

**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 22, 2023

CANDEL THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40629
(Commission
File Number)

52-2214851
(IRS Employer
Identification No.)

117 Kendrick St., Suite 450
Needham, MA
(Address of Principal Executive Offices)

02494
(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 22, 2023, Candel Therapeutics, Inc. (the “Company”) has changed the primary endpoint of its randomized, placebo-controlled (active:placebo is 2:1), phase 2 clinical trial of CAN-2409 in patients with low-to-intermediate-risk, localized, non-metastatic prostate cancer undergoing active surveillance to biopsy-proven progression-free survival, where progression is defined as increase in Gleason grade or increase in tumor volume to > 33%. Because of the event-driven nature of this endpoint and the number of events required, additional follow-up time will be required to accumulate a sufficient number of events to detect a reduction in the hazard for progression or death prior to the unblinding of the clinical trial. This change will affect the timing of top line results that were previously guided to be in the fourth quarter of 2023. Based on the current rate of events, the Company currently anticipates top-line results to be available in the fourth quarter of 2024.

The randomized, double-blind, placebo-controlled phase 2 clinical trial (NCT02768363) is evaluating CAN-2409 in patients with localized prostate cancer undergoing active surveillance. The trial is fully enrolled with 187 patients.

The information in Item 7.01 of this Current Report on Form 8-K 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 filing.

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: February 22, 2023

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