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

Nov 9, 2023

- *Initial survival data from phase 2 clinical trial of CAN-2409 in advanced non-small cell lung cancer (NSCLC) showed survival supportive of an increased tail on the maturing survival curve*
- *Initial data from phase 2 clinical trial of CAN-2409 in borderline resectable pancreatic cancer demonstrated an estimated survival rate of 71.4% at 36 months in patients treated with both CAN-2409 and standard of care (SoC) chemoradiation versus 16.7% in the control arm after standard of care (SoC) chemoradiation*
- *Data published in Nature demonstrated treatment with CAN-3110 nearly doubled expected median overall survival in patients with recurrent high-grade glioma (HGG); immunological changes in the tumor microenvironment and herpes simplex virus-1 seropositivity were associated with improved survival*
- *Significant discovery through the novel enLIGHTEN™ Discovery Platform demonstrated monotherapy activity of Alpha-201-macro1, the first experimental viral immunotherapy agent developed using the enLIGHTEN™ advanced analytics, in a preclinical model of breast cancer*

NEEDHAM, Mass., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing viral immunotherapies to help patients fight cancer, today reported financial results for the third quarter ended September 30, 2023, and provided a corporate update.

“Candel has made very significant progress with our viral immunotherapy platforms and oncology-focused pipeline,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “We are encouraged by the recent clinical and biomarker data for CAN-2409 in NSCLC and pancreatic cancer, and CAN-3110 in recurrent HGG. The quality of the science was recently validated by a publication in *Nature.* Our off-the-shelf investigational medicines are designed to elicit individualized, systemic anti-tumor immune responses and, to date, have shown promise for extended survival beyond historical rates, along with a generally favorable safety and tolerability profile. We observed markedly increased immune cell infiltration in immunosuppressive tumors and systemic immune activation after experimental treatment with both CAN-2409 and CAN-3110.”

“We look forward to multiple anticipated data readouts in 2024, including topline overall survival data from the phase 2 clinical trial of CAN-2409 in NSCLC in Q2 2024, topline progression-free survival data from the randomized phase 2 study of CAN-2409 vs. active surveillance alone in early localized prostate cancer, and topline disease-free survival data from the randomized phase 3 clinical trial of CAN-2409 in intermediate to high risk localized prostate cancer in Q4 2024, in addition to the first data on multiple injections of CAN-3110 in recurrent HGG in the second half of 2024,” Dr. Tak concluded.

Third Quarter 2023 & Recent Highlights

- Program Updates:
  - *CAN-2409 – Non-Small Cell Lung Cancer (NSCLC)*
    - Initial data from the phase 2 NSCLC clinical trial suggested promising extension of overall survival, consistent with an increased tail on the maturing survival curve in patients whose disease progressed despite receiving anti-PD(L)1 treatment (Cohort 2).
    - Data showed 93% of patients with long survival (≥12 months) were low or negative for PD-(L)1 expression, which supports the potential of CAN-2409 to convert patients unresponsive to immune checkpoint inhibitor treatment into long-term survivors.
    - Robust activation of the immune system and immunological correlations between early changes in key effector immune populations after CAN-2409 treatment and survival suggested the potential to use early biological readouts as predictors of clinical response.
  - *CAN-3110 - Recurrent High-Grade Glioma (HGG)*
    - Nature published results from the phase 1 investigator-sponsored clinical trial of CAN-3110 in 41 patients

with recurrent HGG.

- New findings demonstrated that the proposed dual mechanism of CAN-3110 to trigger potent oncolysis and immune activation may be further enhanced in the presence of pre-existing antibodies to HSV (herpes simplex virus)-1.Median overall survival (mOS) of 14.2 months was observed in the patients with antibodies to HSV-1 virus (66%), present either at baseline or developed after CAN-3110 treatment.
- As of the data cut-off of April 20, 2023, data support the continued tolerability of a single injection of CAN-3110 in recurrent HGG with no dose-limiting toxicity and observed nearly doubling of the expected mOS in 50 patients (Arm A and B).
- The observed increase in diversity of the T-cell receptor repertoire associated with improved survival after a single injection, suggests that CAN-3110 can induce a broad and diverse immune response against HSV-1 and against the newly released tumor antigens.
- Arm C, supported by the Break Through Cancer Foundation, is currently evaluating the effects of repeat dosing of CAN-3110 (up to six injections over four months).

- *CAN-2409 – Pancreatic Cancer*

  - Positive overall survival and immunological biomarker data were presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting for 2023, based on an interim analysis of the ongoing, randomized, phase 2 clinical trial of CAN-2409 plus prodrug together with SoC chemoradiation followed by resection for borderline resectable non-metastatic pancreatic ductal adenocarcinoma (PDAC) as of the August 21, 2023 data cutoff date.
  - An estimated survival rate of 71.4% at 36 months was observed in patients who received 2 or 3 injections of CAN-2409 regimen together with SoC chemoradiation prior to surgery, versus only 16.7% estimated survival at 36 months with SoC chemoradiation prior to surgery.
  - Patients whose cancer progressed showed an altered disease course after salvage chemotherapy with improved CA19-9 levels (biomarker of tumor burden) and ongoing survival. Similar responses were not observed in the control arm.
  - Biomarker analysis demonstrated dense aggregates of immune cells that included CD8 positive granzyme B positive cytotoxic T cells, dendritic cells, and B cells in PDAC tissue resections obtained after CAN-2409 treatment, which confirmed activation of a robust antitumoral immune response.

- *enLIGHTEN ™ Discovery Platform*

  - Presented the first experimental agent from the enLIGHTEN™ Discovery Platform, Alpha-201-macro1, during SITC. This new agent is an investigational viral immunotherapy that is designed to interfere with the CD47/ SIRPα pathway and activate innate immune surveillance. Results demonstrated monotherapy activity following local administration in a preclinical model of breast cancer.
  - Additional preclinical data presented at SITC confirmed the capability of the enLIGHTEN™ Advanced Analytics suite to predict optimal gene payload combinations to arm viral vectors, that enable the design of potential combination therapeutics to overcome tumor resistance especially in cancers resistant to immune checkpoint inhibitor treatment.

Anticipated Milestones

- Expect to report topline overall survival data on the phase 2 clinical trial of CAN-2409 plus valacyclovir combined with continued PD-(L)1 targeting agents in patients whose disease progresses despite receiving anti-PD-(L)1 treatment with late-stage NSCLC (Cohort 2) in Q2 2024.
- Expect to report topline disease-free survival data on the fully enrolled, pivotal, placebo-controlled, randomized phase 3 clinical trial of CAN-2409 in combination with valacyclovir in localized intermediate/high-risk prostate cancer in Q4 2024.
- Expect to report topline progression-free survival data on the fully enrolled, placebo-controlled, randomized phase 2 clinical trial of CAN-2409 in patients with low-to-intermediate-risk, localized, non-metastatic prostate cancer in Q4 2024.
- Expect to report clinical and immunological biomarker data in patients with recurrent HGG enrolled into Arm C, evaluating repeat dosing regimen of CAN-3110 in 2H 2024.

Financial Results for the Quarter Ended September 30, 2023

Research and Development Service Revenue, related party: Research and development service revenue, related party, was

$0 for the third quarter of 2023 compared to $31,000 for the third quarter of 2022, as the amortizable $1.0 million up-front license fee that Candel received in 2014 and 2015 from Ventagen LLC was fully recognized as of December 2022.

Research and Development Expenses: Research and development expenses were $5.8 million for the third quarter of 2023 compared to $5.4 million for the third quarter of 2022. The increase was primarily due to manufacturing and regulatory activities in support of the Company's CAN-2409 programs. Research and development expenses included non-cash stock compensation expense of $0.3 million for both the third quarter of 2023 and the third quarter of 2022.

General and Administrative Expenses: General and administrative expenses were $3.0 million for the third quarter of 2023 compared to $3.5 million for the third quarter of 2022. The decrease was primarily due to lower professional service and consulting expenses, recruiting and insurance costs. General and administrative expenses included non-cash stock compensation expense of $0.4 million for both the third quarter of 2023 and the third quarter of 2022.

Net Loss: Net loss for the third quarter of 2023 was $8.4 million compared to a net loss of $8.7 million for the third quarter of 2022, and included net other income of $0.4 million and $0.2 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 September 30, 2023 were $43.0 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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2023	2022	2023	2022
Research and development service revenue, related party	$ —	$ 31	$ —	$ 94
Operating expenses:				
Research and development	5,845	5,376	17,248	15,815
General and administrative	3,016	3,536	10,825	10,900
Total operating expenses	8,861	8,912	28,073	26,715
Loss from operations	(8,861)	(8,881)	(28,073)	(26,621)
Other income (expense):				
Grant income	12	—	36	—
Interest income	502	343	1,666	414
Interest expense	(669)	(519)	(1,922)	(1,130)
Change in fair value of warrant liability	581	369	1,449	13,626
Total other income (expense), net	426	193	1,229	12,910
Net loss	$ (8,435)	$ (8,688)	$ (26,844)	$ (13,711)
Net loss per share, basic and diluted	$ (0.29)	$ (0.30)	$ (0.93)	$ (0.48)
Weighted-average common shares outstanding, basic and diluted	28,919,810	28,891,909	28,919,810	28,798,284

Candel Therapeutics, Inc.
Consolidated Balance Sheet Data
(in thousands)

	SEPTEMBER 30, 2023 (Unaudited)	DECEMBER 31, 2022
Cash and cash equivalents	$ 42,983	$ 70,058
Working capital (1)	34,774	66,330
Total assets	50,061	77,691

Warrant liability	433	1,882
Total other liabilities	26,606	28,095
Accumulated deficit	(125,933)	(99,089)
Total stockholders equity	$ 23,022	$ 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 off-the-shelf viral immunotherapies that elicit an individualized, 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. This leads to in situ vaccination against the injected tumor and uninjected distant metastases.

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 is currently in ongoing clinical trials in NSCLC (phase 2), pancreatic cancer (phase 2), and localized, non-metastatic prostate cancer (phase 2 and phase 3). CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing investigator-sponsored phase 1 clinical trial in recurrent high-grade glioma. In addition, 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 the timing and availability of additional data, key data readout milestones and presentations, the possibility to use early biological readouts as predictor of clinical response and, expectations regarding the therapeutic benefit of its programs, including the potential for CAN-2409its programs to extend patient survival, 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; the timing of data readout milestones and presentations; that final data from our pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; 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; the Company's ability to continue as a going concern; 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
Aljanae Reynolds
Director
Wheelhouse Life Science Advisors
areynolds@wheelhouselsa.com

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