Werewolf Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

March 11, 2025

– Full enrollment in cutaneous melanoma dose-expansion arms of Phase 1/1b clinical trial evaluating WTX-124 as monotherapy and in combination with pembrolizumab expected by the end of the first half and the second half of 2025, respectively –

– Plan to meet with the FDA in the second half of 2025 to discuss potential registrational pathways for both monotherapy and combination therapy for WTX-124 in select indications –

– Interim data from Phase 1/1b clinical trial of WTX-124 as monotherapy and in combination with pembrolizumab anticipated to be released in the fourth quarter of 2025 –

– On track to initiate Phase 1/2 dose- and regimen-finding clinical trial of WTX-330 by the end of the first quarter of 2025 –

WATERTOWN, Mass., March 11, 2025 (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 and other immune-mediated conditions, today provided a business update and reported financial results for the fourth quarter and full year ended December 31, 2024.

"Werewolf made considerable progress in 2024 with promising preliminary evidence of durable anti-tumor activity and tolerability for cytokine therapeutics as we completed the dose-escalation phase of our Phase 1/1b clinical trial in both monotherapy and in combination with pembrolizumab," said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. "We expect to build on these promising data in 2025, targeting full enrollment in the monotherapy cutaneous melanoma dose-expansion arm of the WTX-124 Phase 1/1b clinical trial by the end of the first half of 2025, and in combination with pembrolizumab by the end of the year. These data will guide conversations with regulators on potential registrational pathways for WTX-124 in the second half of the year. We anticipate providing a clinical data readout for both monotherapy and combination data and providing an update on our plans for further clinical development of WTX-124 in the fourth quarter of 2025. In addition, our PREDATOR® platform continues to demonstrate its effectiveness as we presented updated interim safety, pharmacokinetics, biomarker, and efficacy data from the WTX-330 Phase 1 clinical trial at SITC in November, which demonstrated anti-tumor activity in patients with refractory solid tumors. A Phase 1/2 dose and regimen-finding clinical trial is expected to be initiated by the end of the first quarter of 2025, which includes expansion arms in specific indications."

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 pembrolizumab in multiple solid tumor types.*

- Werewolf continues to evaluate WTX-124 as a monotherapy and in combination with pembrolizumab through the ongoing Phase 1/1b clinical trial evaluating the INDUKINE molecule in multiple solid tumor types.
- WTX-124 has shown promising monotherapy activity and an improved tolerability profile versus high dose IL-2 in heavily pretreated patients refractory to all standard-of-care therapies, including immune checkpoint inhibitors. The Company has selected 18 mg administered intravenously every two weeks (IV Q2W) as the recommended dose for monotherapy expansion arms in metastatic melanoma, renal cell carcinoma (RCC) and cutaneous squamous cell carcinoma (CSCC), as well as combination expansion arms in metastatic melanoma, RCC, and non-small cell lung cancer (NSCLC).
- Of the five previously disclosed objective responses, one monotherapy and two combination responses continue to demonstrate no evidence of disease progression, with the monotherapy complete response ongoing at greater than one year off therapy, one combination response improving from a confirmed partial response to a complete response, and both combination responses ongoing at greater than eight months.
- The cutaneous melanoma monotherapy dose-expansion arm of the Phase 1/1b clinical trial evaluating WTX-124 in a more homogeneous, less heavily pre-treated patient population is expected to be fully enrolled in the first half of 2025, and the cutaneous melanoma dose-expansion arm evaluating WTX-124 in combination with pembrolizumab is expected to be fully enrolled by the end of 2025. The Company expects to use the monotherapy and combination data to engage with regulators to discuss potential registrational pathways for WTX-124, including strategies for accelerated approval, in the second half of 2025.
- Anticipated presentation of interim data from monotherapy and combination expansion arms in the fourth quarter of 2025.

WTX-330: *a systemically delivered, conditionally activated Interleukin-12 (IL-12) INDUKINE molecule being developed in advanced or metastatic solid tumors.*

- Presented an interim update from the Phase 1 clinical trial highlighting the tolerability profile and monotherapy efficacy

signals of WTX-330 at the Society for Immunotherapy of Cancer's (SITC) 39 th annual meeting in November 2024.
- On track to initiate a Phase 1/2 dose- and regimen-finding clinical trial by the end of the first quarter of 2025 to optimize the exposure of WTX-330 in the tumor microenvironment.
- Pending data from Phase 1/2 dose- and regimen-finding trial, anticipate opening expansion arms in selected tumor types.

Preclinical Portfolio: *includes development candidates WTX-712 and WTX-518, our Interleukin-21 (IL-21) and binding protein resistant Interleukin-18 (IL-18) INDUKINE molecules, respectively, for treatment of cancer, and WTX-921, a first-of-its-kind Interleukin-10 (IL-10) INDUKINE molecule for the treatment of inflammatory bowel disease (IBD) and potentially other inflammatory diseases.*

Financial Results for the Fourth Quarter and Full Year 2024:

- **Cash position:** As of December 31, 2024, cash and cash equivalents were $111.0 million, compared to $134.3 million as of December 31, 2023. The Company also had restricted cash and cash equivalents of $1.2 million and $21.2 million as of December 31, 2024 and December 31, 2023, respectively. The Company believes its existing cash and cash equivalents at December 31, 2024 will be sufficient to fund operational expenses and capital expenditure requirements through at least the second quarter of 2026.
- **Collaboration revenue:** No collaboration was recognized during fourth quarter of 2024 due to the fact that Werewolf substantially completed its performance obligations under the collaboration agreement with Jazz Pharmaceuticals (Jazz) during the second quarter of 2024. Comparatively, collaboration revenue was $1.5 million for the fourth quarter of 2023. Collaboration revenue was $1.9 million for the full year 2024, compared to $19.9 million for the same period in 2023. Collaboration revenue consists of revenue recognized from the Company's licensing agreement with 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 $15.7 million for the fourth quarter of 2024, compared to $9.6 million for the same period in 2023. Research and development expenses were $56.4 million for the full year 2024, compared to $41.8 million for the full year 2023.
- **General and administrative expenses:** General and administrative expenses were $4.6 million for the fourth quarter of 2024, compared to $4.8 million for the same period in 2023. General and administrative expenses were $19.0 million for the full year 2024, compared to $18.7 million for the full year 2023.
- **Net loss:** Net loss was $20.4 million for the fourth quarter of 2024, compared to $12.0 million for the same period in 2023. Net loss was $70.5 million for the full year 2024, compared to $37.4 million for the full year 2023.

About Werewolf Therapeutics:
Werewolf Therapeutics, Inc., is an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer and other immune-mediated conditions. The Company is leveraging its 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. Werewolf's INDUKINE molecules are intended to remain inactive in peripheral tissue yet activate selectively in the tumor microenvironment. The Company's most advanced clinical stage product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 (IL-2) and Interleukin-12 (IL-12) INDUKINE molecules, respectively, for the treatment of solid tumors. Werewolf is advancing WTX-124 in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor and WTX-330 in multiple tumor types or Non-Hodgkin Lymphoma as a single agent. To learn more visit www.werewolftx.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks 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," "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 or interim data from a clinical trial will be predictive of the future 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue	$ —	$ 1,501	$ 1,885	$ 19,943
Operating expenses:				
Research and development	15,727	9,649	56,434	41,776
General and administrative	4,621	4,814	19,045	18,670
Total operating expenses	20,348	14,463	75,479	60,446
Operating loss	(20,348)	(12,962)	(73,594)	(40,503)
Other (expense) income	(52)	959	3,079	3,135
Net loss	$ (20,400)	$ (12,003)	$ (70,515)	$ (37,368)
Net loss per share, basic	$ (0.46)	$ (0.33)	$ (1.63)	$ (1.05)
Net loss per share, diluted	$ (0.46)	$ (0.33)	$ (1.63)	$ (1.05)
Weighted-average common shares outstanding, basic	44,478,140	36,570,280	43,332,088	35,646,572
Weighted-average common shares outstanding, diluted	44,478,140	36,570,280	43,859,664	35,646,572

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

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 110,995	$ 134,343
Working capital	$ 97,886	$ 118,992
Total assets	$ 126,929	$ 174,833
Total deferred revenue	$ —	$ 1,340
Total notes payable, net of discount and issuance costs	$ 26,095	$ 39,323
Total stockholders' equity	$ 73,390	$ 111,374

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