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): November 10, 2022

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 November 10, 2022, Candel Therapeutics, Inc. announced its financial results for the quarter ended September 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 November 10, 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: November 10, 2022

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

Exhibit 99.1

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

- *Discovery collaboration underway with Center for Cellular Immunotherapies Lab at University of Pennsylvania to Study Combinations of Novel Viral Immunotherapy and CAR-T Cell Therapy Candidates in Solid Tumor Models*
- *Upcoming clinical data presentations at SITC and SNO Annual Meetings*
- *Virtual R&D Day on December 6, 2022, with Candel leadership and renowned oncology experts*

NEEDHAM, Mass., November 10, 2022 (GLOBE NEWSWIRE) — Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on helping patients fight cancer with viral immunotherapies, today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

“Candel made important progress across multiple facets of the organization this quarter,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “We have bolstered the Company’s capabilities and future potential with the appointment of three new board members and two new leadership executives, an orphan drug designation from the European Commission for CAN-2409 in glioma, and most recently a discovery partnership with the University of Pennsylvania’s Center for Cellular Immunotherapies, led by Dr. Carl June, the Richard W. Vague Professor for Immunotherapy, to study the combination of our enLIGHTEN™ Discovery Platform and their CAR-T cells in solid tumors. We will close the year with new clinical results coming from our pipeline being presented at R&D Day and we look ahead with confidence to deliver our world-class viral immunotherapy candidates to patients battling cancer.”

Jason A. Amello, Chief Financial Officer, added, “The third quarter of 2022 was marked by significant momentum as the Company broadened its viral immunotherapy footprint and continued to execute across all of its programs in an efficient and cost-effective manner.”

Third Quarter 2022 and Recent Highlights

- In August, the Company enhanced its Board of Directors with the appointments of three new Board members. (View Release)
    - Joseph Papa, Chief Executive Officer of Bausch + Lomb Corporation
    - Gary Nabel, MD, PhD, Chief Innovation Officer of OPKO and Chief Executive Officer, ModeX Therapeutics, Inc., an OPKO Health company
    - Renee Gaeta, Chief Financial Officer of Eko Devices
- In September, the Company strengthened its executive leadership team with appointments of Jason A. Amello as Chief Financial Officer and Garrett Nichols, MD, MS, as Chief Medical Officer. (View Release)
- Separately in September, the Company submitted the protocol for a phase 3 clinical trial evaluating CAN-2409 in patients living with high-grade glioma (HGG) to a central institutional review board.
- Also in September, the European Medicines Agency (EMA) issued a positive opinion for orphan drug designation for CAN-2409 in glioma. (View Release)
- In October, the European Commission adopted the EMA's decision to grant CAN-2409 orphan drug designation for the treatment of glioma.
- Also in October, the Company formed a partnership with Neil Sheppard, DPhil, Director of the T Cell Engineering Lab at the University of Pennsylvania's Center for Cellular Immunotherapies, led by Carl. H June, MD, the Richard W. Vague Professor of Immunotherapy, to study combinations of novel viral immunotherapy and CAR-T cell therapy candidates in solid tumors. (View Release)
- In early November, Dr. Tak participated in separate fireside chats with Credit Suisse and BMO Capital Markets. (View Webcasts)

Key Upcoming Milestones and Events

- 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) (View Release)
    - On November 11, Anne R. Diers, PhD, Director of Early Research at Candel, will lead an in-person poster session on pre-clinical CAN-2409 data.
    - Also on November 11, Patrick Y. Wen, MD, Principal Investigator from Dana-Farber Cancer Institute, will present new data in an in-person oral session on

CAN-2409 in combination with nivolumab and standard of care from the Company's phase 1b clinical trial in newly diagnosed HGG.

- On November 16, Dr. Tak will take part in an in-person fireside chat at Jefferies London Healthcare Conference. (Register Here)
- 27th Annual Meeting of the Society for Neuro-Oncology (SNO) (View Release)
    - On November 18, new clinical data from the Company's phase 1 trial of CAN-3110 in recurrent HGG will be presented in an in-person oral session by Alexander Ling, PhD, a Postdoctoral Research Fellow from Brigham and Women's Hospital.
- On December 6, the Company will hold its virtual R&D Day with leadership and renowned oncology experts to present an in-depth overview of the Company's viral immunotherapy platforms and clinical pipeline including additional data from its phase 2 clinical trial of CAN-2409 in combination with anti-PD-1 or PD-L1 agents in patients with stage III/IV non-small cell lung cancer.

Financial Results for the Quarter Ended September 30, 2022

Research and Development Service Revenue, related party: Research and Development Service Revenue, related party, for the third quarters ended September 30, 2022 and 2021 was $31,000.

Research and Development Expenses: Research and development expenses were $5.4 million for the quarter ended September 30, 2022 compared to $5.3 million for the comparable period 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. Research and development expenses includes non-cash stock compensation expense of $343,000 and $1.5 million for the third quarter of 2022 and 2021, respectively.

General and Administrative Expenses: General and administrative expenses were $3.5 million for the third quarter of 2022 compared to $2.8 million for the third quarter of 2021. The increase was primarily due to higher recruiting costs, personnel-related costs, and professional and consulting fees associated with operating as a public company. General and administrative expenses includes non-cash stock compensation expense of $400,000 and $390,000 for the third quarter of 2022 and 2021, respectively.

Net Loss: Net loss for the third quarter of 2022 was $8.7 million compared to $16.2 million for the comparable period of 2021. The net loss for the third quarter of 2022 includes non-operating interest, dividend and investment expense of $176,000 and a non-cash credit of $369,000 for the change in the fair value of the Company's warrant liability. The net loss for the third quarter

of 2021 includes net non-operating income of $117,000 and a non-cash charge of $8.3 million for the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents as of September 30, 2022 were $77.2 million compared to $82.6 million as of December 31, 2021, and reflects the receipt of $20.0 million from the term loan with Silicon Valley Bank in February 2022. Based on current plans and assumptions, the Company expects that its existing cash and cash equivalents will be sufficient to fund its current operating plan into the first quarter of 2024.

Candel Therapeutics, Inc.

Consolidated Statements of Operations

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Research and development service revenue, related party	$ 31	$ 31	$ 94	$ 94
Operating expenses:				
Research and development	5,376	5,265	15,815	11,324
General and administrative	3,536	2,795	10,900	6,756
Total operating expenses	8,912	8,060	26,715	18,080
Loss from operations	(8,881)	(8,029)	(26,621)	(17,986)
Other income (expense):				
Grant income	—	131	—	927
Interest, dividend and investment income (expense), net	(176)	(14)	(716)	(42)
Change in fair value of warrant liability	369	(8,250)	13,626	(20,619)
Total other income (expense), net	193	(8,133)	12,910	(19,734)
Net loss	$ (8,688)	$ (16,162)	$ (13,711)	$ (37,720)
Net loss per share, basic and diluted	$ (0.30)	$ (0.69)	$ (0.48)	$ (2.42)
Weighted-average common shares outstanding, basic and diluted	28,891,909	23,325,716	28,798,284	15,579,267

Candel Therapeutics, Inc.

Consolidated Balance Sheet Data

(in thousands)
(amounts are unaudited)

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Cash and cash equivalents	$ 77,183	$ 82,642
Working capital	73,172	79,583
Total assets	85,007	89,205
Warrant liability	4,626	18,252
Total other liabilities	28,254	6,816
Accumulated deficit	(94,006)	(80,295)
Total stockholders equity	$ 52,127	$ 64,137

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

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on helping patients fight cancer with viral immunotherapies that elicit a systemic anti-tumor immune response. 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. Candel 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 CAN-3110 is the lead product candidate from the HSV platform. The enLIGHTEN™ Discovery Platform is the first 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 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.

Media Contact
Cassidy McClain
Account Director
Evoke Canale
Cassidy.McClain@evokegroup.com
(619) 694-6291

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