Jaguar Health, Inc.
Form 8-K
February 26, 2019

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): **February 25, 2019**

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36714**	**46-2956775**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

201 Mission Street, Suite 2375 **San Francisco, California** (Address of principal executive offices)	**94105** (Zip Code)

Registrant s telephone number, including area code: **(415) 371-8300**

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 x

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. x

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Item 8.01 Other Events.

On February 25, 2019, Napo Pharmaceuticals, Inc. (Napo), a wholly-owned subsidiary of Jaguar Health, Inc. (Jaguar), entered into a master contract services agreement with another pharmaceutical company (the Counterparty), pursuant to which Napo will conduct a study evaluating the effects of crofelemer (125 mg film-coated tablets) on tyrosine-kinase inhibitor (TKI) targeted therapy-induced diarrhea in dogs. The study will be funded by the Counterparty and will provide the scientific rationale and support for the use of crofelemer in providing symptomatic relief of noninfectious diarrhea in patients receiving TKI-targeted therapies in future human clinical investigations.

Crofelemer, the active pharmaceutical ingredient in Mytesi, Jaguar s FDA-approved human drug product, is isolated and purified from the *Croton lechleri* tree. Mytesi is indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

Jaguar is pursuing a follow-on indication for Mytesi in humans receiving targeted cancer therapy (TCT) for the symptomatic relief of TCT-related diarrhea. This is an important indication in support of patients who are undergoing cancer treatment with targeted cancer therapy drugs, with or without adjuvant chemotherapy. As part of Jaguar s near-term plan, Jaguar has scheduled a meeting with the FDA in March 2019 to discuss the anticipated protocol for a planned pivotal trial for the evaluation of crofelemer in TCT-related diarrhea. Jaguar plans to use the same formulation and dosing that is used for Mytesi s currently approved indication.

Disclaimer on Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. These include statements regarding Jaguar s plan to pursue a follow-on indication for Mytesi in humans for TCT-related diarrhea, Jaguar s near-term plan to meet with FDA to discuss the anticipated protocol for a planned pivotal trial for the evaluation of crofelemer in TCT-related diarrhea, and Jaguar s plans to use the same formulation and dosing for the possible follow-on indication for TCT-related diarrhea that is used for Mytesi s currently approved indication. In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, aim, anticipate, could, intend, target, believe, estimate, predict, potential or continue or the negative of these terms or other similar expressions. The forward-looking statements in this Current Report on Form 8-K are only predictions. Jaguar has based these forward-looking statements largely on its current expectations and projections about future events. These forward-looking statements speak only as of the date of this Current Report on Form 8-K and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Jaguar s control. Except as required by applicable law, Jaguar does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

JAGUAR HEALTH, INC.

By: /s/ Karen S. Wright
Name: Karen S. Wright
Title: Chief Financial Officer

Date: February 26, 2019