

**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): **May 11, 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 May 11, 2023, Werewolf Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended March 31, 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 May 11, 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: May 11, 2023

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



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

- Progressing Phase 1/1b clinical trial for IL-2 INDUKINE WTX-124 in advanced or metastatic solid tumors; initial first-in-human clinical data from monotherapy dose-escalation arm expected in 4Q 2023 -
- Progressing Phase 1 clinical trial for IL-12 INDUKINE WTX-330 in patients with advanced or metastatic solid tumors or lymphoma; preclinical data published in *Cancer Immunology Research* -
- First preclinical data for new candidate WTX-712, a conditionally active IL-21 INDUKINE molecule targeting oncology indications, presented at AACR Annual Meeting -

Watertown, Mass., May 11, 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 first quarter ended March 31, 2023.

“In the first quarter, Werewolf has focused on execution by progressing our INDUKINE pipeline and enrolling ongoing first-in-human clinical trials for our lead programs, WTX-124 and WTX-330. In addition, preclinical data presented at AACR and published in *Cancer Immunology Research* continues to demonstrate the robustness of our PREDATOR™ platform showing that Werewolf’s conditional activation technology results in potent anti-tumor activity alongside an improved therapeutic index,” said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. “Looking ahead, in the fourth quarter we plan to share initial safety, tolerability, and preliminary efficacy data from our Phase 1/1b clinical trial of WTX-124 in solid tumor types.”

“Finally, we’d like to express our deep appreciation to Reid Leonard, Ph.D., Werewolf’s Chief Operating Officer, who is retiring effective June 30, 2023, after a long and successful career in the biopharmaceutical industry. Reid is a founding member of the Werewolf Executive Team and has been instrumental in leading and advancing all aspects of organizational operations. We have benefited greatly from Reid’s significant expertise, and the strong team he has built and business process he has established will ensure continued operational excellence going forward. We wish Reid the very best in his 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 checkpoint inhibitor therapy in multiple solid tumor types.

- 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 checkpoint inhibitor therapy.
- Enrollment is ongoing in monotherapy dose-escalation cohorts, and the Company anticipates reporting interim safety, tolerability and preliminary efficacy data from these monotherapy cohorts in the fourth quarter of 2023.



- During the American Association for Cancer Research Annual Meeting in April 2023, the Company presented a poster entitled “Trial in progress: a multicenter phase 1/1b dose escalation study of WTX-124 as a monotherapy and in combination with pembrolizumab in patients with selected advanced or metastatic solid tumors.”

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.
- During the American Association for Cancer Research Annual Meeting in April 2023, the Company presented a poster entitled “Trial in progress: a first-in-human, phase 1, multicenter dose escalation and dose expansion study of WTX-330 in adult patients with advanced or metastatic solid tumors or non-Hodgkin lymphoma.”
- Also in April 2023, the Company announced the publication of preclinical data in *Cancer Immunology Research Online First*, demonstrating that mWTX-330 delivers IL-12 selectively to the tumor environment to inhibit tumor growth in mouse models. The preclinical data demonstrate that mWTX-330 stimulates a potent anti-tumor response in mice by activating tumor infiltrating lymphocytes and restoring the metabolic health of these lymphocytes and has the potential to minimize the toxicity previously associated with systemic IL-12 administration.

Early-Stage Pipeline:

- During the American Association for Cancer Research Annual Meeting in April 2023, The Company presented a poster entitled “Generation of IL-21 INDUKINE molecules for the treatment of cancer,” which featured preclinical data supporting the recent nomination of Werewolf’s third wholly owned candidate, WTX-712, a conditionally activated IL-21 INDUKINE molecule in development for treatment of cancer. Highlights of the presentation include:
 - IL-21 INDUKINE polypeptides demonstrated improved tolerability and therapeutic window in mouse syngeneic tumor models.
 - Efficacy in these tumor models was linked to expansion and activation of tumor infiltrating T cells, increased polyfunctionality in CD8+ T cells, and signs of increased activation of B cells.

Financial Results for the First Quarter of 2023:

- **Cash position:** As of March 31, 2023, cash and cash equivalents were \$147.9 million, compared to \$129.3 million as of December 31, 2022. The Company also has restricted cash and cash equivalents of \$21.2 million, compared to \$1.2 million as of December 31, 2022. These increases are primarily due to proceeds from the Company’s at-the-market sales facility, the drawdown of remaining capital available under its term loan agreement with Pacific Western Bank, and funding received in connection with the Company’s licensing agreement with Jazz Pharmaceuticals (“Jazz”). 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 \$4.5 million for the first quarter of 2023, compared to zero 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 \$11.7 million for the first quarter of 2023, compared to \$10.9 million for the same period in 2022. The increase in research and development expenses was primarily due to increased personnel costs.
- **General and administrative expenses:** General and administrative expenses were \$5.0 million for the first quarter of 2023, compared to \$4.4 million for the same period in 2022. The increase in general and administrative expenses was primarily due to increased costs to support the increasing size and complexity of Werewolf's research, development and manufacturing activities.
- **Net loss:** Net loss was \$12.0 million for the first quarter of 2023, compared to \$15.3 million for the same period in 2022.

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. 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. To learn more visit www.werewolfth.com.



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; the impact of the COVID-19 pandemic on the Company's business and operations; as well as the risks and uncertainties identified in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2021, 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 per share data)

	Three Months Ended March 31,	
	2023	2022
Revenue:		
Collaboration revenue	\$ 4,464	\$ —
Operating expenses:		
Research and development	11,706	10,945
General and administrative	4,981	4,421
Total operating expenses	16,687	15,366
Operating loss	(12,223)	(15,366)
Other income	241	23
Net loss	\$ (11,982)	\$ (15,343)
Net loss per share, basic and diluted	\$ (0.34)	\$ (0.56)
Weighted-average common shares outstanding, basic and diluted	34,785	27,393

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

	March 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 147,868	\$ 129,315
Working capital	\$ 134,840	\$ 116,211
Total assets	\$ 195,069	\$ 160,245
Total deferred revenue	\$ 5,317	\$ 7,660
Total notes payable, net of discount and issuance costs	\$ 39,063	\$ —
Total stockholders' equity	\$ 121,073	\$ 122,337

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