

**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 11, 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**

1030 Massachusetts Avenue, Suite 210, Cambridge, Massachusetts 02138

(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 11, 2022, Werewolf Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing financial results for the quarter ended June 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 August 11, 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: August 11, 2022

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



Werewolf Therapeutics Reports Second Quarter 2022 Financial Results and Provides Business Highlights

- FDA granted IND clearance for lead candidate WTX-124 for evaluation as a treatment for advanced solid tumors -

- Submission of IND application for WTX-330 planned in 2H22 -

- Q2 cash and cash equivalents balance of \$145.7 million provides runway through at least the fourth quarter of 2023 -

Watertown, Mass., Aug. 11, 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 second quarter ended June 30, 2022.

“Werewolf continues to advance our conditionally activated INDUKINE™ therapies into clinical development,” said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. “Most notably, we received FDA clearance to launch our first-in-human study of WTX-124, an IL-2 INDUKINE, for treatment of advanced solid tumors, marking our transition to a clinical-stage company. Additionally, we are planning to submit an IND for our IL-12 INDUKINE, WTX-330, in the second half of 2022. We believe that these initial candidates offer compelling opportunities not just to advance patient outcomes in their respective indications, but also to validate the distinct advantages of our platform. Importantly, we believe that we remain well-capitalized to advance clinical development for both programs as we proceed with novel discovery efforts in parallel.”

Recent Highlights and Upcoming Milestones

WTX-124: *a systemically delivered, conditionally activated Interleukin-2 (IL-2) INDUKINE molecule in development as monotherapy or in combination with checkpoint inhibitors in multiple solid tumor types.*

- During the second quarter of 2022, Werewolf received clearance from the U.S. Food and Drug Administration (FDA) on its Investigational New Drug (IND) application for WTX-124. This Phase 1/1b clinical trial will evaluate WTX-124 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced or metastatic solid tumors.
- The Company plans to provide an update after dosing the first patient in the WTX-124 Phase 1/1b clinical trial.

WTX-330: *a systemically delivered, conditionally activated Interleukin-12 (IL-12) INDUKINE molecule in development as monotherapy or in combination with checkpoint inhibitors in refractory and/or immunologically unresponsive tumors.*

- Werewolf is concluding IND-enabling work for WTX-330 and is planning to submit an IND application for this program in the second half of 2022.



Corporate:

- In April 2022, Jazz Pharmaceuticals (Jazz) and Werewolf entered into a collaboration and license agreement under which Werewolf granted Jazz certain licenses to develop and commercialize WTX-613 (now known as JZP898), an Interferon alpha (IFN α) molecule. During the second quarter of 2022, Werewolf received an upfront payment of \$15.0 million from Jazz and is eligible to receive up to \$520.0 million in development and regulatory milestones and up to \$740.0 million in commercial milestone payments, as well as a tiered, mid-single-digit percentage royalty on net sales, pending approval.

Second Quarter 2022 Financial Highlights

- **Cash position:** As of June 30, 2022, cash and cash equivalents were \$145.7 million, compared to \$157.5 million as of December 31, 2021. The Company expects that its existing cash and cash equivalents will be sufficient to enable funding of its operating expenses and capital expenditure requirements through at least the fourth quarter of 2023.
- **Collaboration revenue:** Collaboration revenue was \$4.1 million for the second 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 \$13.9 million for the second quarter of 2022, compared to \$7.3 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 future clinical trial materials associated with the Company's product candidates WTX-124, WTX-330 and WTX-613, increased employee compensation costs related to increased headcount and increased contract research organization expenses incurred to support IND-enabling studies and clinical start-up activities for WTX-124 and WTX-330.
- **General and administrative expenses:** General and administrative expenses were \$5.2 million for the second quarter of 2022, compared to \$3.7 million for the same period in 2021. The increase in general and administrative expenses was primarily due to increased personnel and other costs attributable to operating as a public company.
- **Net loss:** Net loss was \$14.6 million for the second quarter of 2022, compared to \$10.9 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.

To learn more visit www.werewolf.tx.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 for submitting an IND for WTX-330, the planned commencement of the Phase 1/1b clinical trial of WTX-124, the expected cash runway, and the potential activity of product candidates in future preclinical and clinical studies constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "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; the timing of and our ability to submit and obtain regulatory approval for investigational new drug applications and commence clinical trials; 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 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 presentation. 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,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	\$ 4,148	\$ —	\$ 4,148	\$ —
Operating expenses:				
Research and development	13,887	7,265	24,832	12,082
General and administrative	5,233	3,691	9,654	6,326
Total operating expenses	19,120	10,956	34,486	18,408
Operating loss	(14,972)	(10,956)	(30,338)	(18,408)
Other income	378	35	401	52
Net loss	(14,594)	(10,921)	(29,937)	(18,356)
Accretion of redeemable convertible preferred stock to redemption value	—	(56,926)	—	(151,942)
Net loss attributable to common stockholders	\$ (14,594)	\$ (67,847)	\$ (29,937)	\$ (170,298)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.53)	\$ (3.82)	\$ (1.09)	\$ (17.86)
Weighted-average common shares outstanding, basic and diluted	27,517	17,750	27,455	9,535

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

	June 30, 2022		December 31, 2021	
Cash and cash equivalents	\$	145,712	\$	157,531
Working capital	\$	123,797	\$	149,194
Total assets	\$	175,329	\$	179,250
Total deferred revenue	\$	13,071	\$	—
Total stockholders' equity	\$	129,841	\$	152,787

Investor Contact:

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

Media Contact:

Amanda Sellers
VERGE Scientific Communications
301.332.5574
asellers@vergescientific.com

Company Contact:

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