

**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 10, 2022**

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 November 10, 2022, Werewolf Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended September 30, 2022. 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 November 10, 2022
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: November 10, 2022

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



Werewolf Therapeutics Reports Third Quarter 2022 Financial Results and Provides Business Update

- Dosed first patient in Phase 1/1b study evaluating WTX-124 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) in advanced solid tumors; initial data anticipated in the fourth quarter of 2023 -
- FDA granted clearance of investigational new drug (IND) application for WTX-330, an IL-12 targeted cytokine in development for relapsed/refractory and/or immunologically resistant tumors -
- Q3 cash balance of \$140.5 million plus anticipated collaboration revenue and access to term loan agreement provides runway through at least the second quarter of 2024 -

Watertown, Mass., Nov. 10, 2022 – 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 third quarter ended September 30, 2022.

“Werewolf continues to deliver against key corporate objectives with notable pipeline progress highlighted by our transition into a clinical-stage company,” said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. “During the third quarter, we initiated the first-in-human clinical trial of our lead program, WTX-124, for treatment of advanced solid tumors. In addition, we have received IND clearance from the FDA for WTX-330, our IL-12 program, which puts us on track to have two actively enrolling clinical trials in 2023. Finally, Werewolf remains well-capitalized with runway that we project will carry us through at least the second quarter of 2024, which supports the development plans for both clinical programs and continued value creation for our early-stage pipeline assets.”

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.*

- During the third quarter of 2022, Werewolf announced the initiation of patient dosing in its Phase 1/1b clinical trial evaluating WTX-124 (WTX-124x2101), the Company’s lead INDUKINE molecule, targeting IL-2 for the treatment of solid tumors. The Phase 1/1b clinical trial is a first-in-human, multi-center, open-label trial evaluating WTX-124 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 (programmed death receptor-1) therapy, in patients with immunosensitive advanced or metastatic solid tumors who have failed standard of care, including checkpoint inhibitor therapy.
- Werewolf is actively enrolling patients in monotherapy dose-escalation cohorts in Study WTX-124x2101. The Company anticipates reporting preliminary interim data from this study in the fourth quarter of 2023. These data are expected to provide initial safety and activity profiles of WTX-124.

WTX-330: *a systemically delivered, conditionally activated Interleukin-12 (IL-12) INDUKINE molecule being developed as monotherapy in relapsed/refractory and/or immunologically resistant or unresponsive tumors.*



- Following submission in the third quarter of 2022, Werewolf received clearance from the U.S. Food and Drug Administration (FDA) of its IND application for WTX-330. The Company has begun activating sites for a Phase 1 clinical trial (WTX-330x2101) evaluating the safety and tolerability of WTX-330 monotherapy in patients with advanced or metastatic tumors which are either immunotherapy resistant or unresponsive.

Third Quarter 2022 Financial Highlights

- **Cash position:** As of September 30, 2022, cash and cash equivalents decreased to \$140.5 million, compared to \$157.5 million as of December 31, 2021. Based on updated forecasting, the Company has extended its runway to project that its existing cash and cash equivalents, together with anticipated collaboration revenue and access to the term loan agreement with Pacific Western Bank, will be sufficient to fund its operational expenses and capital expenditure requirements through at least the second quarter of 2024.
- **Collaboration revenue:** Collaboration revenue was \$5.0 million for the third quarter of 2022, compared to zero for the same period in 2021. Collaboration revenue is related to amortization 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 \$13.1 million for the third quarter of 2022, compared to \$9.8 million for the same period in 2021. The increase in research and development expenses was primarily due to manufacturing expenses incurred to support the production of preclinical and current and future clinical trial materials associated with the Company's product candidates WTX-124, WTX-330 and WTX-613 and increased employee compensation costs related to increased headcount.
- **General and administrative expenses:** General and administrative expenses were \$4.4 million for the third quarter of 2022, compared to \$4.0 million for the same period in 2021.
- **Net loss:** Net loss was \$11.9 million for the third quarter of 2022, compared to \$13.8 million for the same period in 2021.

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 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 both WTX-124 and WTX-330 in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor.

To learn more visit www.werewolfTx.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 strategy, future operations, prospects, plans, objectives of management, the expected timeline regarding preclinical and clinical development for product candidates, including the announcement of data, the potential activity and efficacy of product candidates in preclinical studies and clinical trials, and Werewolf's expected cash runway 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 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	\$ 4,970	\$ —	\$ 9,118	\$ —
Operating expenses:				
Research and development	13,070	9,787	37,902	21,869
General and administrative	4,439	4,008	14,093	10,334
Total operating expenses	17,509	13,795	51,995	32,203
Operating loss	(12,539)	(13,795)	(42,877)	(32,203)
Other income	596	37	997	89
Net loss	(11,943)	(13,758)	(41,880)	(32,114)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(151,942)
Net loss attributable to common stockholders	\$ (11,943)	\$ (13,758)	\$ (41,880)	\$ (184,056)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.40)	\$ (0.51)	\$ (1.48)	\$ (11.89)
Weighted-average common shares outstanding, basic and diluted	29,764	27,188	28,233	15,485

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

	September 30, 2022		December 31, 2021	
Cash and cash equivalents	\$	140,450	\$	157,531
Working capital	\$	123,787	\$	149,194
Total assets	\$	172,424	\$	179,250
Total deferred revenue	\$	10,801	\$	—
Total stockholders' equity	\$	130,947	\$	152,787

Investor Contact:

Josh Rappaport
Stern IR
212.362.1200
Josh.rappaport@sternir.com

Media Contact:

Peg Rusconi
VERGE Scientific Communications
301.332.5574
prusconi@vergescientific.com

Company Contact:

Ellen Lubman
Chief Business Officer
Werewolf Therapeutics
elubman@werewolftx.com