

**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): **August 8, 2024**

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40366
(Commission
File Number)

82-3523180
(IRS Employer
Identification No.)

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

02472
(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 August 8, 2024, Werewolf Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended June 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 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release issued by the Company on August 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 8, 2024

By: /s/ Timothy W. Trost

Timothy W. Trost

Chief Financial Officer and Treasurer



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

- Positive data from ongoing Phase 1/1b clinical trial of WTX-124 presented at American Society of Clinical Oncology (ASCO) Annual Meeting –
 - Encouraging signs of clinical activity at tolerable doses disclosed from ongoing Phase 1 clinical trial of WTX-330 –
- Updated data on WTX-124 in combination with pembrolizumab and opening of expansion arms anticipated in the second half of 2024 –
 - Update on WTX-330 dose escalation and expansion data anticipated at a medical meeting in the fourth quarter of 2024 –

Watertown, Mass., August 8, 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 second quarter ended June 30, 2024.

“We believe the data recently presented from our WTX-124 and WTX-330 clinical programs displays the meaningful impact we can have on patients through our INDUKINE™ approach, and we are well positioned to advance both programs towards key inflection points in the coming quarters,” said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. “We continue to focus on enrollment in these two clinical trials and look forward to providing additional clinical data updates as we look to address the unmet medical needs for cancer patients with late-stage disease.”

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 June 2024, at the American Society for Clinical Oncology (ASCO) Annual Meeting, Werewolf presented additional interim data from the monotherapy dose-escalation arm and preliminary dose-escalation data from the combination arm of its ongoing Phase 1/1b clinical trial of WTX-124. The updated data showcased that WTX-124 was clinically active and generally well-tolerated in patients, with highlights as follows as of the May 1, 2024, cutoff date:
 - WTX-124 as a monotherapy achieved three objective clinical responses, including one durable confirmed complete response and two partial responses in patients who were relapsed/refractory to immune checkpoint inhibitor therapy.
 - Responding patients had 100% regression of target lesions with responses occurring within the first two cycles of therapy and showing durability at the recommended dose for expansion (RDE).
 - Related treatment emergent adverse events were primarily mild to moderate in severity, manageable and reversible; no new safety signals were identified when WTX-124 was combined with pembrolizumab.
 - Analysis of paired tumor biopsies by NanoString suggests that WTX-124 robustly activated/expanded effector T cells preferentially over Tregs.
 - WTX-124 was clinically active and generally well tolerated in patients, not all of whom would be eligible for high dose IL-2 based on age, indication or other factors.
- Werewolf has selected 18 mg administered intravenously every two weeks (IV Q2W) as the monotherapy RDE to progress into the Phase 1b dose expansion portion of the trial based on clinical activity and acceptable safety in the outpatient setting.
- Werewolf disclosed data that demonstrated that the combination of WTX-124 with pembrolizumab was generally well tolerated with biomarker activity supporting the potential for combination efficacy and clinical activity was observed in two melanoma patients at the 12 mg combination dose level.



- Dose escalation is ongoing for WTX-124 in combination with pembrolizumab, with updated data and opening of expansion arms anticipated in the second half of 2024.

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

- In June 2024, Werewolf announced initial 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. The data demonstrated that administration of WTX-330 reached therapeutically relevant exposure levels of systemically delivered IL-12 prodrug, with highlights as follows as of the June 12, 2024, cutoff date:
 - Compared to previous IL-12 therapeutic strategies at 500 ng/kg, at the 0.024 mg/kg dose, WTX-330 demonstrated an approximately 23-fold higher systemic drug concentration of IL-12 prodrug delivered to patients in the outpatient setting, with low free IL-12 levels across all dose levels.
 - One patient with metastatic melanoma achieved an unconfirmed partial response when treated with 0.024 mg/kg WTX-330 IV Q2W. Two additional patients with microsatellite stable colorectal cancer were treated with 0.032 mg/kg WTX-330 IV Q2W and achieved Response Evaluation Criteria in Solid Tumors (RECIST) stable disease.
 - All patients exhibited mild to moderate treatment-related toxicities primarily associated with the first dose, with no Grade 4 or Grade 5 related adverse events. Two patients experienced reversible dose-limited toxicities at the 0.032 mg/kg dose level.
- Werewolf anticipates sharing additional results from the checkpoint inhibitor-resistant or -naïve relapsed or refractory advanced tumor patient expansion arms in the fourth 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 and an INDUKINE molecule delivering IL-10 for treatment of Irritable Bowel Disease.*

- During the American Association for Cancer Research Annual Meeting in April 2024, Werewolf presented two posters detailing progress of WTX-518 and WTX-712 preclinical programs, which the Company is progressing through investigational new drug application-enabling studies:
 - **WTX-518:** Demonstrated in vitro activity unimpeded by IL-18BP and selectivity that delivers active binding protein resistant (BPR) IL-18 to the tumor microenvironment, eliciting complete tumor regression in an MC38 mouse tumor model.
 - **WTX-712:** Demonstrated antitumor activity and tumor regression in the MC38 mouse tumor model. IL-21 was observed to achieve superior anti-tumor efficacy compared to IL-2 therapy in mouse tumor models that are highly resistant to anti-PD-1/PD-L1 treatment.
- During the American Association of Immunologists Meeting in May 2024, Werewolf presented a poster for its conditionally active IL-10 INDUKINE™ molecules for the treatment of inflammatory bowel disease.
 - **Novel INDUKINE Molecules:** Data demonstrated application of the Company's PREDATOR® platform in immune-mediated disease, indicating that IL-10 INDUKINE molecules were peripherally inactive and conditionally active in target tissue thereby preventing intestinal histological damage and inhibiting inflammatory cytokine production in mouse models of colitis.

Financial Results for the Second Quarter of 2024:

- **Cash position:** As of June 30, 2024, cash and cash equivalents were \$135.3 million, compared to \$139.2 million as of March 31, 2024. The Company believes its existing cash and cash equivalents as of June 30, 2024, will be sufficient to fund operational expenses and capital expenditure requirements through at least the first quarter of 2026.
- **Collaboration revenue:** Collaboration revenue was \$1.1 million for the second quarter of 2024, compared to \$8.1 million for the same period in 2023. Collaboration revenue consists of revenue recognized from the Company's collaboration agreement with Jazz Pharmaceuticals (Jazz) and includes fixed payments received from Jazz, plus costs incurred for research services to be reimbursed by Jazz. As of June 30, 2024, Werewolf substantially completed its performance obligations under the collaboration agreement, so all remaining deferred revenue related to the collaboration agreement has been recognized.
- **Research and development expenses:** Research and development expenses were \$15.3 million for the second quarter of 2024, compared to \$9.6 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 \$4.8 million for the second quarter of 2024, compared to \$4.6 million for the second quarter of 2023.
- **Net loss:** Net loss was \$17.2 million for the second quarter of 2024, compared to \$5.1 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. 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 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. We expect to advance 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.

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-K 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[®], the WEREWOLF logo, PREDATOR[®], INDUKINE[™] and other Werewolf trademarks, service marks, graphics and logos are trade names, trademarks or registered trademarks of Werewolf Therapeutics, Inc., in the United States or other countries. All rights reserved.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue	\$ 1,143	\$ 8,081	\$ 1,885	\$ 12,545
Operating expenses:				
Research and development	15,271	9,583	28,179	\$ 21,289
General and administrative	4,832	4,565	9,828	9,546
Total operating expenses	20,103	14,148	38,007	30,835
Operating loss	(18,960)	(6,067)	(36,122)	(18,290)
Other income	1,711	969	2,680	1,210
Net loss	\$ (17,249)	\$ (5,098)	\$ (33,442)	\$ (17,080)
Net loss per common share, basic	\$ (0.40)	\$ (0.14)	\$ (0.79)	\$ (0.49)
Net loss per common share, diluted	\$ (0.43)	\$ (0.14)	\$ (0.82)	\$ (0.49)
Weighted-average common shares outstanding, basic	43,521,406	35,557,701	42,564,342	35,173,327
Weighted-average common shares outstanding, diluted	44,043,184	35,557,701	42,825,231	35,173,327

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

	June 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 135,303	\$ 134,343
Working capital	\$ 127,346	\$ 118,992
Total assets	\$ 153,703	\$ 174,833
Total deferred revenue	\$ —	\$ 1,340
Total notes payable, net of discount and issuance costs	\$ 25,163	\$ 39,323
Total stockholders' equity	\$ 104,018	\$ 111,374

Investor Contact:

John Norton
Precision AQ
212.362.1200
John.norton@precisionaq.com

Media Contact:

Amanda Sellers
Deerfield Group
301.332.5574
amanda.sellers@deerfieldgroup.com

Company Contact:

Ellen Lubman
Chief Business Officer
Werewolf Therapeutics
elubman@werewolf.tx.com