

**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): **June 28, 2018**

**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

**Item 1.01 Entry into a Material Definitive Agreement.**

On June 28, 2018, Napo Pharmaceuticals, Inc. ("Napo"), a wholly-owned subsidiary of Jaguar Health, Inc. (the "Company"), entered into a definitive co-promotion agreement (the "Agreement") with RedHill Biopharma Ltd. ("RedHill"), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary drugs for gastrointestinal ("GI") diseases, pursuant to which Napo granted RedHill the exclusive right to co-promote Mytesi, Napo's FDA-approved drug, to certain gastroenterologists and primary care physicians in the United States for the current approved indication of Mytesi.

In consideration for RedHill's services, Napo will pay RedHill a specified amount per unit of product dispensed. The Agreement specifies that Napo will grant RedHill a royalty-free right to use trademarks and copyrights relating to the Mytesi in connection with the promotion of Mytesi in the United States. The Agreement also contains provisions regarding payment terms, confidentiality and indemnification, as well as other customary provisions.

The co-promotion of Mytesi in the United States pursuant to the terms of the Agreement will be supervised and managed by a joint promotion committee composed of representatives from Napo and RedHill. Among other things, the committee is responsible for monitoring compliance with the Agreement and

the promotion plan and discussing the overall strategy for the marketing, promotion and sale of Mytesi in the United States.

The Agreement expires on December 28, 2018 unless extended by mutual agreement. The Agreement may be terminated by RedHill for convenience, in whole or in part, at any time upon 30 days' prior written notice to Napo. The Agreement may also be terminated by either party (i) for the other party's material breach or violation of law, where such breach or violation is not cured within the timeframe specified by the agreement, (ii) upon the bankruptcy, insolvency or dissolution of the other party, or (iii) upon the occurrence of a state or federal agency or administrative action due to any act or omission of the other party. Upon expiration of the term of the Agreement or termination by either party, all rights granted to RedHill under the Agreement will automatically terminated and revert to Napo.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2018, portions of which will be subject to a FOIA Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The omitted material will be included in the request for confidential treatment.

On June 28, 2018, the Company issued a press release announcing the Agreement. A copy of the press release is furnished as Exhibit 99.1 to this report.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated June 28, 2018.</a>

2

**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: July 5, 2018

By: /s/ Karen S. Wright  
Name: Karen S. Wright  
Title: Chief Financial Officer

3

**Jaguar Health (NASDAQ: JAGX) Subsidiary Napo Pharmaceuticals and RedHill Biopharma Enter U.S. Co-Promotion Agreement for Mytesi, Napo's FDA-Approved Drug Product**

- **RedHill (NASDAQ: RDHL) has been granted the exclusive right to co-promote Mytesi® (crofelemer 125 mg delayed-release tablets) to certain gastroenterologists and primary care physicians for the approved indication in people living with HIV/AIDS by Napo Pharmaceuticals**
- **Mytesi® is an FDA-approved antidiarrheal prescription drug indicated for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on antiretroviral therapy (ART) currently promoted by Napo's direct salesforce primarily to infectious disease specialists who are high ART prescribers**

**SAN FRANCISCO, CA - June 28, 2018** — Napo Pharmaceuticals, Inc. (Napo), a human health company developing and commercializing novel gastrointestinal prescription products from plants used traditionally in rainforest areas, and a wholly-owned subsidiary of Jaguar Health, Inc. (NASDAQ: JAGX) (Jaguar), today announced that it has entered into an agreement (the Agreement) with RedHill Biopharma Ltd. (RedHill) (NASDAQ: RDHL), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary drugs for gastrointestinal diseases and cancer, to establish a U.S. co-promotion program for Mytesi® (crofelemer 125 mg delayed-release tablets), Napo's FDA-approved drug, for the current approved indication. Mytesi is indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART).

As of the second quarter of 2018, Napo deploys 18 dedicated, highly experienced Mytesi sales representatives—strategically positioned to cover U.S. geographies with the highest potential—in addition to a national sales director, a regional business director, and a telesales representative. Napo's direct salesforce is supported by a full complement of patient and healthcare practitioner education programs, direct-to-consumer advertising campaigns, publication-focused efforts, the NapoCares™ Patient Assistance Program, and government affairs activities regarding neglected comorbidities of HIV.

Under the terms of the Agreement, which became effective June 28, 2018, RedHill's specialized, GI-focused U.S. field salesforce will promote Mytesi to healthcare practitioners in 38 territories within the U.S. that contain significant numbers of HIV patients and healthcare practitioners that are not currently covered by Napo's field salesforce. In these regions, RedHill sales representatives will target gastroenterologists who see large populations of people living with HIV (PLWH) along with other practitioners who see high volumes of PLWH, including nurse practitioners and physician assistants. Additionally, RedHill field representatives will target lower-decile infectious disease specialists in regions currently covered by Napo's salesforce, and four RedHill inside sales representatives will actively target healthcare practitioners in other regions not covered by the Napo or RedHill field representatives.

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“We believe this co-promotion program will play a significant role in extending the reach of our commercial efforts into the GI medical community in support of the treatment of PLWH with Mytesi, a novel, first-in-class gastrointestinal product,” Lisa Conte, Jaguar's president and CEO, stated. “Under the terms of the Agreement, RedHill will be compensated based on performance, and the program can be extended by agreement between the two companies.”

Dror Ben-Asher, RedHill's CEO, stated, “We look forward to working with Napo to make this important drug available to more patients suffering from diarrhea associated with HIV/AIDS. Mytesi is the fourth product to be promoted by RedHill and the first first-in-class FDA-approved drug promoted by our gastrointestinal-focused U.S. sales force. We share Napo's enthusiasm that Mytesi will be a successful, novel entry to GI care, and we are eager to support its commercial expansion.”

Napo will continue to book revenue for Mytesi sales and RedHill will be compensated based on performance. RedHill expects to initiate promotion of Mytesi in the coming weeks.

Mytesi is the only antidiarrheal studied in and U.S. FDA-approved for the symptomatic relief of noninfectious diarrhea in adults living with HIV/AIDS on antiretroviral therapy (ART). Mytesi is a prescription treatment for diarrhea that works differently, by acting locally in the GI tract to normalize the flow of water. Mytesi does not have any clinically relevant drug-drug interactions and has side effects that are similar to placebo.

#### **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](http://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 RedHill Biopharma Ltd.:**

RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases. More information about the Company is available at: [www.redhillbio.com](http://www.redhillbio.com).

#### **About Jaguar Health, Inc.**

Jaguar Health, Inc. is a commercial stage natural-products 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](http://jaguar.health). For more information about Napo, visit [napopharma.com](http://napopharma.com).

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## Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the belief that this co-promotion program will play a significant role in extending the reach of Napo’s sales efforts into the GI medical community in support of the treatment of PLWH with Mytesi, and the belief of Napo and RedHill that Mytesi will be a successful, novel entry to gastrointestinal care. 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:**

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