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): August 10, 2023

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 August 10, 2023, Candel Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2023. 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 August 10, 2023
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 thereunto duly authorized.

Candel Therapeutics, Inc.

Date: August 10, 2023

By: /s/ Paul Peter Tak

Paul Peter Tak, M.D., Ph.D., FMedSci

President and Chief Executive Officer

Candel Therapeutics Reports Second Quarter 2023 Financial Results and Recent Corporate Highlights

NEEDHAM, Mass., August 10, 2023 (GLOBE NEWSWIRE) — Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing viral immunotherapies to help patients fight cancer, today reported financial results for the second quarter ended June 30, 2023, and provided a corporate update.

“We continue to be encouraged by the therapeutic potential of our pipeline of oncology drug candidates that have shown clinical activity across multiple hard-to-treat solid tumor cancers,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “With multiple clinical trials underway, we are well-positioned for a number of upcoming data catalysts. We expect to announce additional clinical and immunological biomarker data from our phase 2 clinical trial in late stage PD-(L)1 inhibitor therapy-resistant non-small cell lung cancer in the third quarter of this year and topline overall survival data in the second quarter of 2024. In addition, we plan to announce initial overall survival and immunological biomarker data from the phase 2 clinical trial of CAN-2409 in patients with borderline resectable pancreatic adenocarcimoma in the fourth quarter of 2023.”

Dr. Tak further commented, “For our CAN-3110 drug candidate, recent data presented from our phase 1 clinical trial in 50 patients with recurrent high-grade glioma demonstrated that a single injection of CAN-3110 was associated with encouraging median overall survival without dose-limiting toxicities. We have also begun evaluating whether multiple injections of CAN-3110 in this patient population could further boost the anti-tumor immune response with added drug exposure. This clinical trial program may also enable future expansion into other indications that are characterized by Nestin expression. We remain determined in our efforts to bring the next generation of viral immunotherapies to patients with cancer.”

Second Quarter 2023 & Recent Highlights

- Program Updates:
    - *CAN-2409 – Non-Small Cell Lung Cancer (NSCLC)*

- Fast Track Designation granted by the U.S. Food and Drug Administration for CAN-2409 plus valacyclovir in combination with continued pembrolizumab in order to improve survival or delay progression in patients with stage III/IV NSCLC 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.

- Presented an overview of the phase 2 NSCLC clinical trial design, study protocol, and dosing regimen in a trials-in-progress poster session at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

- Based on the estimated completion of patient enrollment in Cohort 2, expect to report topline overall survival data from the phase 2 NSCLC clinical trial in Q2 2024.

  - *CAN-3110 - Recurrent High-Grade Glioma (HGG)*

- Presented new data at the 2023 American Society of Gene and Cell Therapy (ASGCT) Annual Meeting. The data from the phase 1 investigator-sponsored clinical trial demonstrated that a single injection of CAN-3110 resulted in a median overall survival (mOS) of 11.8 months in patients with recurrent HGG who had failed standard of care (SoC) treatment. Further results demonstrated CAN-3110 to be well tolerated with no dose-limiting toxicities.

- Advanced patient enrollment in Arm C, supported by the Break Through Cancer Foundation, to evaluate the repeat dosing regimen of CAN-3110 (up to six injections over four months) and whether additional doses can increase mOS.

- Corporate Updates:
  - Appointed experienced manufacturing leader Nicoletta Loggia, PhD, RPh, to the Candel Board of Directors.

Anticipated 2023 Milestones

- Expect to announce additional clinical and immunological biomarker activity data from newly enrolled patients and additional follow-up on the 26 patients who received two injections of CAN-2409 in Cohort 2 of the phase 2 clinical trial of CAN-2409 plus valacyclovir combined with continued PD-(L)1 targeting agents in patients with late-stage NSCLC in Q3.

- Expect to announce initial overall survival and immunological biomarker data from the open-label, randomized phase 2 clinical trial of CAN-2409 plus valacyclovir combined with SoC for patients with borderline resectable pancreatic adenocarcimoma in Q4.

Financial Results for the Quarter Ended June 30, 2023

Research and Development Service Revenue, related party: Research and development service revenue, related party, was $0 for the second quarter of 2023 compared to $31,000 for the second quarter of 2022, as the amortizable $1.0 million up-front license fee that Candel received in 2014 and 2015 from Ventagen LLC was fully recognized as of December 2022.

Research and Development Expenses: Research and development expenses were $5.9 million for the second quarter of 2023 compared to $5.0 million for the second quarter of 2022. The increase was primarily due to personnel-related costs for additional headcount and manufacturing activities in support of the Company's CAN-2409 programs. Research and development expenses included non-cash stock compensation expense of $0.3 million for the second quarter of 2023 compared to $57,000 for the second quarter of 2022.

General and Administrative Expenses: General and administrative expenses were $3.6 million for the second quarter of 2023 compared to $3.8 million for the second quarter of 2022. The decrease was primarily due to lower recruiting and insurance costs, partially offset by an increase in professional service and consulting expenses as well as personnel-related costs for additional headcount. General and administrative expenses included non-cash stock compensation expense of $0.4 million for both the second quarter of 2023 and the second quarter of 2022.

Net Loss: Net loss for the second quarter of 2023 was $9.6 million compared to a net loss of $4.1 million for the second quarter of 2022, and included net other expense of $35,000 and net other income of $4.6 million, respectively, primarily related to the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents as of June 30, 2023 were $51.9 million. The Company expects that its existing cash and cash equivalents will be sufficient to fund its current operating plan into the second quarter of 2024.

Candel Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

(Unaudited)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2023	2022	2023	2022
Research and development service revenue, related party	$ —	$ 31	$ —	$ 63
Operating expenses:				
Research and development	5,934	5,022	11,403	10,438
General and administrative	3,645	3,762	7,809	7,364
Total operating expenses	9,579	8,784	19,212	17,802
Loss from operations	(9,579)	(8,753)	(19,212)	(17,739)
Other income (expense):				
Grant income	12	—	24	—
Interest income	453	70	1,164	71
Interest expense	(644)	(435)	(1,253)	(611)
Change in fair value of warrant liability	144	4,969	868	13,256
Total other income (expense), net	(35)	4,604	803	12,716
Net loss	$ (9,614)	$ (4,149)	$ (18,409)	$ (5,023)
Net loss per share, basic and diluted	$ (0.33)	$ (0.14)	$ (0.64)	$ (0.17)
Weighted-average common shares outstanding, basic and diluted	28,919,810	28,810,224	28,919,810	28,750,431

Candel Therapeutics, Inc.

Consolidated Balance Sheet Data

(in thousands)

	JUNE 30, 2023 (Unaudited)	DECEMBER 31, 2022
Cash and cash equivalents	$ 51,894	$ 70,058
Working capital (1)	45,199	66,330
Total assets	58,708	77,691
Warrant liability	1,014	1,882
Total other liabilities	26,923	28,095
Accumulated deficit	(117,498)	(99,089)
Total stockholders equity	$ 30,771	$ 47,714

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

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on developing off-the-shelf viral immunotherapies that elicit an individualized, systemic anti-tumor immune response to help patients fight cancer. Candel's engineered viruses are designed to induce immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens while creating a pro-inflammatory microenvironment at the site of injection. This leads to in-situ vaccination against the injected tumor and uninjected distant metastases.

The Company has established two clinical stage viral 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 (phase 2), pancreatic cancer (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 phase 1 clinical trial in recurrent glioblastoma. In addition, 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 key data readout milestones and presentations; expectations regarding the therapeutic benefit of its programs; 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 timing of data readout milestones and presentations; expectations regarding the therapeutic benefit of the Company's programs; 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; the Company's ability to raise additional capital; and strategic plans for the Company's business and product candidates, and other risks identified in the Company's SEC filings, 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.

Media Contact
Aljanae Reynolds
Director
Wheelhouse Life Science Advisors
areynolds@wheelhouselsa.com

Investor Contact
Sylvia Wheeler
Principal
Wheelhouse Life Science Advisors
swheeler@wheelhouselsa.com