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 6, 2020**

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**	**94105**
(Address of principal executive offices)	(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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, Par Value $0.0001 Per Share	JAGX	The NASDAQ Capital Market

Item 7.01 Regulation FD Disclosure.

On August 6, 2020, Jaguar Health, Inc. (the "Company") issued a press release announcing the activation of the investigational new drug (IND) application filed by the Company's wholly owned subsidiary Napo Pharmaceuticals, Inc. ("Napo") with the U.S. Food and Drug Administration (FDA) for the use of crofelemer (Mytesi®) for prophylaxis and symptomatic relief of diarrhea in adult patients with solid tumors receiving targeted therapy with or without standard chemotherapy ("cancer therapy-related diarrhea" (CTD)). A copy of the press release is furnished as Exhibit 99.1.

The information in Item 7.01 and the press release furnished as Exhibit 99.1 hereto 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, or incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 6, 2020.

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/ Lisa A. Conte
Name: Lisa A. Conte
Title: Chief Executive Officer & President

Date: August 6, 2020

Exhibit 99.1

Jaguar Health Announces Activation of Investigational New Drug (IND) for Crofelemer (Mytesi) for Prophylaxis and Symptomatic Relief of Cancer Therapy-Related Diarrhea

A significant proportion of patients undergoing cancer therapy experience diarrhea

San Francisco, CA (August 6, 2020): Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") announced today the activation of the investigational new drug (IND) application filed by the Company's wholly owned subsidiary Napo Pharmaceuticals, Inc. ("Napo") with the U.S. Food and Drug Administration (FDA) for the use of crofelemer (Mytesi®) for prophylaxis and symptomatic relief of diarrhea in adult patients with solid tumors receiving targeted therapy with or without standard chemotherapy ("cancer therapy-related diarrhea" (CTD)). Activation of this IND is a key milestone for Napo to initiate its pivotal trial with Mytesi in CTD in adult solid tumor patients.

"We are very pleased that Napo's IND for CTD is now active," Lisa Conte, Jaguar's president and CEO, stated. "Many cancer patients on targeted therapy require drug holidays or dose reductions in their therapy due to diarrhea. Reducing frequency of watery stools will provide symptomatic relief of diarrhea and may allow better adherence to the therapeutic dosing of targeted therapies and/or chemotherapy, potentially leading to better clinical outcomes. In addition to tumor burden reduction, the adoption and/or continued use of targeted cancer therapies is also related to the ability of patients to tolerate their cancer therapies — highlighting the potential importance of Mytesi to help manage cancer treatment-related diarrhea in this patient population. Our planned study for diarrhea related to CTD will use the same formulation and dosing that is used for the current commercialized Mytesi for the symptomatic relief of HIV/AIDS associated diarrhea in adult patients receiving antiretroviral therapy."

According to the Centers for Disease Control and Prevention (CDC), approximately 650,000 cancer patients in the U.S. receive chemotherapy in an outpatient oncology clinic each year. A significant proportion of patients undergoing cancer therapy experience diarrhea, and diarrhea has the potential to cause dehydration, potential infections, and non-adherence to treatment in this population.

Novel "targeted cancer therapy" agents, such as epidermal growth factor receptor (EGFR) antibodies and tyrosine kinase inhibitors (TKIs), with or without cycle chemotherapy agents, may activate intestinal chloride ion channel-mediated secretory pathways, leading to increased electrolyte and fluid content in the gut lumen, which results in passage of loose/watery stools (i.e. secretory diarrhea). Diarrhea has been reported as one of the most common side effects of TKIs, including the recently approved irreversible pan-HER TKI neratinib (Nerlynx®), with occurrence ranging from 86% to >95% in published studies. Diarrhea is also a common side effect of some CDK 4/6 inhibitors.

The Company previously announced a preclinical study evaluating the effects of crofelemer (Mytesi) in providing symptomatic relief of diarrhea associated with neratinib (Nerlynx) at the American Association for Cancer Research Virtual Annual Meeting II, which took place June 22 - 24, 2020. The study was conducted by Napo in collaboration with Puma Biotechnology, Inc. (Puma). Nerlynx, a Puma drug product, is approved for the extended adjuvant treatment of adult patients with early stage HER2 positive breast cancer and for metastatic HER2 positive breast cancer.

Mytesi is a non-opiate, plant-based, chloride ion channel modulating antidiarrheal medicine that is currently FDA approved for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS receiving antiretroviral therapy. Mytesi has a novel mechanism of action that works locally in the gut by gently and effectively modulating and normalizing the flow of water and electrolytes with minimal systemic absorption.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, sustainably derived gastrointestinal products on a global basis. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy and the only oral plant-based prescription medicine approved under FDA Botanical Guidance.

For more information about Jaguar, please visit https://jaguar.health. For more information about Napo, visit www.napopharma.com.

About Mytesi®

Mytesi (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at Mytesi.com. Crofelemer, the active ingredient in Mytesi, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the development of crofelemer for the potential additional indication of prophylaxis and symptomatic relief of CTD, and the expectation that reducing frequency of watery stools will allow better adherence to the therapeutic dosing of targeted therapies and/or chemotherapy, potentially leading to better clinical outcomes. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “aim,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this release 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 release 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. Some of the factors that could affect our actual results are included in the periodic reports on Form 10-K and Form 10-Q that we file with the Securities and Exchange Commission. 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.

Source: Jaguar Health, Inc.

Contact:
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Jaguar-JAGX