Werewolf Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

March 7, 2024

– Additional monotherapy dose-escalation data from ongoing Phase 1/1b clinical trial of WTX-124 expected to be presented in the first half of 2024 –

– WTX-124 recommended dose for expansion (RDE), initiation of monotherapy dose expansion arms and initial combination dose-escalation data also expected in the first half of 2024 –

– Preliminary data from Phase 1 clinical trial of WTX-330 expected in the second quarter of 2024 –

– Updated cash guidance provides runway through at least the second quarter of 2025 –

WATERTOWN, Mass., March 07, 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 reported financial results for the fourth quarter and full year ended December 31, 2023.

“Werewolf made considerable progress in 2023, setting up 2024 as a year of execution across our pipeline,” said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. “In the first half of this year, we plan to present additional clinical data from our Phase 1/1b clinical trial of WTX-124, including updated monotherapy data and initial combination data, which we anticipate will build on the promising signals of antitumor activity and improved therapeutic index that we observed in the data presented at SITC last year. In addition, we plan to share data further demonstrating the performance of our platform in our preclinical programs at AACR. We also plan to share initial clinical data from WTX-330, our second clinical candidate, in the second quarter of 2024.”

“Additionally, I would like to express my deep appreciation to Cindy Seidel-Dugan, Ph.D., Werewolf’s Chief Scientific Officer, who is retiring effective March 29, 2024, after a long and successful career in the biopharmaceutical industry. Cindy was a founding member of the Werewolf Executive Team and has been instrumental in establishing Werewolf's innovative science, developing our INDUKINE technology, and shepherding our lead candidates through the discovery and IND-enabling process. We have benefited greatly from Cindy’s significant expertise, and the strong scientific leadership team she has built that will ensure continued success going forward. We wish Cindy the very best in her retirement.”

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.

- In November 2023, at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting, Werewolf presented first-in-human monotherapy data from the Phase 1/1b clinical trial of WTX-124. These preliminary data established proof of mechanism for WTX-124 and proof of concept for Werewolf’s INDUKINE design hypothesis.
- In the first half of 2024, Werewolf expects to present additional interim dose-escalation data from the monotherapy dose-escalation arm, nominate a recommended dose for expansion and initiate monotherapy dose expansion arms.
- Additionally, Werewolf continues to progress combination dose escalation cohorts of the Phase 1/1b clinical trial and plans to report initial clinical data from this arm in the first half of 2024.

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

**Preclinical Portfolio**: includes development candidates WTX-712 and WTX-518, INDUKINE molecules targeting IL-21 and IL-18, respectively, for treatment of cancer.

- Werewolf plans to present preclinical data from WTX-712 and WTX-518 at the 2024 AACR Annual Meeting on antitumor activity in the delivery of IL-21 or IL-18, respectively, to the tumor microenvironment in mouse tumor models. These programs are currently progressing through IND-enabling work.

  - Abstract Number: 4078
  - Title: WTX-712, a conditionally active IL-21 INDUKINETM molecule, induces a strong anti-tumor phenotype through
Quarter and Full Year:
As of December 31, 2023, cash and cash equivalents were $134.3 million, compared to $129.3 million as of December 31, 2022.

Net loss was $12.0 million for the fourth quarter of 2023, compared to $11.9 million for the same period in 2022.

Research and development expenses were $9.6 million for the fourth quarter of 2023, compared to $4.6 million for the same period in 2022. General and administrative expenses were $18.7 million for the fourth quarter of 2023, compared to $15.9 million for the same period in 2022.

Collaboration revenue: Collaboration revenue was $1.5 million for the fourth quarter of 2023, compared to $7.3 million for the same period in 2022, and $19.9 million for the full year 2023, compared to $16.4 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 $9.6 million for the fourth quarter of 2023, compared to $15.9 million for the same period in 2022. Research and development expenses were $41.8 million for the full year 2023, compared to $53.8 million for the full year 2022.

General and administrative expenses: General and administrative expenses were $4.8 million for the fourth quarter of 2023, compared to $4.6 million for the same period in 2022. General and administrative expenses were $18.7 million for the full year 2023, compared to $18.7 million for the full year 2022.

Net loss: Net loss was $12.0 million for the fourth quarter of 2023, compared to $11.9 million for the same period in 2022. Net loss was $37.4 million for the full year 2023, compared to $53.8 million for the full year 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 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 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.

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

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<thead>
<tr>
<th></th>
<th>Three Months Ended December 31,</th>
<th>Year Ended December 31,</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>2023</td>
<td>2022</td>
</tr>
<tr>
<td>Revenue:</td>
<td></td>
<td></td>
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<tr>
<td>Collaboration revenue</td>
<td>$1,501</td>
<td>$7,283</td>
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<td>Operating expenses:</td>
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<tr>
<td>Research and development</td>
<td>9,649</td>
<td>15,859</td>
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<tr>
<td>General and administrative</td>
<td>4,814</td>
<td>4,603</td>
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<tr>
<td>Total operating expenses</td>
<td>14,463</td>
<td>20,462</td>
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<tr>
<td>Operating loss</td>
<td>(12,962)</td>
<td>(13,179)</td>
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<tr>
<td>Other income</td>
<td>959</td>
<td>1,249</td>
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<tr>
<td>Net loss</td>
<td>$ (12,003)</td>
<td>$ (11,930)</td>
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<tr>
<td>Net loss per share, basic and diluted</td>
<td>$ (0.33)</td>
<td>$ (0.39)</td>
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<tr>
<td>Weighted-average common shares outstanding, basic and diluted</td>
<td>36,570,280</td>
<td>30,734,797</td>
</tr>
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Werewolf Therapeutics, Inc.
Selected Consolidated Balance Sheet Data (unaudited)
(amounts in thousands)

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2023</th>
<th>December 31, 2022</th>
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<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$134,343</td>
<td>$129,315</td>
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<td>Working capital</td>
<td>$118,992</td>
<td>$116,211</td>
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<tr>
<td>Total assets</td>
<td>$174,833</td>
<td>$160,245</td>
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<td>Total deferred revenue</td>
<td>$1,340</td>
<td>$7,660</td>
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<tr>
<td>Total notes payable, net of discount and issuance costs</td>
<td>$39,323</td>
<td>$ —</td>
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<tr>
<td>Total stockholders’ equity</td>
<td>$111,374</td>
<td>$122,337</td>
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</table>

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