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): September 8, 2021

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)**	**(I.R.S. Employer Identification No.)**

Candel Therapeutics, Inc.
117 Kendrick St Suite 450
Needham, Massachusetts 02494
(Address of principal executive offices, including zip code)

(617) 916-5445
(Registrant's telephone number, including area code)

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	Trade 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 September 8, 2021, Candel Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2021. 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 Form 8-K (including Exhibit 99.1) 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

99.1	Press Release dated September 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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: September 8, 2021

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

Exhibit 99.1

Candel Therapeutics Reports Second Quarter 2021 Financial Results and Recent Corporate Highlights

NEEDHAM, Mass., Sept. 8, 2021 (GLOBE NEWSWIRE) — Candel Therapeutics, Inc. ("the Company") (Nasdaq: CADL), a late clinical stage biopharmaceutical company developing novel oncolytic viral immunotherapies, today reported financial results for the quarter ended June 30, 2021 and provided a corporate update.

"This has been a transformational year for Candel Therapeutics as we continue to execute on our corporate strategy by advancing the development of our lead product candidate from our adenovirus platform, CAN-2409, and our lead product candidate from our HSV platform, CAN-3110, both in areas of significant unmet need," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel Therapeutics. "With the close of our IPO, and multiple data readouts across our broad pipeline over the next 12 months, we are in a strong position to advance our strategy and well-capitalized to support achievement of important milestones toward bringing novel immunotherapies to patients with cancer."

Second Quarter 2021 & Recent Highlights

- On April 13, the Company announced formation of new Research Advisory Board that included 2018 Nobel Laureate, James Allison, Ph.D. (MD Anderson Cancer Center), Henry Brem, M.D. (Johns Hopkins University), Roy S. Herbst, M.D., Ph.D. (Yale Cancer Center), Elizabeth Jaffee, M.D. (Johns Hopkins University), Philip Kantoff, M.D. (Memorial Sloan Kettering Cancer Center), and Padmanee Sharma, M.D., Ph.D. (MD Anderson Cancer Center).
- On April 22, the Company completed enrollment in a phase 1 clinical trial in patients with newly diagnosed high-grade glioma to evaluate the safety and efficacy of CAN-2409 in combination with Opdivo® (*nivolumab*) and standard of care radiation therapy, as well as temozolomide for patients who have a methylated MGMT promoter.
- On June 4, the Company reported data from an ongoing phase 1 clinical trial of its oncolytic virus, CAN-3110, in patients with high-grade glioma that has recurred after initial treatment. The data presented at the 2021 American Society of Clinical Oncology (ASCO) demonstrated a favorable safety and tolerability profile and durable responses in a number of patients.
- On June 22, the U.S. Food and Drug Administration granted Fast Track designation for CAN-2409 in combination with standard of care surgery and chemoradiation to improve survival in adults with newly diagnosed high-grade glioma.
- On July 15, the Company announced the appointment of Diem Nguyen, Ph.D., M.B.A. to its Board of Directors.
- On August 17, the Company announced the closing of Initial Public Offering, raising gross proceeds of $79.1 million, before deducting underwriting discounts and commissions and offering expenses, to support ongoing research and development efforts.
- On September 7, the Company announced it completed enrollment in its phase 3 clinical trial of CAN-2409 in combination with valacyclovir for the treatment of intermediate- to high-risk localized prostate cancer.

Key Upcoming Milestones

- Initial efficacy and safety data from a phase 1 trial of CAN-2409 in combination with Opdivo® (nivolumab) in patients with high-grade glioma are expected to be presented in the fourth quarter of 2021.

- Blinded safety data from a phase 2 trial of CAN-2409 in patients undergoing active surveillance for prostate cancer will be presented in the third quarter of 2021.
- Biomarker results from a phase 1 trial of CAN-3110 in patients with recurrent high-grade glioma are expected to be presented in the fourth quarter of 2021.

Financial Results for the Second Quarter Ended June 30, 2021

Cash Position: Cash and cash equivalents and marketable as of June 30, 2021 were $24.3 million, as compared to $35.1 million as of December 31, 2020. Subsequent to June 30, 2021, we completed our initial public offering in which we issued 9,887,994 shares of common stock at a price of $8.00 per share, including the partial exercise of the underwriters' overallotment option, for net proceeds of $71.5 million after deducting underwriting discounts and commissions and offering expenses. Based on current plans and assumptions, the Company expects its existing cash and cash equivalents, including the net proceeds of the IPO, will be sufficient to fund its operations into the second quarter of 2023.

Research & Development Expenses: Research and development expenses were $3.3 million and $6.0 million for the three and six month periods ended June 30, 2021, respectively, as compared to $1.8 million and $3.4 million for the comparable periods of 2020. The increase was primarily due to increased personnel-related costs due to additional headcount to support the ongoing clinical trials for Candel's product candidates as well as increased clinical development costs. Excluding stock-based compensation expense of $0.4 million for the three months ended June 30, 2021 and $0.5 million for the six months ended June 30, 2021, research and development expenses for the three and six months ended June 30, 2021 were $2.9 million and $5.5 million, respectively.

General and Administrative Expenses: General and administrative expenses were $2.0 million and $4.0 million for the three and six months ended June 30, 2021, respectively, as compared to $0.9 million and $1.6 million for the comparable periods of 2020. The increase was primarily due to an increase in personnel-related costs, including stock-based compensation, for additional headcount required to support the growth of the Company increased clinical development costs. and an increase in professional fees associated with Candel's preparation for the IPO completed in July 2021. Excluding stock-based compensation expense of $0.7 million for the three months ended June 30, 2021 and $ 1.0 million for the six months ended June 30, 2021, general and administrative expenses for the three and six months ended June 30, 2021 were $1.3 million and $3.0 million, respectively.

Total Operating Expenses: Total operating expenses were $5.3 million and $10.0 million for the three and six months ended June 30, 2021, respectively, as compared to $2.7 million and $5.0 million for the comparable periods of 2020. The increase was primarily due to an increase in personnel-related costs, including stock-based compensation, for additional headcount required to support the growth of the Company, an increase in professional fees associated with Candel's preparation for the IPO completed in July 2021 and increased clinical development costs. Excluding stock-based compensation expense of $1.1 million for the three months ended June 30, 2021 and $1.5 million for the six months ended June 30, 2021, total operating expenses for the three and six months ended June 30, 2021 were $4.2 million and $8.5 million, respectively.

Net Loss: Net loss was $17.1 million and $21.6 million for the three and six months ended June 30, 2021, respectively, as compared to $2.9 million and $4.6 million for the comparable periods of 2020. The net loss for the three and six months ended June 30, 2021 includes a noncash charge of $12.4 million for the change in the fair value of the Company's warrant liability and stock-based compensation of $1.1 million and $1.5 million, respectively. Excluding the noncash charges for the change in the warrant liability and stock-based compensation, the net loss for the three and six months ended June 30, 2021 was $3.6 million and $7.7 million, respectively

Candel Therapeutics, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)

(unaudited)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2021	2020	2021	2020
Research and development service revenue, related party	$ 31	$ 31	$ 63	$ 63
Operating expenses:				
Research and development	3,292	1,795	6,048	3,417
General and administrative	2,040	855	3,972	1,583
Total operating expenses	5,332	2,650	10,020	5,000
Loss from operations	(5,301)	(2,619)	(9,957)	(4,937)
Other income (expense):				
Grant income	605	156	796	319
Interest, dividend and investment income (expense), net	(15)	94	(28)	22
Change in fair value of warrant liability	(12,369)	(507)	(12,369)	(52)
Total other income (expense), net	(11,779)	(257)	(11,601)	289
Net loss	$ (17,080)	$ (2,876)	$ (21,558)	$ (4,648)
Other comprehensive gain:				
Unrealized gain on available-for-sale securities	—	307	—	73
Comprehensive loss	$ (17,080)	$ (2,569)	$ (21,558)	$ (4,575)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.46)	$ (0.25)	$ (1.85)	$ (0.40)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	11,720,530	11,614,754	11,684,374	11,614,551

Candel Therapeutics, Inc.

Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	JUNE 30, 2021	DECEMBER 31, 2020
Cash, cash equivalents and marketable securities	$ 24,316	$ 35,053
Working capital	19,932	30,433
Total assets	30,744	38,282
Warrant liability	19,200	6,831
Total other liabilities	5,659	5,953
Accumulated deficit	$ (65,729)	$ (44,171)
Total stockholder deficit	(43,175)	(23,562)

About Candel Therapeutics

Candel is a late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Candel's engineered viruses are designed to induce immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. Candel has established two oncolytic viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform and CAN-3110 is the lead product candidate from the HSV platform. New discovery programs are based on the HSV platform.

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, include key data readout milestones; 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; 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, 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 Registration Statement on Form S-1, the Company's Quarterly Report on Form 10-Q to be filed on or about the date of this press release, 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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