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 9, 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 9, 2024, Candel Therapeutics, Inc. (the "Company") will present a poster during the American Association for Cancer Research Annual Meeting announcing the development of a second candidate from its novel enLIGHTEN™ Discovery Platform.

A copy of the full press release announcing the presentation is filed 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 is 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 9, 2024, the Company announced the development of a second candidate from its novel enLIGHTEN™ Discovery Platform. The candidate is a first-in-class multimodal immunotherapy candidate for induction of tertiary lymphoid structures ("TLS"), being developed as a novel therapeutic strategy for solid tumors. TLSs are ectopic lymphocyte aggregation structures found in the tumor microenvironment and their induction could potentially improve anti-tumor immunity. The enLIGHTEN™ Advanced Analytics suite was applied to immune checkpoint inhibitor-treated patient datasets, and the predicted payload components included factors regulating the development of TLS. Delivery of two unique in silico predicted payload combinations, using an enLIGHTEN™ programmable vector, resulted in TLS induction, monotherapy anti-tumoral activity, and enhanced responses in combination with anti-PD-1 antibody therapy in mouse models of solid tumors.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated April 9, 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 9, 2024

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

Exhibit 99.1

Candel Therapeutics Presents Preclinical Data at AACR on Immunotherapy Candidate for Induction of Tertiary Lymphoid Structures in Solid Tumors

- *First-in-class multimodal immunotherapy candidate, for induction of tertiary lymphoid structures, being developed as a novel therapeutic strategy for solid tumors from the enLIGHTEN™ Discovery Platform*
- *Delivery of two unique payload combinations, predicted in silico using the enLIGHTEN™ Advanced Analytics suite, was shown to induce tertiary lymphoid structure formation, inhibit tumor growth, and improve response to immune checkpoint inhibitor therapy in preclinical models of cancer*
- *This presentation accelerates the milestone associated with the second immunotherapy candidate based on the enLIGHTEN™ Discovery Platform, which was originally anticipated in the third quarter of 2024*

NEEDHAM, Mass., Apr. 9, 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 the presentation of a poster during the American Association for Cancer Research (AACR) Annual Meeting, taking place April 5 through 10 in San Diego, which focused on a first-in-class multimodal immunotherapy candidate for induction of tertiary lymphoid structures (TLS), being developed as a novel therapeutic strategy for solid tumors from Candel's enLIGHTEN™ Discovery Platform.

TLSs are ectopic lymphocyte aggregation structures found in the tumor microenvironment and their induction could potentially improve anti-tumor immunity. The presentation describes the development of an investigational TLS-inducing multimodal therapeutic using the enLIGHTEN™ Discovery Platform. The enLIGHTEN™ Advanced Analytics suite was applied to immune checkpoint inhibitor-treated patient datasets, and the predicted payload components included factors regulating the development of TLS. Delivery of two unique in silico predicted payload combinations, using an enLIGHTEN™ programmable vector, resulted in TLS induction, monotherapy anti-tumoral activity, and enhanced responses in combination with anti-PD-1 antibody therapy in mouse models of solid tumors.

“The recent observation that the presence of TLS in tumors is an important prognostic factor associated with an improved response to immunotherapy has fueled drug development efforts in this area. However, TLS assembly is complicated and requires a series of events, including antigen presentation, stromal cell activation, and immune cell activation and aggregation, which are difficult to obtain with a single therapeutic,” said Francesca Barone, MD, PhD, Chief Scientific Officer at Candel. “The enLIGHTEN™ Discovery Platform enables the generation of multimodal agents through the integration of artificial intelligence-driven payload combinations into programmable vectors. This makes it possible to create a single asset that may induce TLS formation and enhance anti-tumor immunity.”

“The delivery of the second immunotherapy candidate based on the enLIGHTEN™ Discovery Platform, on an accelerated timeline, further validates the ability of this innovative platform to create new therapeutic candidates at a fast pace,” added Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “Our platform is flexible and scalable, which makes it suitable for strategic partnerships, for example to create synergy with CAR-T cell therapy or other immunotherapies, potentially resulting in improved survival rates.”

Further detail from Candel’s AACR full poster presentation is available on the Candel website at: www.candeltx.com/media.

About the enLIGHTEN™ Discovery Platform

The enLIGHTEN™ Discovery Platform is a systematic, iterative herpes simplex virus (HSV)-based discovery platform leveraging human biology and advanced analytics to create new multimodal biological immunotherapies for solid tumors. The enLIGHTEN™ Discovery Platform has been designed to deconvolute the characteristics of the tumor microenvironment related to clinical outcomes. These characteristics are rapidly translated into optimized multi-gene payloads of tumor modulators that can be delivered to the tumor microenvironment for specific indications, disease stages, and rationally designed therapeutic combinations. In 2022, the Company announced a discovery partnership with the University of Pennsylvania Center for Cellular Immunotherapies to create new viral immunotherapies that could enhance the efficacy of chimeric antigen receptor T cell (CAR-T) therapy in solid tumors. During the Society for Immunotherapy of Cancer (SITC) 2023 Annual Meeting and the 2023 International Oncolytic Virus Conference, Candel presented encouraging data on the first candidate from this platform, Alpha 201-macro-1, which was designed to interfere with the CD47/SIRP1α pathway, in mouse models of breast cancer and lung cancer.

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.

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, and expectations regarding the therapeutic benefit of the Company's programs, and the ability of the enLIGHTEN™ Discovery Platform to create new multimodal biological immunotherapies for solid tumors and result in further diversification of the Company's portfolio as well as strategic partnerships. 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 of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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