Candel Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Corporate Highlights

March 30, 2023

- *Expects to announce clinical trial data from multiple oncology programs in the second half of 2023*
- *Extends cash runway into second quarter of 2024*

NEEDHAM, Mass., March 30, 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 fourth quarter and full year ended December 31, 2022 and provided a corporate update.

“Our 2022 achievements reaffirm our belief that using our viral immunotherapies to mobilize the patient’s immune system to fight cancer represents a promising approach for the treatment of solid tumors,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “Throughout the year, we presented encouraging data, expanded our leadership team, and announced a partnership with the University of Pennsylvania, leveraging Candel’s enLIGHTEN™ Discovery Platform to create novel viral immunotherapies to enhance CAR-T cell therapies in solid tumors. Over the next few quarters of 2023, we anticipate multiple additional clinical data readouts as well as topline data in the fourth quarter of 2024 from our phase 3 clinical trial in early localized prostate cancer. We remain confident in our belief that our investigational medicines have the potential to improve the lives of patients living with cancer.”

“Our investigational viral immunotherapies have shown early clinical promise, including a persistent immune response and have been generally well tolerated,” said W. Garrett Nichols, MD, MS, Chief Medical Officer of Candel. “More specifically, data from our CAN-2409 clinical trial demonstrated robust evidence of local and systemic anti-tumor activity in patients with non-small cell lung cancer who had an inadequate response to immune checkpoint inhibitors. In addition, a single injection of CAN-3110 in patients with recurrent high-grade glioma resulted in a median overall survival of 11.6 months. We are encouraged by these data, which we believe underscore our mission to save, extend and improve the lives of patients through viral immunotherapies.”

Jason A. Amello, Chief Financial Officer of Candel, added, “I am pleased that the prudent and disciplined management of our expenditures and programs has enabled us to extend our cash runway into the second quarter of 2024, bringing us another quarter closer to our anticipated phase 3 topline data readout for prostate cancer in 2024.”

Fourth Quarter 2022 & Recent Highlights

- In October 2022, Candel entered into a collaboration with the University of Pennsylvania (UPenn) Center for Cellular Immunotherapies to use Candel’s enLIGHTEN™ Discovery Platform to potentially strengthen the effects of UPenn’s investigational CAR-T cell therapies in solid tumor models.
- On December 6, 2022, Candel hosted its R&D Day during which the Company’s leadership team and renowned external experts in oncology provided an in-depth review of the Company’s viral immunotherapy platforms and clinical pipeline.
- Program Updates:
  - *CAN-2409 – Non-Small Cell Lung Cancer (NSCLC)*
    - In December 2022, the Company announced updated data from its open-label phase 2 clinical trial evaluating CAN-2409 and valacyclovir in combination with continued PD-1/PD-L1 agents in patients with late-stage NSCLC at the Company’s R&D Day. The data demonstrated evidence of local and systemic anti-tumor activity in patients with inadequate response to previous immune checkpoint inhibitor (ICI) treatment and showed a disease control rate of 77 percent (20/26) in patients entering the trial with disease progression despite ICI treatment. Importantly, CAN-2409 demonstrated a favorable change in the trajectory of tumor growth in all patients for whom pre-enrollment scans were available. The Company is encouraged by the results and plans to present additional data in Q3 2023.
  - *CAN-2409 – Prostate Cancer*
    - In September 2021, the Company completed enrollment of 711 evaluable patients in its pivotal, placebo-controlled, randomized phase 3 clinical trial of CAN-2409 in combination with valacyclovir in localized intermediate/high-risk prostate cancer. The primary endpoint of the study is disease-free survival, which is an event-driven endpoint. The Company anticipates reporting topline data in Q4 2024.

- In May 2019, the Company completed enrollment of 187 patients in its placebo-controlled, randomized phase 2 clinical trial of CAN-2409 in patients with low-to-intermediate-risk, localized, non-metastatic prostate cancer. The primary endpoint is biopsy-proven progression-free survival. As the primary endpoint is event-driven, in February 2023 and based on a blinded review of the event rate, the Company determined that additional time is required for patient follow-up in order to collect a sufficient number of events. Accordingly, as previously communicated, the Company expects to announce topline results in Q4 2024.

- *CAN-2409 – High-Grade Glioma (HGG)*
  - In November 2022, late-breaking data from a phase 1 mechanistic clinical trial of CAN-2409 in combination with nivolumab and standard of care (SoC) treatment in patients with HGG was selected as an oral presentation at the 37th Annual Meeting of Society for Immunotherapy of Cancer. The data suggested strong systemic immune activation after a single administration of CAN-2409 into the brain during surgery. The Company believes these results provided additional evidence of the potential of CAN-2409 to induce systemic immune activation and supports the mechanistic rationale across various indications.

  - During its December R&D Day, the Company announced as part of its HGG portfolio prioritization that it plans to continue development of CAN-3110 in recurrent HGG but does not plan to pursue a phase 3 clinical trial of CAN-2409 in HGG.

- *CAN-2409 – Pancreatic Cancer*
  - In March 2023, in connection with its cost management and dynamic portfolio management initiatives, the Company elected to pause new enrollment in its randomized phase 2 clinical trial evaluating CAN-2409 in borderline resectable pancreatic adenocarcinoma subject to additional funding. Despite the pause in patient enrollment, the Company continues to expect to present initial phase 2 clinical data in Q4 2023.

  - In a previous phase 1b trial, patients with pancreatic cancer treated with CAN-2409 in addition to SoC demonstrated a greater survival duration over the expected survival of the patients treated with the existing SoC alone in a comparison to historical trial results.

- *CAN-3110 - Recurrent HGG*
  - In November 2022, the Company presented data from its phase 1 clinical trial of CAN-3110 in patients with recurrent HGG at the 27th Annual Meeting of the Society for Neuro-Oncology. Results demonstrated that a single dose of CAN-3110 resulted in a median overall survival of 11.6 months in patients who had failed SoC treatment. Furthermore, results showed that the treatment remained well tolerated with no dose limiting toxicity observed.

  - The Company believes the CAN-3110 program in recurrent HGG could be an enabling indication for future clinical trials in solid tumors outside of the brain that are characterized by Nestin expression.

- *enLIGHTEN ™ Discovery Platform*
  - During its December R&D Day, the Company introduced Candel's enLIGHTEN Discovery Platform. enLIGHTEN is a systematic, data-driven platform based on human biology to create new herpes simplex virus (HSV)-based gene constructs to modulate the tumor microenvironment by design.

Anticipated 2023 Milestones

- Updated data from the phase 2 clinical trial of CAN-2409 and valacyclovir combined with continued PD-1 or PD-L1 targeting agents in patients with NSCLC is expected in the third quarter.
- Initial data from the phase 2 clinical trial of CAN-2409 followed by valacyclovir combined with SoC for patients living with pancreatic cancer is expected in the fourth quarter.

Financial Results for the Fourth Quarter and Full-Year Ended December 31, 2022

Research and Development Service Revenue, related party: Research and development service revenue, related party, for each of the fourth quarters and full- years ended December 31, 2022 and 2021 was $31,000 and $125,000, respectively.

Research and Development Expenses: Research and development expenses were $5.0 million for the fourth quarter of 2022 compared to $3.9 million for the fourth quarter of 2021, and $20.8 million for the full-year 2022 compared to $15.2 million for the full-year 2021. The increase was primarily due to personnel-related costs for additional headcount, as well as operating expenses related to the conduct of four ongoing clinical studies. Research and development expenses included non-cash stock compensation expense of $0.2 million and $0.8 million for the fourth quarter and full-year of 2022, respectively, as compared to a non-cash stock compensation credit of $0.8 million and non-cash stock compensation expense of $1.2 million for the comparable periods in 2021.

General and Administrative Expenses: General and administrative expenses were $3.2 million for the fourth quarter of 2022 compared to $3.9 million for the fourth quarter of 2021, and $14.1 million for the full-year 2022 compared to $10.7 million for the full-year 2021. The increase was primarily due to an increase in insurance expense, recruiting and personnel-related costs, as well as professional and consulting fees associated with operating as a public company. General and administrative expenses included non-cash stock compensation expense of $0.4 million and $1.5 million for the fourth quarter and full-year of 2022, respectively, as compared to $0.4 million and $1.7 million for the comparable periods in 2021.

Net Loss: Net loss for the fourth quarter of 2022 was $5.1 million compared to net income of $1.6 million for the fourth quarter of 2021, and included net other income of $3.0 million and $9.3 million, respectively, related primarily to the change in the fair value of the Company's warrant liability. Net loss for the full-year 2022 was $18.8 million compared to a net loss of $36.1 million for the full-year 2021, and included net other income of $15.9 million and net other expense of $10.4 million, respectively, related primarily to the change in the fair value of the Company's warrant liability.

Cash Position: Cash and cash equivalents as of December 31, 2022 were $70.1 million, as compared to $82.6 million as of December 31, 2021, and reflected 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 second quarter of 2024.

Candel Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2022	**2021**	**2022**	**2021**
Research and development service revenue, related party	$ 31	$ 31	$ 125	$ 125
Operating expenses:				
Research and development	4,972	3,854	20,787	15,178
General and administrative	3,160	3,917	14,060	10,673
Total operating expenses	8,132	7,771	34,847	25,851
Loss from operations	(8,101)	(7,740)	(34,722)	(25,726)
Other income (expense):				
Grant income	48	149	48	1,076
Interest and dividend income (expense), net	226	(11)	(490)	(53)
Change in fair value of warrant liability	2,744	9,198	16,370	(11,421)
Total other income (expense), net	3,018	9,336	15,928	(10,398)
Net income (loss)	$ (5,083)	$ 1,596	$ (18,794)	$ (36,124)
Net income (loss) per share, basic	$ (0.18)	$ 0.06	$ (0.65)	$ (1.91)
Net income (loss) per share, diluted	$ (0.18)	$ 0.05	$ (0.65)	$ (1.91)
Weighted-average common shares outstanding, basic	28,899,426	28,689,842	28,823,480	18,873,048
Weighted-average common shares outstanding, diluted	28,899,426	34,642,325	28,823,480	18,873,048

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

	DECEMBER 31, 2022	**DECEMBER 31, 2021**
Cash and cash equivalents	$ 70,058	$ 82,642
Working capital (1)	66,330	79,583
Total assets	77,691	89,205
Warrant liability	1,882	18,252
Total other liabilities	28,095	6,816
Accumulated deficit	(99,089)	(80,295)
Total stockholders equity	$ 47,714	$ 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 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 is the lead product candidate from the adenovirus platform and CAN-3110 is the 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.

About CAN-2409

CAN-2409, Candel's most advanced viral immunotherapy candidate, is a replication-defective adenovirus that delivers the herpes simplex virus thymidine kinase (HSV-tk) gene to cancer cells. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. The intra-tumoral administration results in the release of tumor-specific neoantigens in the microenvironment. At the same time, the adenoviral serotype 5 capsid protein elicits a strong pro-inflammatory signal in the tumor microenvironment. This creates the optimal conditions to induce a specific CD8+ T cell mediated response against the injected tumor and uninjected distant metastases for broad anti-tumor activity. Because of its versatility, CAN-2409 has the potential to treat a broad range of solid tumors. Monotherapy activity as well as combination activity with standard of care radiotherapy, surgery, chemotherapy, and immune checkpoint inhibitors have previously been shown in several preclinical and clinical settings. Furthermore, CAN-2409 presents a favorable tolerability profile; more than 950 patients have been dosed to date, supporting the potential for combination with other therapeutic strategies without inordinate concern of overlapping adverse events. Currently, Candel is evaluating the effects of treatment with CAN-2409 in non-small cell lung cancer, pancreatic cancer, and localized, non-metastatic prostate cancer in ongoing clinical trials.

About CAN-3110

CAN-3110 is a herpes simplex virus (HSV) replication-competent viral immunotherapy candidate engineered to enhance selective killing of malignant cells while sparing healthy normal neighboring cells. CAN-3110 has been shown to selectively express ICP34.5, a key gene in HSV replication, in tumor cells that overexpress Nestin, a cytoskeletal protein. Nestin is highly expressed in glioma cells and other tumor tissue, but is absent in the healthy adult brain. The effects of multiple doses of CAN-3110 in recurrent glioblastoma are currently being evaluated in an ongoing phase 1 clinical trial.

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, include key data readout milestones; 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 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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