

**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 5, 2022

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 2.02 Results of Operations and Financial Condition.

On August 5, 2022, Candel Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2022. 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

Exhibit Number	Description
99.1	Press Release dated August 5, 2022
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 5, 2022

By: /s/ Paul Peter Tak

Paul Peter Tak, M.D., Ph.D., FMedSci
President and Chief Executive Officer



Candel Therapeutics Reports Second Quarter 2022 Financial Results and Recent Corporate Highlights

NEEDHAM, Mass., August 5, 2022 (GLOBE NEWSWIRE) — Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies, today reported financial results for the second quarter ended June 30, 2022 and provided a corporate update.

“Candel remains on track to achieve several milestones in the second half of 2022,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “We are encouraged by the initial phase 2 clinical trial data for CAN-2409 in non-small cell lung cancer presented in June at ASCO. The data presented at ASCO showed an 87.5 percent disease control rate in heavily pretreated patients whose cancer was progressing on PD-1 agents at clinical trial entry. In the second half of this year, we are planning for multiple inflection points, including updated clinical data from the phase 2 lung cancer clinical trial, initiation of a phase 3 clinical trial in high-grade glioma, and we will present initial data from our enLIGHTEN™ Discovery Platform. I am thrilled to see the rapid progress the Candel team continues to make on the discovery and development of our oncolytic viral immunotherapies for patients with cancer.”

Second Quarter 2022 & Recent Highlights

- Presented initial data on its open-label phase 2 clinical trial of CAN-2409 in combination with anti-PD-1 or PD-L1 targeting agents in patients with stage III/IV non-small cell lung cancer (NSCLC) in June 2022.
 - o The data showed cytotoxic T cell response and a disease control rate of 87.5 percent achieved in patients whose cancer was progressing on anti-PD-1 therapy at clinical trial entry.
 - o These findings were presented by co-principal investigator Charu Aggarwal, MD, MPH, at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.
 - o In addition to the ASCO poster session, the Company hosted a discussion with key experts Roy Herbst, MD, PhD, and Daniel Serman, MD, to review these initial data.
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- The Company appointed three new members to its Board of Directors: Gary Nabel, MD, PhD, renowned virologist and immunologist; Joseph Papa, prominent business leader; and Renee Gaeta, strategic financial expert. Effective August 8, 2022, these new members will replace current Board members: Alan E. Smith, PhD, Shaan Ghandi, MD, D.Phil, and Udi Meirav, PhD, maintaining Candel's nine-seat Board.

Key Upcoming Milestones

- In the fourth quarter of 2022, the Company expects to present new data from three clinical trials:
 - o A phase 1b clinical trial of CAN-2409 in combination with nivolumab (Opdivo[®]) combined with standard of care in first line treatment in patients with high-grade glioma.
 - o A phase 1 clinical trial of CAN-3110 in patients with recurrent high-grade glioma.
 - o A phase 2 clinical trial of CAN-2409 in combination with anti-PD-1 or PD-L1 agents in patients with stage III/IV NSCLC.
- The Company anticipates initiating a phase 3 clinical trial evaluating CAN-2409 in patients with high-grade glioma in the third quarter of 2022.
- The Company also plans to debut initial data from its new discovery platform, enLIGHTEN[™], in the fourth quarter of 2022.

Financial Results for the Quarter Ended June 30, 2022

Cash Position: Cash and cash equivalents as of June 30, 2022 were \$86.8 million compared to \$82.6 million as of December 31, 2021. The net increase was due to receipt of \$20.0 million from a term loan with Silicon Valley Bank in February 2022, offset by costs to fund operating activities and the purchase of fixed assets. Based on current plans and assumptions, the Company expects that its existing cash and cash equivalents will be sufficient to fund its operations into the first quarter of 2024.

Research and Development Expenses: Research and development expenses were \$5.0 million and \$10.4 million for the three- and six-month period ended June 30, 2022 compared to \$3.3 million and \$6.0 million for the comparable periods in 2021. The increase was primarily due to personnel-related costs for additional headcount, as well as operating expenses related to the conduct of five ongoing clinical studies, the expected initiation of a phase 3 clinical study, and the expansion of manufacturing capabilities. Excluding stock-based compensation expense of \$57,000 for the three months ended June 30, 2022 and \$199,000 for the six-month period ended June 30, 2022, research and development expenses for the three- and six-month period ended June 30, 2022 were \$5.0 million and \$10.2 million.

General and Administrative Expenses: General and administrative expenses were \$3.8 million and \$7.4 million for the three- and six-month period ended June 30, 2022 compared to \$2.0 million and \$4.0 million for the comparable periods in 2021. The increase was primarily due to higher insurance costs, personnel-related costs and professional consulting fees associated with operating as a public company. Excluding stock-based compensation expense

of \$381,000 for the three-month period ended June 30, 2022, and \$730,000 for the six-month period ended June 30, 2022, general and administrative expenses for the three- and six-month period ended June 30, 2022 were \$3.4 million and \$6.6 million.

Total Operating Expenses: Total operating expenses were \$8.8 million and \$17.8 million for the three- and six-month period ended June 30, 2022 compared to \$5.3 million and \$10.0 million for the comparable periods in 2021. The increase was primarily due to increased personnel-related costs and research and development activities and resulting expenses as well as increased operating expenses associated with being a public company. Excluding stock-based compensation expense of \$438,000 for the three-month period ended June 30, 2022, and \$929,000 for the six-month period ended June 30, 2022, total operating expenses for the three- and six-month period ended June 30, 2022 were \$8.3 million and \$16.9 million.

Net Loss: Net loss was \$4.1 million and \$5.0 million for the three- and six-month period ended June 30, 2022, as compared to \$17.1 million and \$21.6 million for the comparable periods in 2021. The net loss for the three- and six-month period ended June 30, 2022 includes a non-cash credit of \$5.0 million and \$13.3 million, and the net loss for the three- and six-month period ended June 30, 2021 includes a non-cash charge of \$12.4 million for the change in the fair value of the Company's warrant liability, and includes stock-based compensation expense of \$438,000 and \$929,000 for the three- and six-month period ended June 30, 2022, and \$1.1 million and \$1.5 million for the three- and six-month period ended June 30, 2021. Excluding non-cash credits for the changes in the warrant liability and charges for stock-based compensation, the net loss for the three- and six-month period ended June 30, 2022 was \$8.7 million and \$17.4 million, as compared to \$3.6 million and \$7.7 million for the comparable periods in 2021.

Candel Therapeutics, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)
(amounts are unaudited)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2022	2021	2022	2021
Research and development service revenue, related party	\$ 31	\$ 31	\$ 63	\$ 63
Operating expenses:				
Research and development	5,022	3,292	10,438	6,048
General and administrative	3,762	2,040	7,364	3,972
Total operating expenses	<u>8,784</u>	<u>5,332</u>	<u>17,802</u>	<u>10,020</u>
Loss from operations	<u>(8,753)</u>	<u>(5,301)</u>	<u>(17,739)</u>	<u>(9,957)</u>
Other income (expense):				
Grant income	—	605	—	796
Interest, dividend and investment income (expense), net	(365)	(15)	(540)	(28)
Change in fair value of warrant liability	4,969	(12,369)	13,256	(12,369)
Total other income (expense), net	<u>4,604</u>	<u>(11,779)</u>	<u>12,716</u>	<u>(11,601)</u>
Net loss	<u>\$ (4,149)</u>	<u>\$ (17,080)</u>	<u>\$ (5,023)</u>	<u>\$ (21,558)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.14)</u>	<u>\$ (1.46)</u>	<u>\$ (0.17)</u>	<u>\$ (1.85)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>28,810,224</u>	<u>11,720,530</u>	<u>28,750,431</u>	<u>11,684,374</u>

Candel Therapeutics, Inc.
Consolidated Balance Sheet Data

(in thousands)
(amounts are unaudited)

	JUNE 30, 2022	DECEMBER 31, 2021
Cash and cash equivalents	\$ 86,782	\$ 82,642
Working capital (1)	81,448	79,583
Total assets	93,301	89,205
Warrant liability	4,996	18,252
Total other liabilities	28,233	6,816
Accumulated deficit	(85,318)	(80,295)
Total stockholders equity	\$ 60,072	\$ 64,137

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

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 enLIGHTEN™ 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, including key data readout milestones and indications; 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 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.

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