UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 7, 2024**

WEREWOLF THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40366**	**82-3523180**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Talcott Ave, 2nd Floor Watertown, Massachusetts	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: **(617) 952-0555**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	HOWL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2024, Werewolf Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing financial results for the quarter ended September 30, 2024. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On November 7, 2024, the Company issued a press release announcing certain preclinical and clinical data being presented at the Society for Immunotherapy of Cancer's 39th Annual Meeting taking place from November 6-10, 2024, in Houston, Texas. A copy of the Company's press release is attached as exhibit 99.2 hereto and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release issued by the Company on November 7, 2024
99.2	Press release issued by the Company on November 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Cautionary Note Regarding Forward-Looking Statements

Any statements in this Current Report on Form 8-K about the Company's future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to substantial risks and uncertainties and actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include statements regarding the Company's strategy, future operations, prospects, plans, objectives of management, the expected timeline regarding the clinical development of product candidates, including the announcement of data, the potential activity and efficacy of product candidates in preclinical studies and clinical trials, and the timing and outcome of planned meetings with regulatory authorities. 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, 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 interim or 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 Current Report on Form 8-K represent the Company's views as of the date of this Current Report on Form 8-K. 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 Current Report on Form 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

WEREWOLF THERAPEUTICS, INC.

Date: November 7, 2024

By: /s/ Timothy W. Trost
Timothy W. Trost
Chief Financial Officer and Treasurer

Exhibit 99.1

Werewolf Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

– *Interim data from ongoing Phase 1 clinical trial of WTX-330, further characterizing tolerability and activity profile, to be presented at SITC Annual Meeting* –

– *Monotherapy and combination expansion arms open and enrolling in ongoing Phase 1/1b clinical trial of WTX-124; initial efficacy data from monotherapy expansion arms anticipated in the first half of 2025* –

– *Introduced WTX-921, a promising new development candidate and first-of-its kind IL-10 INDUKINE™ molecule for the treatment of inflammatory diseases* –

– *Updated cash guidance provides runway through at least the second quarter of 2026* –

Watertown, Mass., November 7, 2024 – 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 third quarter ended September 30, 2024.

"Werewolf continues to progress our pipeline of INDUKINE therapeutics, led by WTX-124 and WTX-330, which have together provided preliminary clinical validation of our innovative design. To date, initial datasets from both programs have highlighted well-tolerated monotherapy activity in the outpatient setting, establishing WTX-124's potential best-in-class profile among next-generation approaches to IL-2 and WTX-330's potential first-in-class design which enables a wider exposure and therapeutic window of IL-12 than previously achieved," said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. "We continue to progress WTX-124, with both monotherapy and combination expansion arms enrolling in multiple indications. We anticipate sharing monotherapy expansion data in the first half of 2025, which we expect will guide the next steps for the development program. In addition, we look forward to presenting interim data from our Phase 1 WTX-330 clinical trial at SITC this weekend, including the emerging tolerability and clinical activity profile for WTX-330."

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 progress the ongoing Phase 1/1b clinical trial evaluating WTX-124 as a monotherapy and in combination with pembrolizumab.
  - Following the selection of 18 mg WTX-124 administered intravenously every two weeks (IV Q2W) as the monotherapy recommended dose for expansion (RDE), the Company has opened monotherapy expansion arms and is actively enrolling patients with metastatic melanoma, renal cell carcinoma (RCC) and cutaneous squamous cell carcinoma (CSCC) who have failed immune checkpoint inhibitor therapy.
  - The Company has also selected 18 mg WTX-124 administered IV Q2W as its RDE for the combination with pembrolizumab and has opened combination expansion arms in metastatic melanoma, RCC, and non-small cell lung cancer (NSCLC).
  - Previously, the Company disclosed that two patients with metastatic melanoma treated in the 12 mg combination dose escalation cohort had partial and near-partial responses observed in preliminary data. Both patients now have confirmed partial responses, and both patients have remained progression free on study for more than 7 months.
  - The Company also previously disclosed that one patient with advanced CSCC treated in the 12 mg monotherapy dose escalation cohort had a documented complete response and then discontinued study drug at 21 weeks. This patient has remained in complete remission for over twelve months.
  - Cumulative biomarker data from tumor biopsies continue to provide evidence that baseline CD8+ effector T cells are relevant to clinical responses and that there is no evidence of Treg activation with treatment.

- In the first half of 2025, Werewolf expects to provide an update on the WTX-124 clinical development program, including data from the monotherapy expansion arms that are evaluating WTX-124 in more homogenous, less heavily pre-treated patient populations to inform future development priorities.
- Pending additional insight into the clinical profile, Werewolf intends to engage with regulators to discuss potential registrational pathways for WTX-124, including strategies for monotherapy accelerated approval.

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

- Werewolf plans to present updated interim safety and efficacy data from its ongoing Phase 1 clinical trial of WTX-330 in patients with advanced or metastatic solid tumors or non-Hodgkin lymphoma at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, being held November 6-10, 2024, in Houston, Texas. Presentation details are as follows:
  - **Title:** The tumor-activated IL-12 prodrug WTX-330 expanded/activated tumor infiltrating lymphocytes and caused tumor regression in patients with refractory solid tumors: Interim data from an ongoing Ph1 study
  - **Abstract Number:** 672
  - **Session Date and Time:** Saturday, Nov. 9, 2024; 9:00 a.m.–8:30 p.m. CT.
  - **Location:** George R. Brown Convention Center - Exhibit Halls A B
- In June 2024, the Company shared a preliminary program update, reflecting the same June 12, 2024, data cut-off as captured in the SITC abstract, showing an improved therapeutic index with systemic administration of WTX-330, producing clinical activity at generally well-tolerated doses, with a 22-fold higher systemic prodrug exposure compared to recombinant IL-12 at its maximum tolerated dose.
- The data to be presented at SITC will expand on this initial update, further characterizing safety, pharmacokinetics (PK), biomarkers and clinical activity and capturing additional patients treated since this data cut-off.

Preclinical Portfolio: *includes development candidates WTX-712 and WTX-518, INDUKINE molecules targeting IL-21 and IL-18, respectively, for treatment of cancer and WTX-921, an INDUKINE molecule delivering IL-10 for treatment of inflammatory diseases.*

- In October 2024, Werewolf announced the addition of WTX-921, a novel IL-10 INDUKINE development candidate for the treatment of inflammatory bowel disease and potentially other inflammatory diseases, to its pipeline, thereby increasing the breadth of the PREDATOR™ platform approach in therapeutic areas outside of oncology.
- At SITC, the Company plans to present a poster highlighting the distinct mechanisms by which IL-2, IL-12, binding protein resistant IL-18, and IL-21 accomplish antitumor immunity in mice. Presentation details are as follows:
  - **Title:** INDUKINE™ Molecules Delivering Various Cytokines Utilize Unique Mechanisms of Action to Drive Anti-Tumor Efficacy in Murine Syngeneic Tumor Models
  - **Abstract Number:** 955
  - **Session Date and Time:** Friday, Nov. 8, 2024; 9:00 a.m. – 8:30 p.m. CT.
  - **Location:** George R. Brown Convention Center - Exhibit Halls A B

Financial Results for the Third Quarter of 2024:

- **Cash position:** As of September 30, 2024, cash and cash equivalents were $122.8 million, compared to $135.3 million as of June 30, 2024. The Company believes its existing cash and cash equivalents as of September 30, 2024, will be sufficient to fund operational expenses and capital expenditure requirements through at least the second quarter of 2026.
- **Collaboration revenue:** No collaboration revenue was recognized during the third 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 $5.9 million for the third quarter of 2023, which 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 $12.5 million for the third quarter of 2024, compared to $10.8 million for the same period in 2023. The increase in research and development expenses was primarily due to the Company's development efforts for WTX-124 and

WTX-330, which continue to progress through their respective clinical trials, resulting in higher clinical trial costs and higher manufacturing costs to support those trials.

- **General and administrative expenses:** General and administrative expenses were $4.6 million for the third quarter of 2024, compared to $4.3 million for the same period in 2023.
- **Net loss:** Net loss was $16.7 million for the third quarter of 2024, compared to $8.3 million for the same period in 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; the anticipated safety profile of product candidates; and the upcoming presentations at SITC; 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 or interim 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.
Condensed Consolidated Statements of Operations (unaudited)
(amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Collaboration revenue	$ —	$ 5,897	$ 1,885	$ 18,442
Operating expenses:				
Research and development	12,528	10,838	40,707	$ 32,127
General and administrative	4,596	4,310	14,424	13,856
Total operating expenses	17,124	15,148	55,131	45,983
Operating loss	(17,124)	(9,251)	(53,246)	(27,541)
Other income	451	966	3,131	2,176
Net loss	$ (16,673)	$ (8,285)	$ (50,115)	$ (25,365)
Net loss per common share, basic	$ (0.38)	$ (0.23)	$ (1.17)	$ (0.72)
Net loss per common share, diluted	$ (0.38)	$ (0.23)	$ (1.19)	$ (0.72)
Weighted-average common shares outstanding, basic	43,704,836	35,653,924	42,947,282	35,335,286
Weighted-average common shares outstanding, diluted	43,704,836	35,653,924	43,386,287	35,335,286

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

	September 30, 2024	**December 31, 2023**
Cash and cash equivalents	$ 122,827	$ 134,343
Working capital	$ 113,371	$ 118,992
Total assets	$ 140,036	$ 174,833
Total deferred revenue	$ —	$ 1,340
Total notes payable, net of discount and issuance costs	$ 25,617	$ 39,323
Total stockholders' equity	$ 89,379	$ 111,374

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Exhibit 99.2

Werewolf Therapeutics Presents Preclinical and Clinical Data at the Society for Immunotherapy of Cancer's (SITC) 39th Annual Meeting

– *Interim phase 1 clinical trial update reveals the clinical potential of the tumor-activated IL-12 prodrug WTX-330, with favorable tolerability profile and encouraging efficacy signals* –

– *Additional preclinical data demonstrate INDUKINE™ molecules' anti-tumor potency with distinct immune activation profiles across four cytokines* –

WATERTOWN, Mass., November 7, 2024 – 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 shared clinical and preclinical data at the 2024 Society for Immunotherapy of Cancer's (SITC) 39th Annual Meeting, taking place November 6-10 in Houston, Texas.

WTX-330, a potential first-in-class systemically delivered IL-12 therapy selectively activated in the tumor microenvironment, is currently being evaluated in a Phase 1 clinical trial: NCT05678998. This is Werewolf's second clinical program to validate the INDUKINE design, delivering potent immune mechanisms to the tumor with improved tolerability and evidence of clinical efficacy. Preliminary clinical findings presented at SITC demonstrate WTX-330's promising therapeutic potential as a monotherapy, exhibiting a favorable tolerability profile and inducing tumor shrinkage in patients with treatment-resistant solid tumors, including those tumors that are less sensitive to immunotherapy. A Phase 1/2 dose- and regimen-finding clinical trial, designed to optimize WTX-330 exposure in the tumor microenvironment and explore activity in selected indications, is expected to begin enrolling in the first half of 2025.

"The data from this first-in-human trial of WTX-330 combined with the observed monotherapy activity seen in both immunotherapy sensitive and resistant solid tumors in heavily pretreated patients, reinforces our belief in WTX-330's potential to address critical unmet needs in oncology," said Randi Isaacs, M.D., Chief Medical Officer. "We are excited to advance the development of this novel therapeutic and explore its full clinical potential for the benefit of patients."

As of October 7, 2024, the study had enrolled twenty-five patients with diverse solid tumors, including microsatellite stable colorectal cancer (MSS CRC), cholangiocarcinoma, metastatic cutaneous melanoma, and non-small cell lung cancer (NSCLC), with more than 70% of patients having received at least two prior lines of therapy for metastatic disease. Key findings include:

- **Favorable tolerability profile:** Treatment-related adverse events (AEs) were primarily mild to moderate (most commonly fatigue, increased aspartate transaminase/alanine transaminase (AST/ALT), pyrexia, and neutropenia); severe AEs occurred but were manageable and reversible.
- **Pharmacokinetic improvements over rhIL-12:** WTX-330 had 22-fold greater plasma exposure than the reported maximum tolerated dose of rhIL-12 but with low levels of active IL-12 (<1.6% of prodrug).
- **IL-12 activity and tumor immune activation:** Evidence of IL-12 activity in the tumor microenvironment with four patients with MSS CRC showing evidence of tumor immune activation in on-treatment tumor biopsies.
- **Antitumor activity**: A 76 year old patient with diffuse in-transit metastatic melanoma who had progressed on adjuvant pembrolizumab achieved a Response Evaluation Criteria in Solid Tumors (RECIST) confirmed partial response.

Additionally, Werewolf presented preclinical data demonstrating the ability of INDUKINE molecules containing IL-2, IL-12, IL-21, or IL-18 cytokines to generate cytokine-specific antitumor immunity as monotherapy in mice bearing syngeneic tumors. These data revealed unique pharmacological profiles for each cytokine, underscoring the strategic rationale to develop each as an INDUKINE molecule for targeted therapeutic applications.

About WTX-330
WTX-330 was designed to be a systemically dosed prodrug with the ability to deliver fully active IL-12 selectively into the tumor microenvironment via targeted intratumoral activation of the INDUKINE molecule, potentially broadening the therapeutic window and promoting local activation and immune response against the tumor.

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