

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **April 7, 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.)

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

Title of each class

Common Stock, Par Value \$0.0001 Per Share

Trading Symbol(s)

JAGX

Name of each exchange on which registered

The NASDAQ Capital Market

Explanatory Note

On April 10, 2020, Jaguar Health, Inc. (the “Company”) filed with the Securities and Exchange Commission a Current Report on Form 8-K (the “Original Filing”). This Amendment No. 1 to the Original Filing is being filed solely to clarify the disclosure regarding the communications between the Company and the National Institute of Allergy and Infectious Diseases. The Company has not made any other changes to the Original Filing.

Item 8.01 Other Events.

As previously disclosed, on April 2, 2020, Jaguar Health, Inc. (the “Company”) submitted a request to the U.S. Food and Drug Administration (“FDA”) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (“FDCA”) 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. On April 7, 2020, the FDA notified the Company that it was declining to issue an EUA for crofelemer at this time based on its consideration of section 564 of the FDCA and prioritization factors for the review of EUA requests, including but not limited to the public health need for the product and the urgency of treatment need.

The Company has offered to provide crofelemer to the National Institute of Allergy and Infectious Diseases (“NIAID”) for antiviral screening, which has not yet been accepted by NIAID for *in vitro* screening prioritization against SARS-CoV-2. For clarity, this is not Mytesi finished product and the testing does not involve COVID patients.

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 NIAID’s potential evaluation of antiviral activity of crofelemer. 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: Chief Executive Officer & President

Date: May 13, 2020