Werewolf Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Update

November 14, 2023

– Preliminary data from the WTX-124 monotherapy dose-escalation arm of the ongoing Phase 1/1b clinical trial provide compelling early evidence of dose-dependent anti-tumor and biomarker activity –

– Safety data indicate WTX-124 is generally well tolerated through cohort 4 (12 mg), with a wide therapeutic index supportive of continued dose escalation –

– Additional interim WTX-124 monotherapy data and recommended dose for expansion expected in the first half of 2024 –

– Announcing the addition of WTX-518, a novel conditionally activated IL-18 INDUKINE™molecule designed to promote activation of immune cells in the tumor microenvironment resulting in antitumor immunity, to Werewolf's pipeline of preclinical development candidates –

WATERTOWN, Mass., Nov. 14, 2023 (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 reported financial results for the third quarter ended September 30, 2023.

"Werewolf has made tremendous strides since last quarter, most notably with the presentation of promising first-in-human data from our lead clinical program, WTX-124. Preliminary data presented at SITC indicate that WTX-124 is well-tolerated and elicits monotherapy biomarker and clinical activity, including two patients with ongoing unconfirmed partial responses in the 12 mg cohort," said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. "We look forward to sharing additional data to inform our recommended dose to proceed into monotherapy expansion arms in the first half of 2024. We are also pleased to announce the addition of WTX-518, an IL-18 INDUKINE molecule, as our newest pipeline candidate and expect to present preclinical data on this molecule in the first half of 2024."

Recent Highlights and Upcoming Milestones

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

- In November 2023, at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting, Werewolf presented preliminary clinical data from the first four monotherapy dose escalation cohorts of Study WTX-124x2101, its Phase 1/1b, multi-center, open-label clinical trial evaluating WTX-124 in patients with immunotherapy sensitive advanced or metastatic solid tumors who have failed standard of care treatment, including checkpoint inhibitor therapy. The preliminary data established proof of mechanism for WTX-124 and proof of concept for Werewolf's INDUKINE design, with highlights as follows, as of the data cut-off date of October 18, 2023:
    - WTX-124 was generally well-tolerated across 16 patients, with no Grade 3 or higher treatment-related adverse events, no related serious adverse events and no evidence of vascular leak syndrome, at doses up to and including 12 mg.
    - Early evidence of antitumor activity was observed in monotherapy dose escalation cohorts 3 (6 mg) and 4 (12 mg), including two patients with ongoing unconfirmed partial responses (PR) dosed at 12 mg. An additional patient dosed at 12 mg showed evidence of anti-tumor activity.
    - These WTX-124 data are consistent with key INDUKINE pharmaceutical properties, including systemic delivery of the WTX-124 prodrug with preferential activation in the tumor microenvironment while preserving a wide therapeutic index supportive of continued dose escalation.
- Werewolf is progressing Study WTX-124x2101, and dose escalation is ongoing in both the monotherapy and combination therapy arms of the study. The Company expects to report additional interim data from monotherapy dose escalation cohorts, declaration of a recommended dose for expansion, and opening of the monotherapy expansion arms in the first half of 2024.
- In September 2023, Werewolf hosted a virtual event reviewing the IL-2 landscape and opportunity for WTX-124 among next-generation therapeutic approaches. The event featured key opinion leader in cytokines and cancer immunotherapy, Michael Atkins, M.D., William M. Scholl Professor and Vice Chair of the Department of Oncology at Georgetown University.

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

- Werewolf is progressing Study WTX-330x2101, its Phase 1, multi-center, open-label trial evaluating WTX-330 as a monotherapy in patients with immunotherapy insensitive or resistant advanced or metastatic solid tumors or non-Hodgkin

lymphoma. Enrollment is ongoing in dose-escalation.

Additional Updates:

- Werewolf is announcing the addition of WTX-518 as a pipeline candidate for preclinical development. WTX-518 is a conditionally activated IL-18 INDUKINE molecule in development for the treatment of cancer and is wholly owned by Werewolf. IL-18 is designed to promote activation of immune cells in the tumor microenvironment resulting in antitumor immunity. Werewolf expects to present preclinical data regarding this molecule in the first half of 2024.
- At SITC, Werewolf also presented five posters with preclinical and translational data supporting PREDATOR platform capabilities; pipeline programs, including both clinical candidates as well as WTX-712 (IL-21); and the potential of INDUKINE molecules as a complement to other anti-cancer approaches, such as checkpoint inhibitors and cell therapy. All posters are available at investors.werewolftx.com/news-and-events/scientific-resources.

Financial Results for the Third Quarter of 2023:

- **Cash position:** As of September 30, 2023, cash and cash equivalents were $130.1 million, compared to $137.5 million as of June 30, 2023. The Company also had restricted cash and cash equivalents of $21.2 million as of September 30, 2023, and June 30, 2023, respectively. The Company expects that its existing cash and cash equivalents will be sufficient to fund its operational expenses and capital expenditure requirements through at least the fourth quarter of 2024.
- **Collaboration revenue:** Collaboration revenue was $5.9 million for the third quarter of 2023, compared to $5.0 million for the same period in 2022. Collaboration revenue consists of revenue recognized from the Company's licensing agreement with Jazz Pharmaceuticals (Jazz) and includes fixed payments received from Jazz, plus costs incurred for research services to be reimbursed by Jazz.
- **Research and development expenses:** Research and development expenses were $10.8 million for the third quarter of 2023, compared to $13.1 million for the same period in 2022. The decrease in research and development expenses was primarily due to a decrease in contract manufacturing costs associated with WTX-124 and WTX-330. The decline in contract manufacturing costs was partially offset by an increase in clinical trial costs for WTX-124 and WTX-330.
- **General and administrative expenses:** General and administrative expenses were $4.3 million for the third quarter of 2023, compared to $4.4 million for the same period in 2022. The decrease in general and administrative expenses was primarily due to a reduction in insurance premiums, which was offset in part by an increase in costs incurred to protect the Company's intellectual property.
- **Net loss:** Net loss was $8.3 million for the third quarter of 2023, compared to $11.9 million for the same period in 2022.

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.

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 future operations, prospects, and plans; the projection of the cash runway; the expected timeline for the pre-clinical and clinical development of product candidates and availability of data from such pre-clinical and clinical development; and 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," "believe," "contemplate," "continue," "could," "design," "designed to," "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, 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 obtain sufficient 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.

Werewolf Therapeutics, Inc.
Condensed Consolidated Statements of Operations (unaudited)
(amounts in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Collaboration revenue	$ 5,897	$ 4,970	$ 18,442	$ 9,118
Operating expenses:				
Research and development	10,838	13,070	32,127	37,902
General and administrative	4,310	4,439	13,856	14,093
Total operating expenses	15,148	17,509	45,983	51,995
Operating loss	(9,251)	(12,539)	(27,541)	(42,877)
Other income	966	596	2,176	997
Net loss	$ (8,285)	$ (11,943)	$ (25,365)	$ (41,880)
Net loss per share, basic and diluted	$ (0.23)	$ (0.40)	$ (0.72)	$ (1.48)
Weighted-average common shares outstanding, basic and diluted	35,654	29,764	35,335	28,233

Werewolf Therapeutics, Inc.
Selected Condensed Consolidated Balance Sheet Data (unaudited)
(amounts in thousands)

	September 30, 2023	**December 31, 2022**
Cash and cash equivalents	$ 130,058	$ 129,315
Working capital	$ 124,819	$ 116,211
Total assets	$ 176,386	$ 160,245
Total deferred revenue	$ 2,402	$ 7,660
Total notes payable, net of discount and issuance costs	$ 39,231	$ —
Total stockholders' equity	$ 112,443	$ 122,337

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