

**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 10, 2023**

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 10, 2023, Werewolf Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended June 30, 2023. 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.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on August 10, 2023
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 10, 2023

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



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

- Phase 1/1b clinical trial for IL-2 INDUKINE™ WTX-124 progressing in patients with advanced or metastatic solid tumors; initial first-in-human clinical data from monotherapy dose-escalation arm expected in 4Q 2023 -

- Phase 1 clinical trial for IL-12 INDUKINE WTX-330 progressing in patients with advanced or metastatic solid tumors or lymphoma -

Watertown, Mass., August 10, 2023 – 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 second quarter ended June 30, 2023.

“Throughout the second quarter, we have continued advancing our INDUKINE pipeline with ongoing enrollment of our first-in-human clinical trials for WTX-124 and WTX-330, our two lead programs,” said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. “We look towards the fourth quarter, when we anticipate sharing initial safety, tolerability, pharmacokinetics and biomarker data from our Phase 1/1b trial of WTX-124 in multiple solid tumors. Additionally, we are pleased that Jazz Pharmaceuticals has announced the Investigational New Drug (IND) application clearance of JZP898 (formerly WTX-613), an engineered IFN α INDUKINE molecule. Werewolf continues to operate from a position of financial strength with a cash runway projected to carry us through at least the fourth quarter 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 KEYTRUDA® (pembrolizumab) in multiple solid tumors.*

- Werewolf is progressing Study WTX-124x2101, its Phase 1/1b, multi-center, open-label clinical trial evaluating WTX-124 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) in patients with immunotherapy sensitive advanced or metastatic solid tumors who have failed standard of care, including prior checkpoint inhibitor therapy.
- Enrollment is ongoing in monotherapy dose-escalation and combination therapy cohorts, and the Company anticipates reporting initial safety, tolerability, pharmacokinetics and biomarker data from monotherapy dose escalation in the fourth quarter of 2023.

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.



JZP898 (Formerly WTX-613): *an engineered IFN α INDUKINE pro-drug that is activated specifically within the tumor microenvironment where it can stimulate IFN α receptors on cancer-fighting immune effector cells.*

- In April 2022, Werewolf entered into an exclusive global collaboration and license agreement with Jazz Pharmaceuticals under which Werewolf is responsible for certain pre-clinical development and other development activities with respect to JZP898.
- Jazz Pharmaceuticals recently disclosed that in July 2023, JZP898 received Investigational New Drug (IND) application clearance.

Financial Results for the Second Quarter of 2023:

- **Cash position:** As of June 30, 2023, cash and cash equivalents were \$137.5 million, compared to \$147.9 million as of March 31, 2023. The Company also had restricted cash and cash equivalents of \$21.2 million as of June 30, 2023, and March 31, 2023, respectively. The Company expects that its existing cash and cash equivalents, together with anticipated collaboration revenue, 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 \$8.1 million for the second quarter of 2023, compared to \$4.1 million for the same period in 2022. Collaboration revenue is related to partial recognition of the \$15.0 million upfront payment received in April 2022 upon the execution of Werewolf's licensing agreement with Jazz and costs incurred for research services to be reimbursed by Jazz.
- **Research and development expenses:** Research and development expenses were \$9.6 million for the second quarter of 2023, compared to \$13.9 million for the same period in 2022. The decrease in research and development expenses was primarily due to a decrease in the costs incurred with contract manufacturing associated with WTX-124 and WTX-330 and favorable adjustments recognized during the quarter upon the closeout of completed purchase orders.
- **General and administrative expenses:** General and administrative expenses were \$4.6 million for the second quarter of 2023, compared to \$5.2 million for the same period in 2022. The decrease in general and administrative expenses was primarily due to reduced insurance premiums and decreased utilization of outside advisors.
- **Net loss:** Net loss was \$5.1 million for the second quarter of 2023, compared to \$14.6 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, plans, the projection of the cash runway, the expected timeline for the clinical development of product candidates and availability of data from such clinical development, and the potential activity and efficacy of product candidates in preclinical studies and clinical trials 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; 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.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Collaboration revenue	\$ 8,081	\$ 4,148	\$ 12,545	\$ 4,148
Operating expenses:				
Research and development	9,583	13,887	21,289	24,832
General and administrative	4,565	5,233	9,546	9,654
Total operating expenses	14,148	19,120	30,835	34,486
Operating loss	(6,067)	(14,972)	(18,290)	(30,338)
Other income	969	378	1,210	401
Net loss	\$ (5,098)	\$ (14,594)	\$ (17,080)	\$ (29,937)
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.53)	\$ (0.49)	\$ (1.09)
Weighted-average common shares outstanding, basic and diluted	35,558	27,517	35,173	27,455

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

	June 30, 2023		December 31, 2022	
Cash and cash equivalents	\$	137,452	\$	129,315
Working capital	\$	132,393	\$	116,211
Total assets	\$	185,235	\$	160,245
Total deferred revenue	\$	2,389	\$	7,660
Total notes payable, net of discount and issuance costs	\$	39,142	\$	—
Total stockholders' equity	\$	118,599	\$	122,337

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