
**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 16, 2019**

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36714
(Commission File Number)

46-2956775
(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):

- 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))

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 August 16, 2019, Jaguar Health, Inc. (the “Company”) issued a press release announcing the appointment of Carol R. Lizak as Chief Accounting Officer of the Company, as previously disclosed in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2019. A copy of the press release is furnished as Exhibit 99.1 to this report.

On August 19, 2019, the Company issued a press release announcing top line results from a preclinical pharmacological study to evaluate the effects of crofelemer on diarrhea induced in healthy dogs by a maximally tolerated dose of a specific tyrosine kinase inhibitor. A copy of the press release is furnished as Exhibit 99.2 to this report.

The information in this Item 7.01 and the press releases furnished as Exhibits 99.1 and 99.2 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated August 16, 2019.
99.2	Press Release, dated August 19, 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: August 19, 2019



Jaguar Health Appoints Carol Lizak Chief Accounting Officer

San Francisco, CA (August 16, 2019): Jaguar Health, Inc. (NASDAQ: JAGX) (“Jaguar” or the “Company”), a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis, announced today that the Company has promoted Carol Lizak to the role of chief accounting officer for Jaguar. Lizak formerly served as Jaguar’s vice president of finance and corporate controller.

Lizak has 20+ years of corporate controllership and financial planning & analysis experience under U.S. GAAP & IFRS. Prior to joining Jaguar, she served as senior director and corporate controller of Zosano Pharma Corporation, as controller of Quantum Secure, Inc., and as executive director, corporate controller of Alexza Pharmaceuticals, Inc. Prior thereto, she spent nine years as corporate controller of a subsidiary of HID Global Corporation. She holds an Executive MBA from Pepperdine Graziadio Business School.

“We are very pleased to have appointed Carol to this important role. She was instrumental in supporting our recent successful closing of an underwritten public offering of units for gross proceeds of \$16.56 million, and, following the closing of the offering, her effective leadership ensured the timely filing of Jaguar’s 10-Q for the second quarter of 2019. Looking forward, we believe Carol’s extensive financial experience in the life sciences sector will make her a strong addition to our management team as we look to expand our clinical and commercial activities,” Lisa Conte, Jaguar’s president and CEO, commented.

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.

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 expectation that Lizak’s financial leadership experience in the life sciences sector will make her a strong addition to Jaguar’s senior leadership team as the Company looks to expand clinical and commercial activities. 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. 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:

Peter Hodge
Jaguar Health, Inc.
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Jaguar-JAGX



Jaguar Health Achieves Statistically Significant Top Line Results in Study Evaluating Crofelemer for Treatment of Diarrhea Related to Targeted Cancer Therapy

Preclinical Study Results Expected to Provide Key Supportive Data for Future Clinical Investigations Evaluating Crofelemer for Treatment of Noninfectious Diarrhea in Human Cancer Patients Receiving Targeted Cancer Therapy

San Francisco, CA (August 19, 2019): Jaguar Health, Inc. (NASDAQ: JAGX) (“Jaguar” or the “Company”) announced today that statistically significant top line results have been achieved in a key preclinical pharmacological study to evaluate the effects of crofelemer on diarrhea induced in healthy dogs by a maximally tolerated dose of a specific tyrosine kinase inhibitor (TKI) (“the Study”). The results of the Study, which was funded by a third-party cancer agent manufacturer of an FDA-approved TKI, are expected to provide additional scientific rationale and support for the use of crofelemer in providing symptomatic relief of noninfectious diarrhea in human patients receiving TKI-and/or-other targeted cancer therapy-containing regimens in future human clinical investigations.

The top line results of the Study show that combined crofelemer groups demonstrated superior benefit for “responders” ($p=0.01$).

“We are very excited by these results, and hope to see a similar outcome in the interim data, expected to be available in the third quarter of this year, and final data, of a Phase 2 investigator initiated clinical study at Georgetown in human breast cancer patients receiving the targeted cancer therapy regimens Herceptin and Perjeta,” Lisa Conte, Jaguar’s president and CEO, stated. “Certain targeted cancer therapy agents have been reported to have 90% or higher incidence of diarrhea, which can impair the therapeutic use due to dose-reductions and/or result in discontinuation of such agents.”

The Study randomized 24 healthy Beagle dogs into three parallel groups over a treatment period of 28-days dosed with the TKI and placebo or crofelemer (crofelemer 125 mg delayed-release tablets) up to four times a day. Specifically, one group of dogs received crofelemer twice daily (BID group) with the TKI; another group received crofelemer four times daily (QID group) with the TKI; and the third group received placebo capsules four times a day (placebo group) with the TKI.

A key endpoint, a “responder,” was defined as any dog having <7 watery stools per week for at least two out of the four weeks of the Study. This clinical endpoint is similar to the “responder” analysis conducted for crofelemer 125 mg delayed-release tablets in the pivotal ADVENT trial that led to the approval of crofelemer 125 mg delayed-release tablets for the symptomatic relief of diarrhea in adult HIV/AIDS patients on antiretroviral therapy.

Top line results show that dogs enrolled in the QID group were 26.8 times more likely to be a “responder” than dogs in the placebo group ($p=0.02$). Specifically, 7/8 of the dogs in the QID group were “responders” compared to 3/8 of the dogs in the placebo group. Furthermore, dogs randomized to the BID group were 17.8 times more likely to be a “responder” when compared to dogs randomized to the control group ($p=0.03$). Specifically, 6/8 dogs in the BID group were “responders” compared to 3/8 dogs in the placebo group. There was no significant difference between dosing crofelemer twice daily compared to four times daily in providing symptomatic relief from diarrhea in the dogs. As stated above, the combined BID and QID groups demonstrated superior benefit for “responders” ($p=0.01$).

An additional endpoint evaluated the total number of watery stools during the study between the placebo and the two crofelemer treatment groups in the study. This analysis showed that dogs receiving placebo had approximately 33% higher incidence of watery stools when compared to the dogs randomized to the crofelemer BID or QID groups (p=0.04).

“The results from this key preclinical Study shows concordance and remarkable similarity to the substantial benefits that were observed in the pivotal human trial of crofelemer (ADVENT trial) that resulted in the approval of the drug for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. We are applying our lessons from the ADVENT trial and this preclinical Study in our next clinical study design that we are discussing with the FDA to allow the conduct of a single pivotal study for cancer therapy-related diarrhea in all solid tumor human patients,” stated Dr. Pravin Chaturvedi, Jaguar’s Chair of the Scientific Advisory Board and Chief Scientific Officer of Napo Pharmaceuticals, Inc., the Company’s wholly-owned, human-health focused subsidiary.

Dr. Michael Guy, DVM, MS, PhD, Jaguar’s vice president and clinical veterinarian, commented, “No opioids or loperamide were utilized in the Study, as is often the case when targeted therapy is administered to mitigate severe diarrhea, causing alternative issues with absorption of the lifesaving medication, constipation, and lethargy. We are quite impressed with the powerful statistical significance we’ve seen with only 24 dogs. Furthermore, dogs are an important model predictive of the benefit of the first-in-class mechanism of action of crofelemer in human patients.”

Crofelemer is an orally administered botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. As previously announced, crofelemer is in development for the possible indication of symptomatic relief of cancer therapy-related diarrhea (CTD). A significant proportion of patients undergoing cancer therapy experience diarrhea, which can cause some patients to discontinue their treatment or reduce their treatment dosage. Novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and TKIs, with or without cycle chemotherapy agents, may activate intestinal chloride secretory pathways, leading to increased chloride secretion into the gut lumen, coupled with significant loss of water, that would result in secretory diarrhea.

The Company will report additional data from the Study as further analysis is completed.

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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 expectation that the results of the Study, which was funded by a third-party cancer agent manufacturer of an FDA-approved TKI, will provide additional scientific rationale and support for the use of crotelemer in providing symptomatic relief of noninfectious diarrhea in human patients receiving TKI-and/or-other targeted cancer therapy-containing regimens in future human clinical investigations, and the expectation that the interim results of a Phase 2 study will be available in the third quarter of this year. 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. 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.

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