
**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 25, 2020**

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.)

**200 Pine Street, Suite 400
San Francisco, California**
(Address of principal executive offices)

94104
(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.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, Par Value \$0.0001 Per Share	JAGX	The Nasdaq Capital Market

Item 8.01 Other Events

Jaguar Health, Inc. (“Jaguar” or the “Company”) and its wholly-owned subsidiary, Napo Pharmaceuticals, Inc. (“Napo”), are planning to study, develop and commercialize crofelemer, the Company’s novel proprietary drug, for an indication of inflammatory diarrhea, initially in Europe. The Company’s focus on this new indication is driven primarily by the emergence of the long-hauler COVID-19-recovery patients, sometimes referred to as chronic COVID or post-acute COVID syndrome. The Company intends to focus its clinical exploration in Europe, where single-payer healthcare systems focus on preventative measures to diagnose and treat symptoms that can be a precursor to potentially chronic illness. Endpoints being explored would include prophylaxis and/or symptomatic relief of diarrhea, reduction in inflammatory gut markers, and reduction in viral fecal shedding. The Company intends to evaluate various pathways to develop and commercialize crofelemer for inflammatory diarrhea, including collaborative relationships, strategic partnerships, and/or licensing of crofelemer.

Mytesi (crofelemer) is a novel, first-in-class anti-secretory agent which has a basic normalizing effect locally on the gut, and this mechanism of action has the potential to benefit multiple disorders. The Mytesi (crofelemer) product is approved in the U.S. by the U.S. Food and Drug Administration for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy, which includes people living with HIV and enteropathy, an inflammatory chronic syndrome typically affecting long-term HIV/AIDS survivors. Mytesi is in development for multiple possible follow-on indications, including cancer therapy-related diarrhea, a rare disease indication for infants and children with congenital diarrheal disorders (CDD), a rare disease indication for adult and pediatric patients with short bowel syndrome (SBS), supportive care for inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and idiopathic/functional diarrhea. As previously disclosed, Napo initiated its pivotal Phase 3 clinical trial of crofelemer (Mytesi) for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy (“cancer therapy-related diarrhea” (CTD)) this past October.

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, including statements related to the Company’s plan to study, develop and commercialize crofelemer for an indication of inflammatory diarrhea, the Company’s intention to focus its clinical exploration in Europe, the endpoints that the Company intends to explore in such study, and the Company’s intention to evaluate various pathways to develop and commercialize crofelemer for inflammatory diarrhea. The words “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. While the Company believes its plans, intentions and expectations reflected in those forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. The Company’s actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements. For information about the factors that could cause such differences, please refer to the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, including the information discussed under the captions “Item 1 Business,” “Item 1A. Risk Factors” and “Item 7 Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as the Company’s various other filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The Company assumes no obligation to update any forward-looking statement.

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: President and Chief Executive Officer

Date: November 25, 2020