United States securities and exchange commission logo

March 28, 2021

Daniel J. Hicklin, Ph.D.
President and Chief Executive Officer
Werewolf Therapeutics, Inc.
1030 Massachusetts Avenue, Suite 210
Cambridge, MA 02138

Re: Werewolf Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted February 26, 2021
CIK No. 0001785530

Dear Dr. Hicklin:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary, page 1

1. Please revise the Company Overview section to clarify the status of the PREDATOR platform and the nature of the preclinical work performed on product candidates to date. We note that this context is necessary in order to assess the performance claims that are included in the Summary. With respect to the platform, we note that your disclosure at the bottom of page 1 indicates that it is built whereas your risk factor disclosure on page 16 indicates that the platform, as well as your product candidates, are under development. With respect to your product candidates, your Business discussion indicates that preclinical testing has been performed predominantly on mouse models and in certain cases using surrogate molecules; however, your disclosure makes claims which could be

interpreted to indicate that the testing has been performed on humans or on human cells. In this regard, we refer to the disclosure on page 2 which addresses how your platform screens to identify protease-cleavable linkers that are efficiently

cleaved by a broad array
of human tumors with minimal cleavage in non-tumor tissues.
2. We note your statement on page 1 regarding your potentially first-
or best-in-class
therapies and several other references to first-in-class and
best-in-class on pages 3 and
4. These terms suggest that the product candidate is effective and
likely to be approved by
the FDA. Please delete these from the Summary. To the extent your use
of these terms is
intended to convey your belief that the product is based on a novel
technology or approach
and/or is further along in the development process, you may discuss
how your technology
differs from technology used by competitors and, as applicable, that
you are not aware of
competing products that are further along in the development process.
Statements such as
these should be accompanied by cautionary language that the statements
are not intended
to give any indication that the product candidate has been proven
effective or that it will
receive regulatory approval.
3. On page 2 you refer to your potent INDUKINE molecules and state
that your
INDUKINE molecules contain fully potent and functional cytokines
that mediate pro-
inflammatory, anti-cancer mechanisms within the [tumor
microenvironment]. As safety
and efficacy determinations are solely within FDA's authority and they
continue to be
evaluated throughout all phases of clinical trials, please remove
these references, or revise
the presentation to provide additional context so that it is clear
that these claims do not
connote a current or future regulatory finding of safety or efficacy.
Our Pipeline, page 3

4. Please revise to increase the width of the Pre-IND and
IND-Enabling columns so they
are no larger than the columns for Phases 1-3. Also, please remove the
unidentified
discovery programs from your pipeline table. In this regard, we note
that your Business
discussion of these early stage programs is limited to a few
sentences.
Leadership, page 4

5. Please revise here and/or elsewhere in the prospectus to explain the
basis for your claim of
leadership in protein engineering and developing optimized
conditionally activated
molecules.
Our Team, page 4

6. Please revise here, or elsewhere in the prospectus, to discuss the
founding of the company,
including the origins of your technology. In this regard, we note that
MPM Capital
identifies themselves on their website as your "founder" and it
appears that MPM also
controlled Harpoon Therapeutics at the time you and Harpoon first
entered into the license
agreement covering the technology used in your PREDATOR platform. With
a view to
disclosure, also tell us whether the platform, or any material work on
your three product

candidates, derived from work conducted prior to the October 2017
incorporation of the
company and, if so, who conducted such work.
Risks Associated with Our Business, page 4

7. Please revise to highlight the risk on page 39 concerning uncertainty as to whether you will have patents that cover the composition of matter for your product candidates.

Risks Related to this Offering, Ownership o Our Common Stock and Our Status as a Public Company, page 58

8. Please revise the exclusive forum risk factor to disclose that there is also a risk that your exclusive forum provision may result in increased costs for investors to bring a claim.

Our Strategy, page 92

9. Here and in several places in your Business section you discuss the possibility that your product candidate could generate clinical benefit, with the potential . . . to pursue an expedited clinical and regulatory strategy. These references improperly raise the possibility of an expedited process without explaining the type and magnitude of clinical benefit that would be needed to garner an expedited process, and without explaining the nature of and hurdles to completing the expedited processes. Revise to balance your disclosure with these clarifications, and with the fact that, as your candidates are preclinical, there is no assurance the FDA would approve any form of application. Also, provide context to your statement on page 4 concerning your strategy to "rapidly advance" WTX-124 through clinical development. In this regard, we note that your risk factor disclosures explain that clinical development may take several years.

Linker Selection, page 94

10. We note your disclosure on page 95 indicating that your differentiated approach begins with a novel library of peptide sequences. Revise to discuss whether this library is internally developed and owned. Also, clarify whether your screening of prioritized linker sequences similarly relies on novel libraries or other proprietary technology or knowledge.

Our Programs, page 96

11. Please revise to discuss briefly the planned IND-enabling work for each of the three product candidates. With reference to your disclosure on pages 18 and 117, please tell us whether the referenced in vitro pre-clinical work using human cells will need to be performed on each product candidate prior to clinical testing or whether this in vitro testing occurred at the screening stage discussed on page 95.

Our Programs, page 96

12. We refer to your disclosures under the headings WTX-330 Preclinical Results and WTX-613 Preclinical Results. We note that your disclosure on page 107 indicates that

your testing used a surrogate molecule consisting of mouse IFN-a1 which is otherwise identical to WTX-613. By contrast, we do not see similar disclosure concerning the surrogate molecule that you used to assess WTX-330 in mice. Accordingly please revise your disclosure concerning your WTX-330 testing to discuss the comparability of the surrogate. In addition, please tell us whether prior to commencing clinical trials you will need to demonstrate that your product candidates are comparable to the surrogates utilized in your preclinical testing.

Intellectual Property, page 112

13. With reference to your disclosures on pages 94-95, please revise to discuss briefly the aspects of the PREDATOR platform that are covered by patent claims directed to "platform technology."

Principal Stockholders, page 154

14. Please identify the natural person or persons who directly or indirectly exercise sole or shared voting and/or dispositive power with respect to the common stock held by Longwood Fund III. Refer to Item 403 of Regulation S-K.

General

15. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Gary Newberry at (202) 551-3761 or Brian Cascio at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at (202) 551-6902 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

FirstName LastNameDaniel J. Hicklin, Ph.D.

Division of Corporation Finance

Comapany NameWerewolf Therapeutics, Inc.

Office of Life Sciences

cc: Rosemary G. Reilly, Esq.