



Werewolf Therapeutics Provides Business Update and Highlights 2024 Strategic Outlook

January 8, 2024

- Prioritizing development of wholly owned clinical assets, WTX-124 and WTX-330; key updates from both INDUKINE™ programs anticipated in 2024 -
- WTX-124: updated interim monotherapy dose-escalation data and initial combination dose escalation data from Phase 1/1b clinical trial expected in 1H 2024 -
 - WTX-330: preliminary dose-escalation data from Phase 1 clinical trial expected in 2Q 2024 -
 - Updated cash guidance provides runway through at least the first quarter of 2025 -

WATERTOWN, Mass., Jan. 08, 2024 (GLOBE NEWSWIRE) -- Werewolf Therapeutics, Inc. (the "Company" or "Werewolf") (Nasdaq: HOWL), an innovative biopharmaceutical company pioneering the development of conditionally activated therapeutics engineered to stimulate the body's immune system for the treatment of cancer, today provided a business update and outlined its strategic outlook and expected milestones for 2024.

Werewolf outlined the following objectives as the Company's strategic priorities for 2024:

1. **Prioritize development of wholly owned clinical-stage programs** – present data updates from WTX-124 and WTX-330 while advancing their clinical development.
2. **Progress preclinical programs through IND-enabling work** – demonstrate the breadth of Werewolf's platform and portfolio opportunities.
3. **Apply PREDATOR™ platform for non-core opportunities and external innovation** –leverage Werewolf's validated technical capabilities, preclinical programs and opportunities in inflammatory diseases.
4. **Maintain disciplined spend** – prudently allocate resources according to these priorities to optimize cash runway with continued focus on clinical development of lead programs.

"2023 was an important year for Werewolf, highlighted by preliminary monotherapy data from our IL-2 program that offered proof of concept for WTX-124 and for our INDUKINE design more broadly," said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. "In 2024, we expect to share progress from our wholly owned clinical programs, with updated monotherapy data and initial combination data from WTX-124 as well as our first look at WTX-330. In particular, for WTX-124, we hope to build upon the promising signals of antitumor activity and improved therapeutic index that we observed in the highest dose cohort presented at SITC."

Dr. Hicklin continued, "In parallel, we expect to continue to progress our preclinical candidates through IND-enabling work to provide additional validation of the INDUKINE approach for novel targets, namely IL-21 and IL-18. Alongside this prioritization, we intend to seek partners who understand our unique conditional-activation expertise and protein engineering approach in areas beyond Werewolf's core focus of oncology, such as inflammatory diseases, where we believe our approach is viable."

Based on these strategic priorities, Werewolf has provided the following guidance for 2024:

WTX-124: a systemically delivered, conditionally activated Interleukin-2 (IL-2) INDUKINE molecule being developed as monotherapy or in combination with checkpoint inhibitors in multiple solid tumor types.

In November 2023, Werewolf presented first-in-human monotherapy data from the Phase 1/1b clinical trial of WTX-124 at the Society for Immunotherapy of Cancer's (SITC) 38th annual meeting. The preliminary data established proof of concept for WTX-124 and for Werewolf's INDUKINE design hypothesis. In the first half of 2024, Werewolf plans to:

- Report updated interim data from the monotherapy dose-escalation arm of the Phase 1/1b study;
- Select a recommended dose for expansion (RDE) and initiate monotherapy dose expansion arms; and
- Report initial data from the combination dose escalation cohorts of the Phase 1/1b study.

WTX-330: a systemically delivered, conditionally activated Interleukin-12 (IL-12) INDUKINE molecule being developed in refractory and/or immunologically unresponsive tumors.

Werewolf continues to progress the Phase 1 clinical trial evaluating WTX-330 as a monotherapy in patients with immunotherapy insensitive or resistant advanced or metastatic solid tumors or non-Hodgkin lymphoma. In 2024, Werewolf plans to report initial data from the Phase 1 clinical trial in the second quarter of 2024.

Preclinical Portfolio: includes development candidates WTX-712 and WTX-518, INDUKINE molecules respectively targeting IL-21 and IL-18 for treatment of cancer, as well as numerous leads in discovery.

Werewolf intends to progress these programs through IND-enabling work. In 2024, Werewolf plans to:

- Present preclinical data from WTX-712 in the first half of 2024.
- Present preclinical data from WTX-518 in the first half of 2024.
- Present preclinical data demonstrating the potential of INDUKINE molecules for inflammatory diseases by the fourth quarter of 2024.

Cash Position and Financial Guidance:

Based on updated forecasting reflecting the Company's streamlined development plans and careful cash management to date, Werewolf now expects that its cash and equivalents will be sufficient to fund its operational expenses and capital expenditure requirements through at least the first quarter of 2025.

About Werewolf Therapeutics:

Werewolf Therapeutics, Inc. is an innovative clinical-stage biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer. We are leveraging our proprietary PREDATOR™ platform to design conditionally activated molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Our INDUKINE™ molecules are intended to remain inactive in peripheral tissue yet activate selectively in the tumor microenvironment. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 (IL-2), and Interleukin-12 (IL-12) INDUKINE molecules for the treatment of solid tumors. WTX-124 is in development as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) in multiple solid tumor types. WTX-330 is in development as a single agent in refractory and/or immunotherapy unresponsive or resistant advanced or metastatic solid tumors and non-Hodgkin lymphoma. To learn more visit www.werewolfix.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risk and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Werewolf's strategy, future operations, prospects, plans, and objectives of management; the projection of the cash runway; the expected timeline for the preclinical and clinical development of product candidates and the availability of data from such preclinical and clinical development; the potential activity and efficacy of product candidates in preclinical studies and clinical trials; and the anticipated safety profile of product candidates; constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "aim," "anticipate," "approach," "believe," "contemplate," "continue," "could," "design," "designed to," "engineered," "estimate," "expect," "goal," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "promise," "should," "target," "will," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the development of product candidates, including the conduct of research activities and the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and the Company's ability to submit and obtain regulatory approval for investigational new drug applications; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; whether preliminary data from a clinical trial will be predictive of the results of the trial and future clinical trials; the Company's ability to manage cash resources and obtain additional cash resources to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in the "Risk Factors" section of the Company's most recent Form 10-Q filed with the Securities and Exchange Commission ("SEC"), and in subsequent filings the Company may make with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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