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): **March 23, 2023**

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 March 23, 2023, Werewolf Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing financial results for the quarter ended December 31, 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 March 23, 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: March 23, 2023

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

Exhibit 99.1

Werewolf Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

-Initial first-in-human clinical data for IL-2 INDUKINE WTX-124 monotherapy expected in 4Q 2023 from Phase 1/1b clinical trial in advanced or metastatic solid tumors-

-Dosed first patient in Phase 1 clinical trial evaluating IL-12 INDUKINE WTX-330 in patients with advanced or metastatic solid tumors or lymphoma-

-Nominated WTX-712, a conditionally active IL-21 INDUKINE molecule targeting oncology indications; preclinical data to be presented at AACR Annual Meeting 2023 in Orlando, Florida-

-Updated cash runway guidance to fund cash flow requirements through at least 4Q 2024-

Watertown, Mass., March 23, 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 fourth quarter and full year ended December 31, 2022.

"Werewolf enters 2023 with considerable momentum following exceptional execution across our Company in 2022. In particular, we initiated clinical trials for our two lead INDUKINE programs, WTX-124 and WTX-330, and also advanced our newest IL-21 INDUKINE pipeline candidate WTX-712," said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. "This year we anticipate multiple catalysts as we progress our two clinical stage programs, WTX-124 and WTX-330, through first in human testing and expect to share initial clinical data on the safety, tolerability, and preliminary efficacy of WTX-124 in the fourth quarter. Also of note, we have extended our cash runway beyond previous guidance and through at least the fourth quarter of 2024, which provides us the opportunity to reach multiple potential value creating milestones."

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 inhibitors 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.
- 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" will be presented at AACR in the Phase I Clinical Trials in Progress session on Monday April 17, 2023, at 1:30 PM - 5:00 PM in Poster Section 46 under abstract number CT133.

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

- In February 2023, following clearance of its investigational new drug (IND) application by the U.S. Food and Drug Administration (FDA), Werewolf initiated patient dosing in 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.
- 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" will be presented at AACR 2023 in the Phase I and First-in-Human Clinical Trials in Progress session on Tuesday April 18, 2023, at 1:30 PM - 5:00 PM in Poster Section 46 under abstract number CT254.

Early-Stage Pipeline:

- Werewolf has nominated wholly owned candidate WTX-712 for preclinical development. WTX-712 is a conditionally activated IL-21 INDUKINE molecule in development for treatment of cancer. IL-21 is believed to promote expansion of immune cells in the tumor microenvironment resulting in antitumor immunity.
- A poster entitled "Generation of IL-21 INDUKINE molecules for the treatment of cancer" will be presented on Monday April 17, 2023, at 9:00 AM - 12:30 PM at the AACR Annual Meeting 2023 in Poster Section 24 under abstract number 1829.

Financial Results for the Fourth Quarter and Full Year 2022:

- **Cash position:** As of December 31, 2022, cash and cash equivalents were $129.3 million, compared to $157.5 million as of December 31, 2021. After updating our expense forecasting, the Company now 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. This represents an increase of two quarters over the Company's previous guidance. As the Company recently disclosed, it has taken measures to protect the availability of its cash by amending its term loan agreement with Pacific Western Bank to allow the Company to maintain depository accounts outside of Pacific Western Bank. Additionally, substantially all of the Company's accounts invested through Pacific Western Bank are FDIC insured. Lastly, subsequent to quarter close, Werewolf drew down the full $40.0 million available under its term loan agreement with Pacific Western Bank, proceeds of which were previously included in the Company's guidance.
- **Collaboration revenue:** Collaboration revenue was $7.3 million for the fourth quarter of 2022, compared to zero for the same period in 2021, and $16.4 million for the full year 2022, compared to zero for the same period in 2021. 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 $15.9 million for the fourth quarter of 2022, compared to $13.4 million for the same period in 2021. Research and development expenses were $53.8 million for the full year 2022, compared to $35.3 million for the full year 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 JZP898 (formerly WTX-613), our conditionally activated interferon alpha (IFNα) INDUKINE molecule licensed to Jazz Pharmaceuticals, and increased employee compensation costs related to increased headcount.
- **General and administrative expenses:** General and administrative expenses were $4.6 million for the fourth quarter of 2022, compared to $4.5 million for the same period in 2021. General and administrative expenses were $18.7 million for the full year 2022, compared to $14.8 million for the full year 2021. The full year increase in general and administrative expenses was primarily due to the full-year impact of increased personnel, professional services, and other operating costs attributable to operating as a public company and the progression towards clinical development.
- **Net loss:** Net loss was $11.9 million for the fourth quarter of 2022, compared to $17.9 million for the same period in 2021. Net loss was $53.8 million for the full year 2022, compared to $50.0 million for the full year 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 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.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 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 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 Form 10-Q and in subsequent filings the Company may make with the Securities and Exchange Commission ("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.
Consolidated Statements of Operations (unaudited)
(amounts in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	$ 7,283	$ —	$ 16,401	$ —
Operating expenses:				
Research and development	15,859	13,400	53,761	35,269
General and administrative	4,603	4,484	18,696	14,818
Total operating expenses	20,462	17,884	72,457	50,087
Operating loss	(13,179)	(17,884)	(56,056)	(50,087)
Other income	1,249	15	2,246	104
Net loss	(11,930)	(17,869)	(53,810)	(49,983)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(151,942)
Net loss attributable to common stockholders	$ (11,930)	$ (17,869)	$ (53,810)	$ (201,925)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.39)	$ (0.66)	$ (1.86)	$ (10.94)
Weighted-average common shares outstanding, basic and diluted	30,735	27,270	28,864	18,455

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

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 129,315	$ 157,531
Working capital	$ 116,211	$ 149,194
Total assets	$ 160,245	$ 179,250
Total deferred revenue	$ 7,660	$ —
Total stockholders' equity	$ 122,337	$ 152,787

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