

**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): March 29, 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 March 29, 2022, Candel Therapeutics, Inc. announced its financial results for the quarter and year ended December 31, 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated March 29, 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: March 29, 2022

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



Candel Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Corporate Highlights

-Cash position remains strong to support operations into the fourth quarter of 2023-

NEEDHAM, Mass., March 29, 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 fourth quarter and year ended December 31, 2021 and provided a corporate update.

“2021 was a year of significant progress for Candel, filled with important accomplishments in development of our late-stage pipeline of novel oncolytic viral immunotherapies for cancer treatment. We strengthened our organization for future growth with our successful initial public offering, by meeting key clinical trial accrual milestones and by enhancing our talent pool,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “Today, we are well positioned for major catalysts over the next 12 months, namely, multiple data readouts across our product candidates and advancement of our pipeline of promising therapeutics with potential to treat various solid tumors, including lung, brain, pancreatic and prostate cancer. We look forward to delivering on our mission to develop oncolytic viral immunotherapies aimed at tipping the balance in favor of the patient’s immune system to fight cancer.”

Fourth Quarter 2021 & Recent Highlights

- Presented Candel’s novel oncolytic viral immunotherapies at several preeminent industry conferences:
 - o October 2021: Cambridge Healthtech Institute’s 9th Annual Immuno-Oncology Summit
 - o October 2021: Hanson Wade 6th Annual Oncolytic Virotherapy Summit
 - o October 2021: 28th Annual Prostate Cancer Foundation Scientific Retreat
 - o November 2021: 13th International Oncolytic Virus Conference Meeting
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- o November 2021: Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting

- Patrick Y. Wen, MD, principal investigator, presented initial safety data on CAN-2409 in combination with nivolumab from Candel's Phase 1 clinical trial in high-grade glioma at the 26th Annual Meeting of the Society for Neuro-Oncology in November 2021.
- Established a collaboration with Partnership for Accelerating Cancer Therapies and the Cancer Immune Monitoring and Analysis Centers – Cancer Immunologic Data Commons to profile the biomarker response to a combination of CAN-2409 and valacyclovir, in combination with anti-PD-1 and PD-L1 immune checkpoint inhibitors in patients with non-small cell lung cancer (NSCLC) in December 2021.
- Enhanced executive leadership with the promotion of Francesca Barone, MD, PhD to Chief Scientific Officer and appointment of Seshu Tyagarajan, PhD, RAC as Chief Technical and Development Officer in 2022.
- Strengthened cash position with non-dilutive debt financing with Silicon Valley Bank (SVB) in February 2022.
- Appointed Mace Rothenberg, MD, prior Chief Medical Officer of Pfizer, as Senior Advisor to the CEO.

Key Upcoming Milestones

- The Company expects to present initial data from an ongoing Phase 2 clinical trial of CAN-2409 and valacyclovir combined with PD-1 or PD-L1 targeting agents in patients with NSCLC in June 2022.
- In the fourth quarter of 2022, the Company expects to present data from two high grade glioma clinical trials – a Phase 1b clinical trial of CAN-2409 in combination with nivolumab (Opdivo) combined with standard of care first line treatment and a Phase 1 clinical trial of CAN-3110 in recurrent high-grade glioma.

Financial Results for the Year and Fourth Quarter Ended December 31, 2021

Cash Position: Cash and cash equivalents as of December 31, 2021 were \$82.6 million, compared to \$35.1 million as of December 31, 2020. The increase was due to receipt of \$71.3 million of net proceeds from the Company's successful initial public offering (IPO) of common stock in August 2021. In addition, the Company utilized \$22.2 million in the year ended December 31, 2021 to fund operating activities. Subsequent to December 31, 2021, the Company entered into a term loan agreement with SVB and borrowed \$20.0 million. Based on current plans and assumptions, the Company expects that its existing cash and cash equivalents, including the \$20 million in term loan proceeds, will be sufficient to fund its operations into the fourth quarter of 2023.

Research & Development Expenses: Research and development expenses were \$3.9 million and \$15.2 million for the three- and twelve-month periods ended December 31, 2021, respectively, as compared to \$3.5 million and \$8.8 million for the comparable periods of 2020. The increases were primarily due to increased personnel-related costs, including stock-based compensation, for additional headcount to support the ongoing clinical trials for Candel's product candidates as well as increased clinical development costs related to our clinical trial sites and the cost of treatment and follow-up on patients. Excluding stock-based compensation

expense of (\$810,000) and \$1.2 million for the three- and twelve-month periods ended December 31, 2021, respectively, research and development expenses for the three- and twelve-month periods ended December 31, 2021, were \$4.7 million and \$14.0 million, respectively.

General and Administrative Expenses: General and administrative expenses were \$3.9 million and \$10.7 million for the three- and twelve-month periods ended December 31, 2021, respectively, as compared to \$2.6 million and \$5.2 million for the comparable periods of 2020. The increases were primarily due to increased personnel-related costs, including stock-based compensation, for additional headcount required to support the growth of the Company and the transition to a public company, an increase in professional fees associated with Candel's preparation for the IPO completed in August 2021 and costs associated with operating as a public company. Excluding stock-based compensation expense of \$364,000 and \$1.7 million for the three- and twelve-month periods ended December 31, 2021, respectively, general and administrative expenses for the three- and twelve-month periods ended December 31, 2021, were \$3.5 million and \$9.0 million, respectively.

Total Operating Expenses: Total operating expenses were \$7.8 million and \$25.9 million for the three- and twelve-month periods ended December 31, 2021, respectively, as compared to \$6.2 million and \$13.9 million for the comparable periods of 2020. The increases were primarily due to increased personnel-related costs, including stock-based compensation, for additional headcount required to support the growth of the Company and the transition to a public company, an increase in professional fees associated with Candel's preparation for the IPO completed in August 2021, an increase in costs associated with operating as a public company and increased clinical development costs. Excluding stock-based compensation expense of (\$446,000) and \$2.9 million for the three- and twelve-month periods ended December 31, 2021, respectively, total operating expenses for the three- and twelve-month periods ended December 31, 2021, were \$8.2 million and \$23.0 million, respectively.

Net Loss: Net (income) loss was (\$1.6 million) and \$36.1 million for the three- and twelve-month periods ended December 31, 2021, respectively, as compared to a net loss of \$10.5 million and \$17.7 million for the comparable periods of 2020. The net (income) loss for the three- and twelve-month periods ended December 31, 2021, includes a noncash credit and charge of (\$9.2 million) and \$11.4 million, respectively, for the change in the fair value of the Company's warrant liability and stock-based compensation expense of (\$446,000) and \$3.0 million, respectively. Excluding the noncash charges for the change in the warrant liability and the stock-based compensation, the net loss for the three- and twelve-month periods ended December 31, 2021, was \$8.0 million and \$21.7 million, respectively.

Candel Therapeutics, Inc.

Consolidated Statements of Operations

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

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 30,	
	2021	2020	2021	2020
Research and development service revenue, related party	\$ 31	\$ 31	\$ 125	\$ 125
Operating expenses:				
Research and development	3,854	3,534	15,178	8,754
General and administrative	3,917	2,622	10,673	5,181
Total operating expenses	7,771	6,156	25,851	13,935
Loss from operations	(7,740)	(6,125)	(25,726)	(13,810)
Other income (expense):				
Grant income	149	151	1,076	624
Interest, dividend and investment income (expense), net	(11)	49	(53)	111
Change in fair value of warrant liability	9,198	(4,553)	(11,421)	(4,605)
Total other income (expense), net	9,336	(4,353)	(10,398)	(3,870)
Net Income (loss)	\$ 1,596	\$ (10,478)	\$ (36,124)	\$ (17,680)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on available-for-sale securities	—	(50)	—	19
Comprehensive income (loss)	\$ 1,596	\$ (10,528)	\$ (36,124)	\$ (17,661)
Net income (loss) per share attributable to common stockholders, basic				
	\$ 0.06	\$ (0.90)	\$ (1.91)	\$ (1.52)
Net income (loss) per share attributable to common stockholders, diluted				
	\$ 0.05	\$ (0.90)	\$ (1.91)	\$ (1.52)
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders, basic				
	28,689,842	11,615,948	18,873,048	11,615,208
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders, diluted				
	34,642,325	11,615,948	18,873,048	11,615,208

Candel Therapeutics, Inc.
Consolidated Balance Sheet Data

(in thousands)

	DECEMBER 31, 2021	DECEMBER 31, 2020
Cash and cash equivalents	\$ 82,642	\$ 35,053
Working capital (1)	79,583	30,433
Total assets	89,205	38,282
Warrant liability	18,252	6,831
Total other liabilities	6,816	5,953
Accumulated deficit	(80,295)	(44,171)
Total stockholders equity (deficit)	\$ 64,137	\$ (23,562)

(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 Annual Report on Form 10-K filed on March 29, 2022, 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

Heidi Chokeir, PhD

Managing Director

Canale Communications

heidi.chokeir@canalecomm.com

619-203-5391

Investor Contact

Sylvia Wheeler

Principal

Wheelhouse Life Science Advisors

swheeler@wheelhousesa.com
