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): September 18, 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 7.01. Regulation FD Disclosure.

On September 18, 2023, Werewolf Therapeutics, Inc. (the "Company") is making publicly available on its website an updated corporate slide presentation. The updated slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information 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	Corporate slide presentation
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.

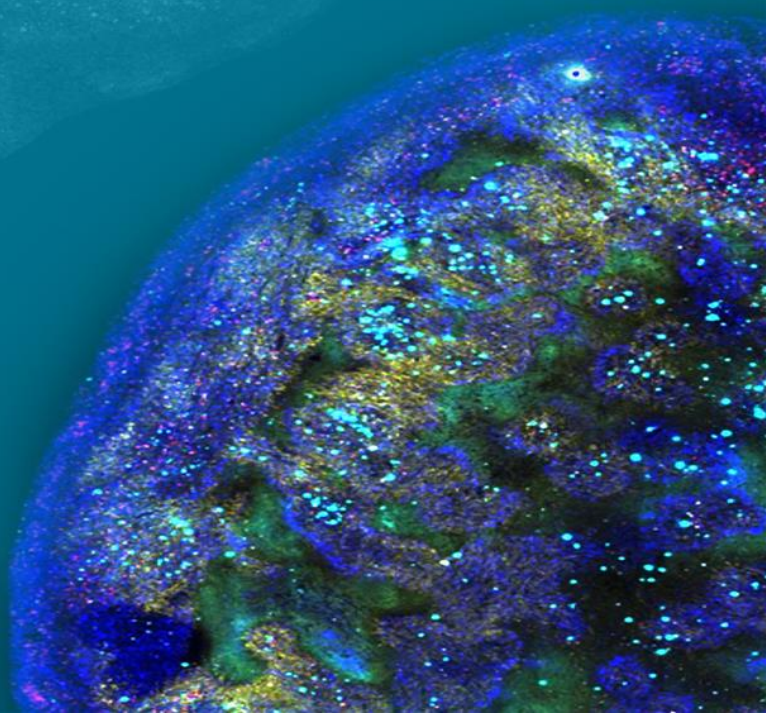
Date: September 18, 2023

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

Exhibit 99.1

Werewolf THERAPEUTICS

Shifting the Balance in Cytokine Therapeutics



Corporate Overview | September 2023

Cautionary Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding Werewolf Therapeutics, Inc.'s (the "Company") 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 future preclinical studies and clinical trials, and the Company's expected cash runway, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "aim," "anticipate," "approach," "believe," "contemplate," "continue," "could," "design," "designed to," "engineered," "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 presentation 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 presentation.

Who we are

Our mission is to unlock the promise of cytokines as more effective immunotherapies

We are a clinical-stage biopharmaceutical company developing next generation, conditionally activated cytokine therapies for the treatment of cancer and other serious diseases

We have two investigational drugs in Phase I clinical trials

Our headquarters and research facilities are located in Watertown, Massachusetts

2023 Value-drivers

WTX-124

Ongoing enrollment in monotherapy dose escalation

Ongoing enrollment in combination dose escalation with pembrolizumab

Initial clinical data readout expected 4Q23

WTX-330

Ongoing enrollment in monotherapy dose escalation

JZP898

Initiating Phase I clinical development

WTX-712

Selection of IL-21 development candidate

On-going Value Creation

PREDATOR™ Platform

Capability to expand the pipeline with new INDUKINE™ molecules for a broad range of mechanisms and indications

Business Development

Broad portfolio of clinical and preclinical stage assets for potential partnering

Financial Stability

Runway through at least 4Q 2024

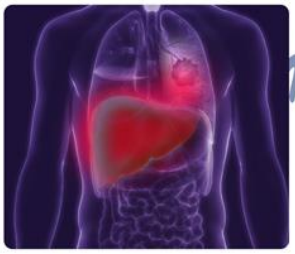
Werewolf THERAPEUTICS

Overcoming Off-Target Toxicity has been a Key Challenge for Cytokine Therapy

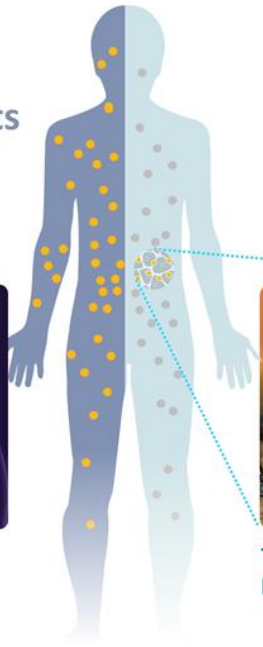
The Challenge:
Off-Tumor Cytokine Toxicity Limits Therapeutic Index

Suboptimal Pharmaceutical Properties

Toxicity

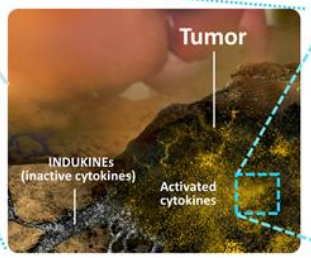


Poor Clinical Outcomes

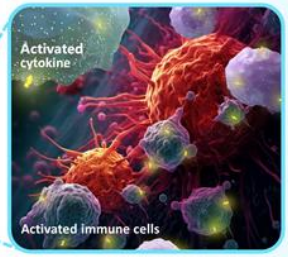


Our Solution:
Conditionally Activated Immunotherapy

With Optimized Therapeutic Index



Targeted Intratumoral Delivery



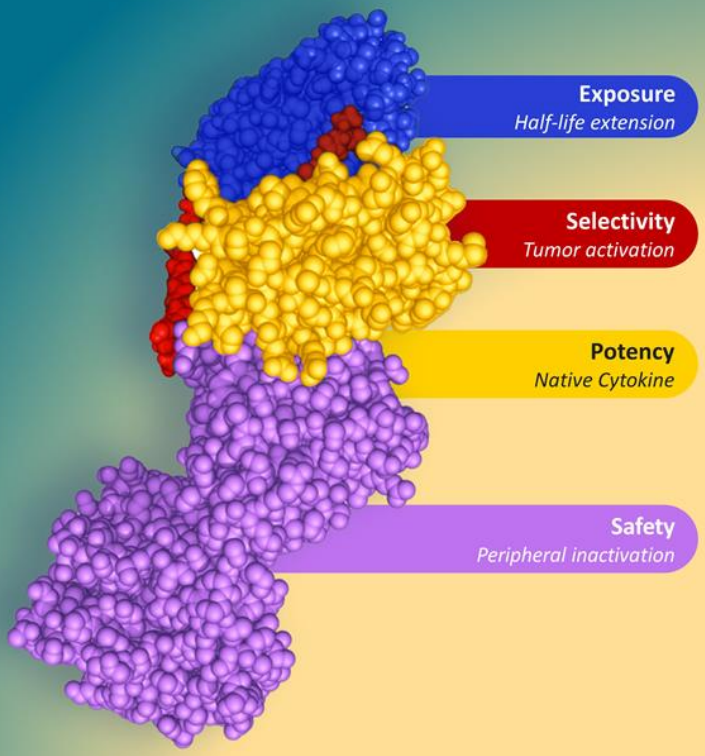
On-Target Immune Activation

Werewolf THERAPEUTICS

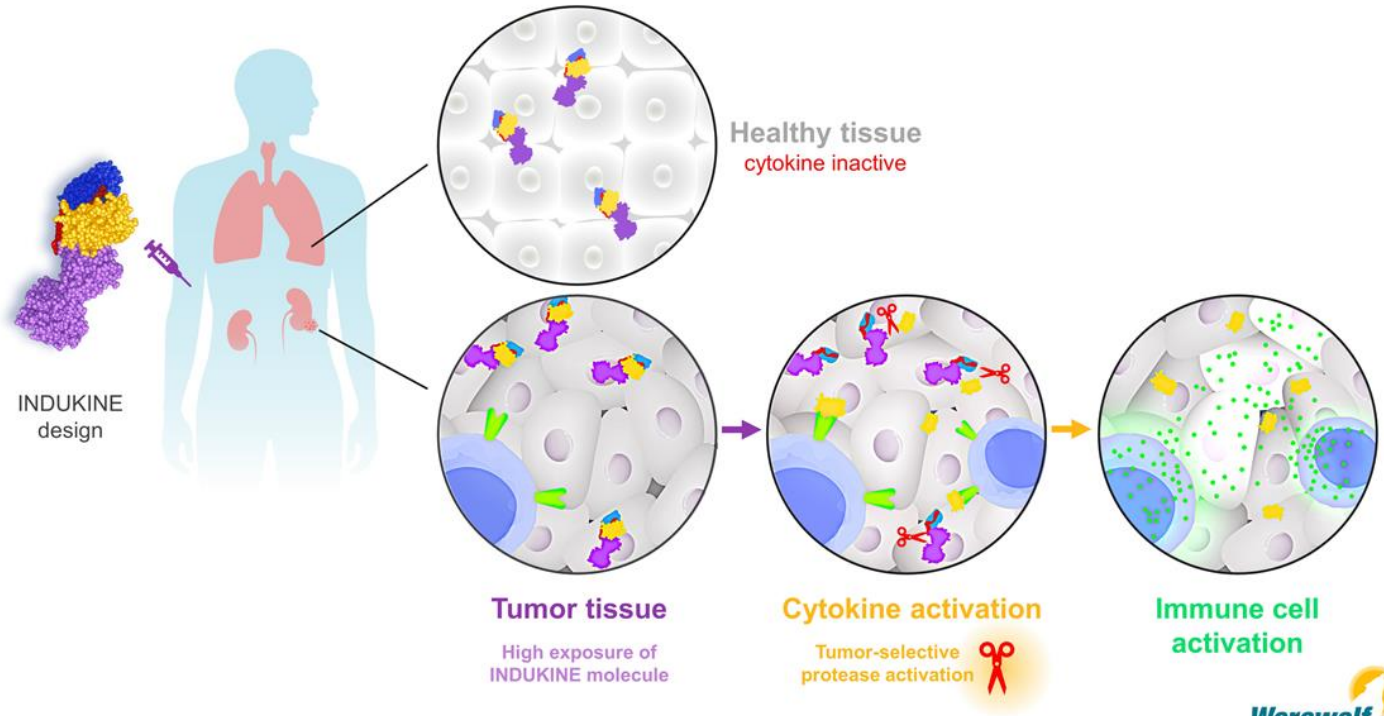
PREDATOR
Platform

Tunable, Tissue-targeted Therapeutics for Cancer and other Diseases

INDUKINE molecules contain multiple domains, each with a unique function that can be 'tuned' for specific mechanisms and pharmaceutical properties necessary to treat disease



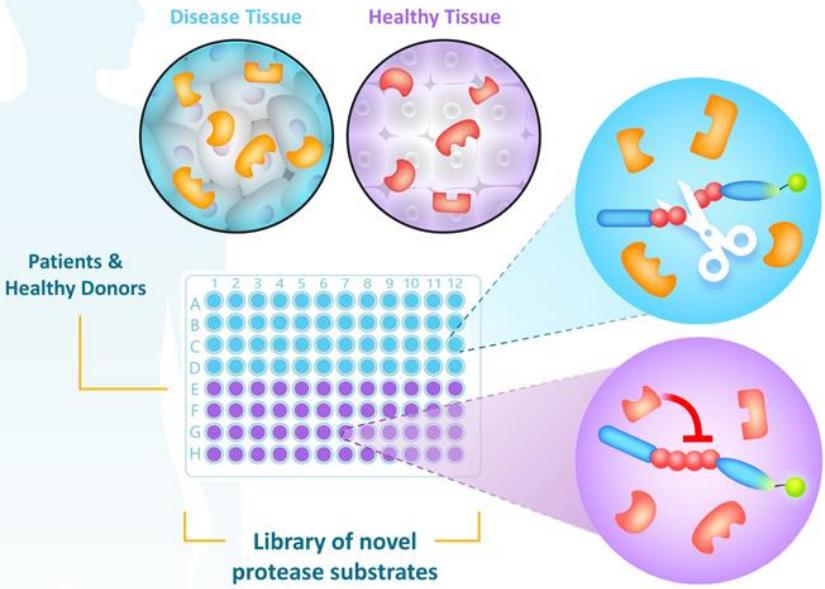
INDUKINE Molecules: Targeting Cytokine Activity to Diseased Tissue



Werewolf THERAPEUTICS

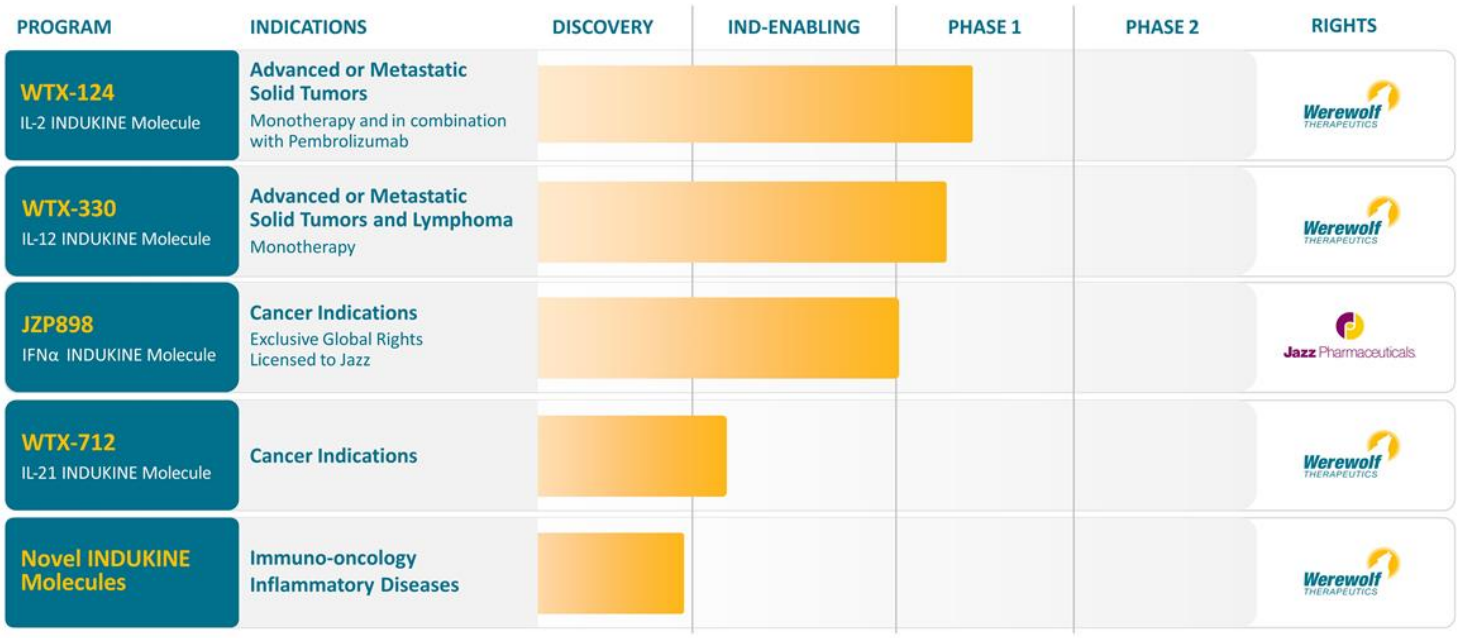
Disease Selective Protease (DSP) Substrate Screen

Innovative Linker Discovery Approach to Address Protease Heterogeneity Across Diseases and Patients



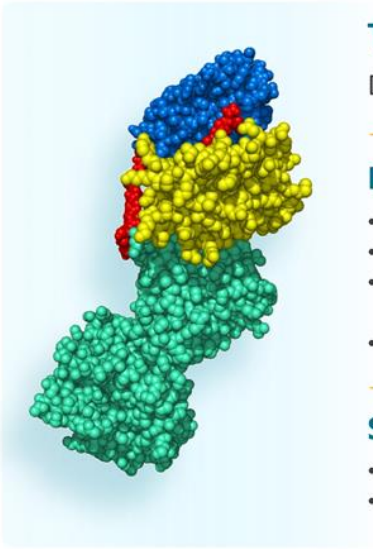
- Highly diverse substrate library
- Unique protease specificities
- Innovative screening approach
- Substrates selected in the context of a globular protein
- Screens possible with a variety of diseased tissues

A Balanced Portfolio of Clinical and Preclinical Drug Candidates



Werewolf THERAPEUTICS

WTX-124: Expanding the Utility of IL-2 Therapy



The Challenge

Deliver the benefits of IL-2 therapy with less toxicity to a broader range of patients

Potential WTX-124 Advantages and Opportunity

- Delivery of IL-2 selectively to the TME to improve the therapeutic index
- Potential for activity beyond approved indications for rhIL2
- IL-2 therapy with an improved therapeutic index could address an immediate unmet medical need for patients who have progressed on checkpoint therapy
- Strong rationale for combination with checkpoint inhibitors in earlier lines of therapy

Status

- Enrolling patients in Phase 1 clinical trial both as a single agent and in combination with Pembrolizumab
- Unpartnered

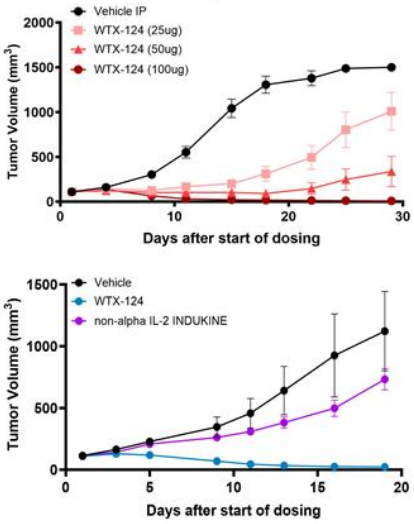
Abbreviation: TME-tumor microenvironment

Werewolf THERAPEUTICS

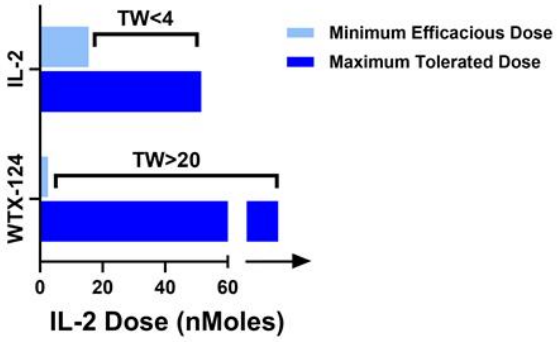
WTX-124 has an Improved Therapeutic Index Compared to Native IL-2

Full potency IL-2 is required for complete tumor regression in preclinical models

WTX-124 antitumor activity in MC38 tumor model



Improved therapeutic window compared to IL-2 cytokine



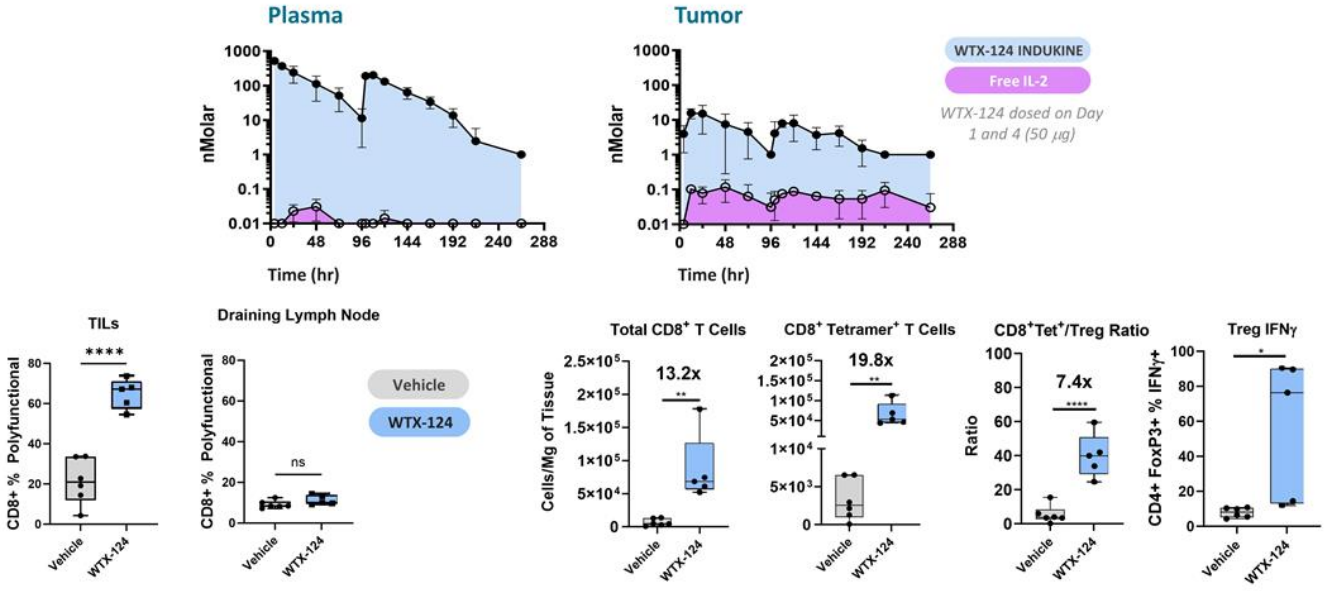
Nirschl CJ et al., Cancer Immunology Research 2022 10(5):581-596

Abbreviations: TW-therapeutic window

Werewolf THERAPEUTICS

WTX-124 Delivers IL-2 Selectively to Tumor Tissue in Preclinical Models

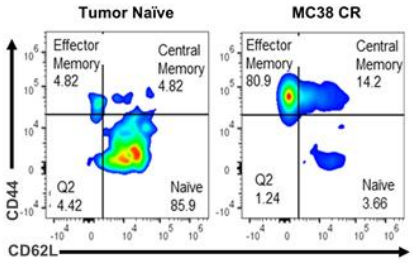
Robust expansion and activation of antitumor CD8+ T effector cells in the TME

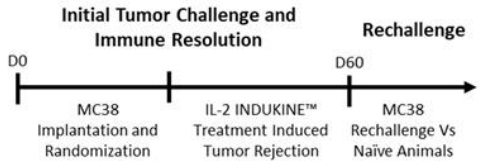


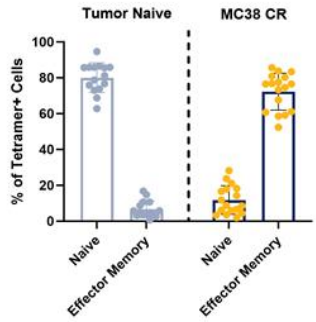
Nirschl CJ et al., Cancer Immunology Research 2022 10(5):581-596

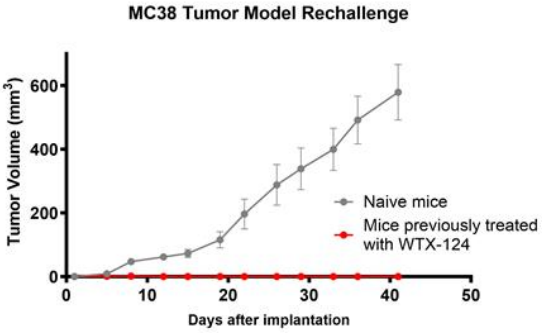
Abbreviations: TIL-tumor infiltrating lymphocytes; TME-tumor microenvironment

WTX-124 Activates Long-term Antitumor Immune Memory in Preclinical Models









Nirschl CJ et al., Cancer Immunology Research 2022 10(5):581-596
Abbreviations: TME-tumor microenvironment; CR-complete regression

First-In-Human Study of WTX-124 Monotherapy and in Combination with Pembrolizumab

Monotherapy Dose Escalation

Patients with IO sensitive tumor types who have exhausted all SOC options or for whom SOC is not indicated

Determination of *monotherapy* MTD/RDE

Combination Dose Escalation with Pembrolizumab

Patients with IO sensitive tumor types who have exhausted all SOC options or for whom SOC is not indicated

Determination of *combination therapy* MTD/RDE

Monotherapy/Combination Dose Expansion

- Advanced or metastatic renal cell carcinoma
- Advanced or metastatic cutaneous malignant melanoma
- Other advanced or metastatic IO sensitive tumor types TBD

Trial Details

Monotherapy and combination therapy dose escalations to enroll in parallel with staggered start for combination	mTPI (Modified Toxicity Probability Interval) design Enrolling ~ 150 patients total	Assessment of safety, pharmacokinetics, MTD/RDE, biomarkers, ADA and efficacy	Concurrent biomarker analysis on blood and tumor tissue to evaluate proof of mechanism and confirm differential activity based on conditional activation

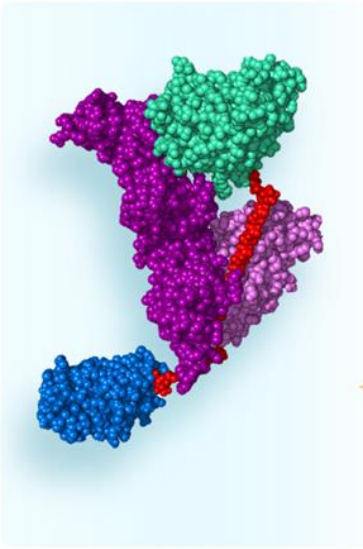
4Q 2023: Anticipated release of initial safety, tolerability, pharmacokinetics and biomarker data

Abbreviations: MTD-maximum tolerated dose; RDE-recommended dose for expansion; ADA-anti drug antibody; IO-immuno-oncology; SOC-standard of care

Werewolf THERAPEUTICS

WTX-330: Leveraging the Potential of IL-12 Therapy

Delivering IL-12 to the Tumor Microenvironment with an Improved Therapeutic Index



The Challenge

Develop a tolerable IL-12 therapy to stimulate innate and adaptive antitumor immune responses

Potential WTX-330 Advantages and Opportunity

- Delivery of IL-12 mechanism selectively to the TME with an improved therapeutic index
- Potent preclinical antitumor activity in poorly immunogenic, anti-PD-1 therapy refractory tumors
- Leverage IL-12 biology in the clinic to address mechanisms of checkpoint inhibitor resistance
- Potential for multiple combination strategies to enhance anti-tumor activity

Status

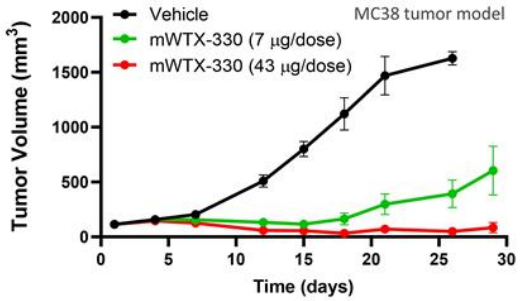
- Phase 1 clinical trial actively recruiting
- Unpartnered

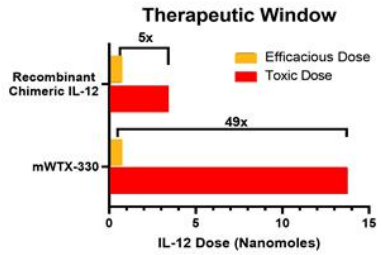
Abbreviations: TME-tumor microenvironment

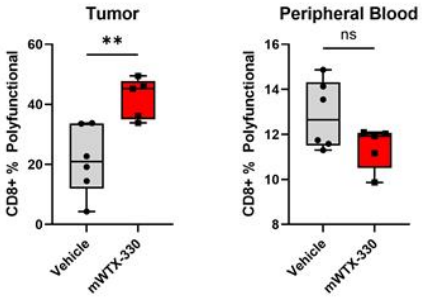
Werewolf THERAPEUTICS

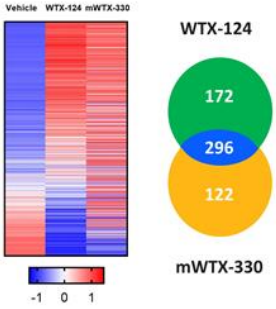
IL-12 INDUKINE Delivers IL-12 Selectively to Tumor Tissue with an Improved Therapeutic Index

Robust activation of antitumor CD8+ T effector cells and pleiotropic immune activation in the TME in preclinical models









Differential Gene Signatures

- ✓ Intratumoral IL-12 pathway activation
- ✓ Activation of multiple antigen presentation mechanisms
- ✓ Th1 lineage skewing
- ✓ Treg instability
- ✓ Increased chemokine expression

Nirschl CJ et al., Cancer Immunology Research, 1 July 2023; 11 (7): 962–977

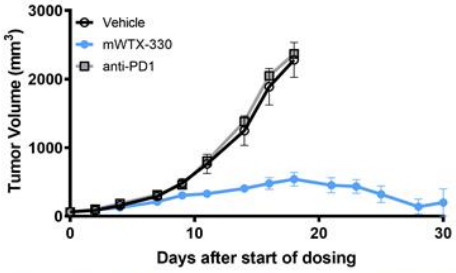
Abbreviation: TME-tumor microenvironment

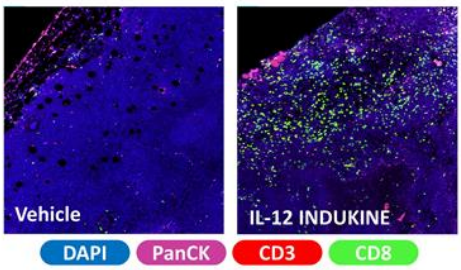
Werewolf THERAPEUTICS

IL-12 INDUKINE Inhibits Growth of Poorly Immunogenic EMT-6 Mouse Tumors

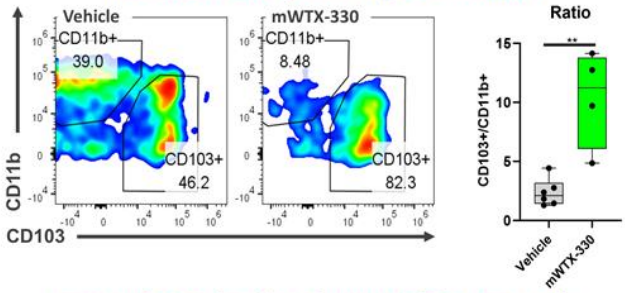
Increased Clonality of Tumor Infiltrating CD8+ T Cells in preclinical models

Efficacy in anti-PD-1 refractory EMT-6 tumors

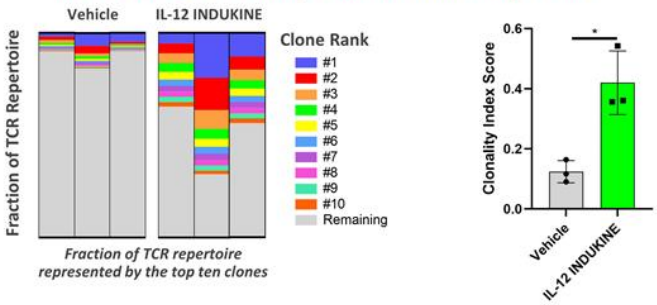




Increase of cross-presenting DCs in tumors



Increased TCR clonality of tumor infiltrating T cells



Nirschl CJ et al., Cancer Immunology Research, 1 July 2023; 11 (7): 962–977

Werewolf THERAPEUTICS

First-In-Human Study of WTX-330 Evaluating Safety, Tolerability and Clinical Activity

Monotherapy Dose Escalation

Relapsed/refractory advanced or metastatic solid tumors failing SOC, including immune checkpoint inhibitors

Monotherapy expansion arms to open after determination of MTD/RDE

Monotherapy Dose Expansion

CPI-naïve relapsed or refractory advanced tumor indications (tumor types for which CPIs are not approved, including NHL and mCRPC)

CPI primary or secondary resistant relapsed or refractory advanced tumor indications

Trial Details

CPI-unapproved and CPI-resistant indications supported by IL-12 biology and preclinical data

Bayesian study design, n~75

Assessment of safety, MTD/RDE, pharmacokinetics, biomarkers, ADA and efficacy

Concurrent biomarker analysis on blood and tumor tissue to evaluate proof of mechanism and confirm differential activity based on conditional activation

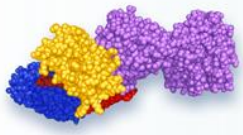
STATUS: Actively Enrolling in Dose Escalation Phase

Abbreviations: MTD-maximum tolerated dose; RDE-recommended dose for expansion; ADA-anti drug antibody; NHL-Non-Hodgkin lymphoma; mCRPC-metastatic castration-resistant prostate cancer; CPI-checkpoint inhibitor

Werewolf THERAPEUTICS

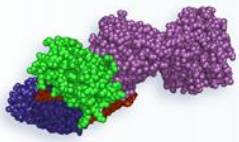
PREDATOR Platform

Werewolf's innovative PREDATOR Platform offers value creation through pipeline expansion and partnering opportunities



Oncology-focused INDUKINE Therapeutics

- Additional proinflammatory mechanisms
- Cell-based therapies
- mRNA therapies



Non-Oncology INDUKINE Therapeutics

- Inflammation
- Other diseases

Expanding Conditional-Activation Technology to New Modalities

- Targeted antibodies, T cell engagers, ADCs
- Cell-based therapies
- Disease-specific linkers

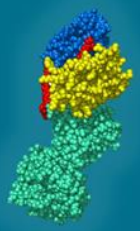
Werewolf THERAPEUTICS

Shifting the Balance in Cytokine Therapeutics

- Two lead programs in Phase 1 development are wholly owned by Werewolf
- Collaboration is central to our growth strategy with Jazz global partnership on JZP898

WTX-124

Phase 1 in Advanced and Metastatic Solid Tumors



WTX-330

Phase 1 in Advanced and Metastatic Solid Tumors and Lymphoma

PREDATOR: Value Creation Engine

Our protein engineering technology optimizes the design of conditionally activated cytokine therapeutics (INDUKINE molecules) to diseased tissues.

Opportunity to pursue non-cancer indications such as inflammatory diseases.

Deep Pipeline

JZP898, partnered with Jazz Therapeutics

WTX-712, an IL-21 INDUKINE molecule, nominated for preclinical development in oncology

Additional undisclosed INDUKINE molecules in development

Strong Cash Position

Approximately $137.5M in cash and cash equivalents (as of June 30, 2023)

Financial runway through at least 4Q 2024 with opportunity for multiple value-enhancing catalysts in the near term

Approximately 35.66M shares outstanding (as of August 4, 2023)

Werewolf THERAPEUTICS

Experienced Leadership

Daniel J. Hicklin, PhD
President and CEO

Randi E. Isaacs, MD
Chief Medical Officer

Chulani Karunatilake, PhD
Chief Technology Officer

Ellen Lubman, MBA
Chief Business Officer

Cynthia Seidel-Dugan, PhD
Chief Scientific Officer

Tim Trost, CPA
Chief Financial Officer

Thank You!