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): **November 14, 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**	**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

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, Par Value $0.0001 Per Share	JAGX	The NASDAQ Capital Market

Item 7.01 Regulation FD Disclosure.

On November 14, 2019, the Company issued a press release announcing that the interim analysis requirement has been met for the third-party investigator-initiated Phase 2 HALT-D study evaluating the effectiveness of Mytesi® (crofelemer) for symptomatic relief in HER2 positive breast cancer patients receiving chemotherapy with trastuzumab, pertuzumab, and docetaxel or paclitaxel or trastuzumab, pertuzumab, carboplatin, and docetaxel. A copy of the press release is furnished as Exhibit 99.1 to this report.

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 November 14, 2019.

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: November 14, 2019

Jaguar Health Announces that Interim Analysis Requirement Met in Phase 2 HALT-D Study Evaluating Mytesi (Crofelemer) for Prevention and Prophylaxis of Diarrhea in Breast Cancer Patients

San Francisco, CA (November 14, 2019): Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), today announced that Georgetown University's Data Safety Monitoring Committee ("DSMC") has reviewed the interim analysis for futility for the third-party, investigator-initiated Phase 2 HALT-D study evaluating the effectiveness of Mytesi® (crofelemer) for symptomatic relief in HER2 positive breast cancer patients receiving chemotherapy with trastuzumab, pertuzumab, and docetaxel or paclitaxel or trastuzumab, pertuzumab, carboplatin, and docetaxel (the "Study"). The DSMC has notified the Principal Investigator that the Study is allowed to enroll to completion. Enrollment in the Study now exceeds 85%, and the treatment period for each patient is 3 months.

"We're very pleased to have been informed of the DSMC's decision and to see this important study milestone — 'Positive Interim Results' as defined in the July 2019 Company prospectus — achieved," Lisa Conte, Jaguar's president and CEO commented. "Although this Study is not required to support the clinical program for Mytesi (crofelemer) for FDA approval for cancer therapy-related diarrhea, the final results may inform us about potential exploratory clinical endpoints for our planned Phase 3 clinical study for cancer therapy-related diarrhea and development activities aimed at additional indications for Mytesi."

As previously announced, the protocol for the HALT-D Study is a randomized, 1:1, stratified, open-label phase II study in patients with HER2 positive breast cancer receiving trastuzumab, pertuzumab, and docetaxel or paclitaxel with or without carboplatin in any setting for three cycles. Mytesi (crofelemer) tablets are administered daily at an oral dose of 125 mg twice daily during cycles 1 and 2 of the treatment period. The endpoints to be analyzed are the total number of patients with all grade diarrhea for two or more consecutive days during cycles 1 and 2 and additional exploratory endpoints. The Study, which is sponsored by Georgetown University and funded by Genentech, a member of the Roche Group, called for an interim analysis for futility when the Study enrollment reached 50%. This interim analysis has now been completed and the Georgetown DSMC has indicated to the Principal Investigator that the Study is allowed to enroll to completion.

As recently announced, a preclinical study conducted in female dogs with an FDA-approved tyrosine kinase inhibitor (TKI), showed that Mytesi (crofelemer) treatment resulted in lesser incidence and severity of diarrhea in dogs with the maintenance and tolerability of up to a 20% higher dose of the selected TKI compared to placebo group.

A significant proportion of patients undergoing cancer treatment experience diarrhea as a major dose-limiting side effect. Novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and TKIs, with or without standard chemotherapy agents, may activate chloride ion channels that result in increased fluid and electrolyte content in the gastrointestinal lumen, potentially leading to secretory diarrhea.

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.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary 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.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the belief that reviewing the final results of the Study may inform the Company about potential exploratory clinical endpoints for the Company’s planned Phase 3 clinical study for cancer therapy-related diarrhea and development activities aimed at additional indications for Mytesi, and the belief that novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and TKIs, with or without standard chemotherapy agents, may activate chloride ion channels that result in increased fluid and electrolyte content in the gastrointestinal lumen, potentially leading to secretory diarrhea. 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.

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