first-in-class multimodal immunotherapy candidate for induction of tertiary lymphoid structures, in a late-breaking presentation at the American Association for Cancer Research (AACR) Annual Meeting. We believe this preclinical candidate offers groundbreaking potential in the treatment of cancer," continued Dr. Tak. "We expect to release additional preclinical and clinical data in the coming year, consistent with our commitment to innovation and patient care."

First Quarter 2024 & Recent Highlights

- Program Updates
  - *CAN-2409 – Pancreatic Cancer*
    - In early April, announced positive updated 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).
      - Data showed notable improvements in estimated median overall survival (mOS) of 28.8 months after experimental treatment with CAN-2409 versus 12.5 months in control group.
      - At 24 months, survival rate was 71.4% in CAN-2409 treated patients versus 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 have been generally well tolerated to date, with no dose-limiting toxicities and no cases of pancreatitis reported.
      - 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.
    - Received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for CAN-2409 for the treatment of pancreatic cancer.
  - *CAN-2409 – Non-small cell lung cancer (NSCLC)*

- Announced a poster titled “Overall survival after treatment with CAN- 2409 plus valacyclovir in combination with continued ICI in patients with stage III/IV NSCLC with inadequate response to ICI” was accepted for the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, and will be presented by Charu Aggarwal, MD, MPH, Associate Professor for Lung Cancer Excellence, Perelman School of Medicine, University of Pennsylvania, on June 3, 2024 in Chicago, IL.

- *CAN-3110 – Recurrent High-Grade Glioma (rHGG)*

  - Received Fast Track Designation from the FDA for CAN-3110 for the treatment of patients with rHGG to improve OS.

  - Announced during the 5th Glioblastoma Drug Development Summit in Boston that six patients have been treated with multiple injections (up to six injections) of CAN-3110 in cohort C of the ongoing phase 1b clinical trial, reporting a favorable safety and tolerability profile.

  - Announced a Trial-in-Progress poster, titled “Longitudinal stereotactic injections of oncolytic immunoactivating rQNestin34.5v.2 (CAN-3110) with concomitant biopsies for “-omic” analyses in recurrent glioblastoma (GBM)” was accepted for the 2024 ASCO Annual Meeting, and will be presented by David A. Reardon, MD, Professor of Medicine at Harvard Medical School and Clinical Director, Center for Neuro-Oncology at Dana Farber Cancer Institute, on June 1, 2024, in Chicago, IL.

- *enLIGHTEN™ Discovery Platform*

  - Presented preclinical data at the AACR Annual Meeting unveiling the second candidate from the enLIGHTEN™ Discovery Platform, a first-in-class multimodal immunotherapy candidate to induce tertiary lymphoid structures (TLS), being developed as a novel therapeutic for solid tumors.

Anticipated Milestones

- Phase 2 topline OS data for CAN-2409 in NSCLC to be presented at ASCO on June 3, 2024
- Updated Phase 1b data (Arm C) for CAN-3110 in rHGG expected in H2 2024
- Phase 2 topline data for CAN-2409 in *low-to-intermediate-risk*, localized, non-metastatic prostate cancer expected in Q4 2024
- Phase 3 topline disease-free survival data for CAN-2409 in localized *intermediate/high-risk* prostate cancer expected in Q4 2024

Financial Results for First Quarter Ended March 31, 2024

Research and Development Expenses: Research and development expenses were $4.1 million for the first quarter of 2024 compared to $5.5 million for the first quarter of 2023. The decrease was primarily due to lower employee-related expenses following the corporate restructuring in the fourth quarter of 2023 and lower clinical development costs driven by a reduction in regulatory costs for CAN-2409 programs. Research and development expenses included non-cash stock compensation expense of $0.6 million for the first quarter of 2024 compared to $0.3 million for the first quarter of 2023.

General and Administrative Expenses: General and administrative expenses were $3.8 million for the first quarter of 2024 compared to $4.2 million for the first quarter of 2023. The decrease was primarily due to lower employee-related expenses following the corporate restructuring in the fourth quarter of 2023 and lower insurance costs. These decreases were partially offset by increased professional and consulting fees. General and administrative expenses included non-cash stock compensation expense of $0.5 million for the first quarter of 2024 compared to $0.4 million for the first quarter of 2023.

Net Loss: Net loss for the first quarter of 2024 was $8.2 million, compared to a net loss of $8.8 million for the first quarter of 2023, and included other expense, net of $0.3 million and other income, net $0.8 million, respectively. The change from other income, net in the first quarter of 2023 to other expense, net in the first quarter of 2024 was primarily due to the change in the fair value of the Company's warrant liability and lower interest income.

Cash Position: Cash and cash equivalents, as of March 31, 2024, were $25.7 million, as compared to $35.4 million as of December 31, 2023. Based on current plans and assumptions, the Company expects that its existing cash and cash equivalents will be sufficient to fund its current operating plan into the fourth quarter of 2024.

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 Pancreatic Ductal Adenocarcinoma 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 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, including key data readout milestones and presentations; expectations regarding early biological readouts as predictor of clinical response; expectations regarding the therapeutic benefit of the Company’s programs, the ability of CAN-2409 to improve the median overall survival of patients with PDAC; the ability of CAN-3110 to improve the median overall survival of patients with recurrent HGG; expectations regarding the potential benefits conferred by Orphan Drug Designation and Fast Track Designation; 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; the Company’s ability to continue as a going concern; 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 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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Candel Therapeutics, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)

(Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2024	2023
Operating expenses:		
Research and development	$ 4,102	$ 5,469
General and administrative	3,800	4,164
Total operating expenses	7,902	9,633
Loss from operations	(7,902)	(9,633)
Other income (expense):		
Grant income	—	12
Interest income	320	711
Interest expense	(646)	(609)
Change in fair value of warrant liability	7	724
Total other income (expense), net	(319)	838
Net loss and comprehensive loss	$ (8,221)	$ (8,795)
Net loss per share, basic and diluted	$ (0.28)	$ (0.30)
Weighted-average common shares outstanding, basic and diluted	29,197,537	28,919,810

Candel Therapeutics, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands)

	MARCH 31, 2024 (Unaudited)	DECEMBER 31, 2023
Cash and cash equivalents	$ 25,713	$ 35,413
Working capital (1)	13,599	22,613
Total assets	31,217	41,201
Warrant liability	909	916
Total other liabilities	24,329	27,540
Accumulated deficit	(145,249)	(137,028)
Total stockholders equity	$ 5,979	$ 12,745

(1) Working capital is calculated as current assets less current liabilities