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

May 11, 2023

NEEDHAM, Mass., May 11, 2023 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing and commercializing viral immunotherapies to help patients fight cancer, today reported financial results for the first quarter ended March 31, 2023, and provided a corporate update.

“In the first quarter, we continued to advance our off-the-shelf investigational viral immunotherapies designed to produce an individualized cancer response, both of which have shown early clinical promise,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “We are well positioned to announce important catalysts throughout the year. In the near-term, we will present new data from our CAN-3110 glioma clinical trial at ASGCT and we will provide an overview of our non-small cell lung cancer clinical trial design, study protocol, and dosing regimen at ASCO. In addition, we remain on track to announce data from our phase 2 non-small cell lung and pancreatic cancer clinical trials in the second half of the year. We remain steadfast in our mission to improve survival while maintaining quality of life for patients living with cancer.”

First Quarter 2023 & Recent Highlights

- Program Updates:
  - *CAN-2409 – Non-Small Cell Lung Cancer (NSCLC)*
    - In April, the U.S. Food and Drug Administration (FDA) granted fast track designation to CAN-2409 with valacyclovir in combination with 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.
    - Charu Aggarwal, MD, MPH, Associate Professor for Lung Cancer Excellence of the Perelman School of Medicine at University of Pennsylvania and Candel’s co-principal investigator, will present a trials-in-progress poster from the phase 2 NSCLC clinical trial at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on June 4 in Chicago.
    - The Company recently added a new cohort to its phase 2 NSCLC clinical trial which will evaluate three injections of CAN-2409.
    - The Company plans to present additional data from its phase 2 NSCLC clinical trial in Q3 2023.
  - *CAN-2409 – Prostate Cancer*
    - The Company’s placebo-controlled, randomized phase 2 clinical trial of CAN-2409 in patients with low-to-intermediate-risk, localized, non-metastatic prostate cancer is ongoing. The Company expects to announce topline data from this clinical trial in Q4 2024.
  - *CAN-2409 – Pancreatic Cancer*
    - In March, the Company elected to pause new enrollment in its randomized phase 2 clinical trial investigating CAN-2409 in borderline resectable pancreatic adenocarcinoma subject to additional funding. The Company continues to expect to present initial phase 2 clinical data, including overall survival, in Q4 2023.
  - *CAN-3110 - Recurrent High-Grade Glioma (HGG)*
    - Francesca Barone, MD, PhD, Chief Scientific Officer of Candel, will present new data from the Company’s phase 1 investigator-sponsored clinical trial evaluating CAN-3110 in patients with recurrent HGG in an oral presentation at the American Society of Gene and Cell Therapy (ASGCT) 26th Annual Meeting on May 19 in Los Angeles.
    - Results to date from the phase 1 clinical trial demonstrated that a single injection of CAN-3110 resulted in a median overall survival (mOS) of 11.6 months in patients who had failed standard of care (SoC) treatment. The Company is pursuing a repeat dosing regimen of CAN-3110, including up to six injections over four months, to determine if additional doses increase mOS.

Anticipated 2023 Milestones

- New data from the Company’s phase 1 clinical trial of CAN-3110 in patients with recurrent HGG has been accepted as an oral presentation at the ASGCT 26th Annual Meeting on May 19.
- A trials-in-progress poster from the Company’s phase 2 clinical trial of CAN-2409 with valacyclovir combined with continued PD-1 or PD-(L)1 targeting agents in patients with late-stage NSCLC will be presented at the ASCO 27th Annual Meeting on June 4.
- Updated data from the phase 2 clinical trial of CAN-2409 with valacyclovir combined with continued PD-1 or PD-(L)1 targeting agents in patients with late-stage NSCLC is expected in Q3.
- Initial data from the phase 2 clinical trial of CAN-2409 with valacyclovir combined with SoC for patients with pancreatic cancer is expected in Q4.

Financial Results for the Quarter Ended March 31, 2023

Research and Development Service Revenue, related party: Research and development service revenue, related party, was $0 for the first quarter of 2023 compared to $31,000 for the first quarter of 2022.

Research and Development Expenses: Research and development expenses were $5.5 million for the first quarter of 2023 compared to $5.4 million for the first quarter of 2022. The increase was primarily due to manufacturing and regulatory activities in support of the Company’s CAN-2409 programs, offset by lower pre-clinical costs and personnel-related expenses. Research and development expenses included non-cash stock compensation expense of $0.3 million for the first quarter of 2023 compared to $0.1 million for the first quarter of 2022.

General and Administrative Expenses: General and administrative expenses were $4.2 million for the first quarter of 2023 compared to $3.6 million for the first quarter of 2022. The increase was primarily due to increased personnel-related costs, including severance costs. General and administrative expenses included non-cash stock compensation expense of $0.4 million for the first quarter of 2023 compared to $0.3 million for the first quarter of 2022.

Net Loss: Net loss for the first quarter of 2023 was $8.8 million compared to a net loss of $0.9 million for the first quarter of 2022, and included net other income of $0.8 million and $8.1 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 March 31, 2023 were $59.3 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 March 31,

	2023	2022
Research and development service revenue, related party	$ —	$ 31
Operating expenses:		
Research and development	5,469	5,417
General and administrative	4,164	3,600
Total operating expenses	9,633	9,017
Loss from operations	(9,633)	(8,986)
Other income (expense):		
Grant income	12	0
Interest income (expense), net	103	(175)
Change in fair value of warrant liability	723	8,287
Total other income, net	838	8,112
Net loss	$ (8,795)	$ (874)
Net loss per share, basic and diluted	$ (0.30)	$ (0.03)
Weighted-average common shares outstanding, basic and diluted	28,919,810	28,690,511

Candel Therapeutics, Inc.

Consolidated Balance Sheet Data

(in thousands)

(Unaudited)

	March 31, 2023	DECEMBER 31, 2022
Cash and cash equivalents	$ 59,258	$ 70,058
Working capital (1)	56,639	66,330
Total assets	67,238	77,691
Warrant liability	1,158	1,882
Total other liabilities	26,428	28,095
Accumulated deficit	(107,884)	(99,089)
Total stockholders equity	$ 39,652	$ 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 and commercializing viral immunotherapies that elicit a 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. 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, Candel's lead product candidate from the adenovirus platform, is an off-the-shelf investigational therapy designed to produce an individualized cancer response. CAN-3110 is Candel's lead product candidate from the HSV platform. 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; 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 Annual Report on Form 10-K 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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