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): **May 4, 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 ☒

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. ☒

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 May 4, 2020, Jaguar Health, Inc. (the "Company") received a letter from the Committee on Oversight and Reform of the U.S. House of Representatives (the "Committee") regarding the list price adjustment of Mytesi® (crofelemer). Among other things, the Committee expressed an interest in understanding whether the price adjustment was connected to the Company's expectation that it could market crofelemer to treat coronavirus patients given the Company's submission of a request to the U.S. Food and Drug Administration ("FDA") for Emergency Use Authorization ("EUA") for crofelemer (Mytesi®) for the symptomatic relief of diarrhea and other gastrointestinal symptoms in patients with COVID-19 and for patients with COVID-19 who have diarrhea associated with certain antiviral treatments, which submission was denied by the FDA on April 7 as previously disclosed.

The Company intends to cooperate with the Committee's inquiry and has prepared a public statement regarding the price adjustment, which is available on the Company's website at https://jaguarhealth.gcs-web.com/company-statement. In its statement, the Company explains that the decision to adjust the price for crofelemer was made in December 2019 as part of expanding the Company's comprehensive patient access program, and had the Company received EUA, it would have deferred the price adjustment until after the emergency use period ended.

A copy of the Company's statement is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. The information in this Item 7.01 and in Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, or otherwise subject to the liabilities thereof, nor shall it be deemed to be incorporated by reference in any filing under the Securities and Exchange Act of 1934 or under the Securities Act of 1933, except to the extent specifically provided in any such filing.

Item 8.01 Other Events.

The information in the first paragraph of Item 7.01 above relating to the Company's receipt of a letter from the Committee is incorporated in this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Jaguar Health Statement on Mytesi® (crofelemer) April 2020 Price Adjustment and Commitment to Ensuring People Living with HIV Have Uninterrupted Access to Only FDA-Approved Non-Opioid, Plant-based, Anti-diarrheal Medication, dated May 4, 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.

Date: May 8, 2020

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

Exhibit 99.1

Jaguar Health Statement on Mytesi® (crofelemer) April 2020 Price Adjustment and Commitment to Ensuring People Living with HIV Have Uninterrupted Access to Only FDA-Approved Non-Opioid, Plant-based, Anti-diarrheal Medication

May 4, 2020

The following provides important context regarding our recent price adjustment for Mytesi® (crofelemer), the first-in-class, non-opioid, plant-based drug product of Napo Pharmaceuticals, Inc. (Napo), Jaguar's wholly owned subsidiary. Mytesi is approved by the U.S. Food and Drug Administration (FDA) for noninfectious diarrhea in adults living with HIV/AIDS who are on antiretroviral therapy.

- This price adjustment decision was made in December 2019 and is part of a comprehensive patient access program which was developed to ensure that no person living with HIV (PLWH) will be denied access to Mytesi due to cost; in fact, our goal is to expand access and create a pricing structure that supports patients and our unique tree-to-bottle business model.

- We presently are not a profitable company. We have one FDA approved product—Mytesi—with net sales of under $6 million in 2019. Our company of approximately 35 people serves a small proportion of the PLWH in the U.S. and we believe our product makes an important difference in their lives.

- Specifically, our team of ethnobotanists and other scientists at Napo started working with traditional healers in the Amazon Rainforest more than 30 years ago. Napo isolated and identified the active ingredient in Mytesi—crofelemer—from the sap of the *Croton lechleri* tree. Our team was the first to drive the development and approval of the first and only natural, fair trade plant-based oral drug approved under FDA botanical guidance.

- Importantly, Mytesi is the only anti-diarrheal specifically tested for chronic use in PLWH. It is locally acting in the gut and does not affect motility. We invested in risk-based R&D and continue to engage in responsible and sustainable harvesting practices while fairly supporting the Indigenous and local communities where our product is harvested.

- We remain 100% committed to ensuring that Mytesi is available to any patient who has a medically appropriate need for it while we continue to manage increasing costs and reimbursement barriers so that we can be a viable business, including supporting our GMP supply chain that extends from the Amazon Rainforest to a finished product in the U.S.

- Our pricing decision takes all of this into consideration along with our need to be a self-sustaining business. While the WAC price of Mytesi has been adjusted, it is important to know that this does not increase the price for Medicaid, ADAP, 340B entities, or for the patients that receive benefits from these programs. On April 1, 2020, we increased the Mytesi NapoCares copay benefit so that no PLWH should be denied access to Mytesi due to cost. We are bringing on a patient hub service provider to help us remove access barriers including insurance prior authorizations and appeals, and we will provide Mytesi at no cost during the period of adjudication of the patient's prior authorization. We've also increased the NapoCares Patient Assistance Program income ceiling from two times the Federal Poverty Limit to 5 times the Federal Poverty Limit, which will allow more low-income patients to receive Mytesi at no cost to them.

- While we did seek approval to provide Mytesi to patients who experience diarrhea as a symptom of their coronavirus infection based on published research that noted up to 40% of COVID-19 patients may experience diarrhea, our request for emergency use authorization was denied on April 7th, before we adjusted the price on April 9th. The price of Mytesi remained unchanged during the entire time it was being considered for emergency use in coronavirus patients. If we had received emergency use authorization, we would have deferred the price adjustment until after the emergency use period ended.

- Currently, Jaguar is not in discussions with the National Institute of Allergy and Infectious Diseases (NIAID) about the effectiveness of Mytesi for coronavirus patients.

“Napo embodies the challenges faced by a small pharmaceutical company with a novel product and pipeline and a long-standing commitment to sustainability in a reimbursement environment that is rarely conducive to supporting innovation,” said Lisa Conte, Jaguar Health President, CEO and Founder. “We look forward to responding to the request for information from the U.S. House Committee on Oversight and Reform, and welcome the opportunity to share our perspective on how we can continue to provide PLWH access to Mytesi and how to encourage a sustainable environment for emerging pharmaceutical companies that support innovation in both drug development and commercialization.”

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