

**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): **September 22, 2017**

**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

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.

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

On September 25, 2017, Jaguar Health, Inc. (the "Company") announced that its wholly-owned subsidiary, Napo Pharmaceuticals, Inc. ("Napo"), entered into the Termination, Asset Transfer and Transition Agreement (the "Agreement"), dated September 22, 2017 (the "Transfer Date"), with Glenmark Pharmaceuticals Ltd. ("Glenmark"). Glenmark is Napo's primary manufacturer of crofelemer, the active pharmaceutical ingredient (API) in Mytesi®, the Company and Napo's human prescription drug product approved by the U.S. Food and Drug Administration. The Agreement supersedes the Collaboration Agreement, dated July 2, 2005, by and between Napo and Glenmark (the "Collaboration Agreement") and returns to Napo certain rights which Napo licensed to Glenmark pursuant to the Collaboration Agreement related to the development and commercialization of crofelemer for certain specified human indications in India and 140 other countries largely in developing regions (the "Transferred Assets").

As a result of the execution of the Agreement, the Company, through Napo, now controls commercial rights for Mytesi® for all indications, territories and patient populations globally, and also holds commercial rights to the existing regulatory approvals for crofelemer in Brazil, Ecuador, Zimbabwe and Botswana.

In consideration for Glenmark's assignment and transfer of the Transferred Assets to Napo, Napo agreed to pay Glenmark in cash, within 45 days after receipt by Napo, 25% of any payment that Napo receives from a third party to whom Napo grants a license or sublicense or with whom Napo partners in respect of, or sells or otherwise transfers any of the Transferred Assets, subject to certain exclusions, until Glenmark has received a total of \$7 million. As additional consideration for the assignment and transfer of the Transferred Assets, Napo agreed (i) to enter into, within 90 days after the Transfer Date, a manufacturing and supply agreement with Glenmark for crofelemer, which will be manufactured at either or both of Glenmark's facilities in India and (ii) to transfer and assign to Glenmark all right, title and interest in and to certain required dedicated equipment used to manufacture crofelemer located at Glenmark's Ankleshwar facility, subject to certain conditions.

On September 25, 2017, the Company issued a press release announcing the Agreement. The Company is furnishing a copy of the press release, which is attached as Exhibit 99.1 of this Form 8-K.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

Exhibit No.	Description
99.1	<a href="#">Press Release, dated September 25, 2017.</a>

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**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: September 25, 2017

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

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**Jaguar Subsidiary Napo Pharmaceuticals and Glenmark Pharmaceuticals Sign Agreement Returning Key Rights in 141 Countries to Napo, Solidifying Jaguar's Global Commercial Control of Mytesi (Crofelemer), Jaguar's FDA-Approved Human Drug**

**Glenmark Will Continue to Serve as the cGMP-compliant Commercial Manufacturer of Crofelemer for Jaguar and Napo at its FDA-Approved Facilities in India**

**Agreement Also Provides Napo with Commercial Rights to the Existing Regulatory Approvals for Crofelemer in Brazil, Ecuador, Zimbabwe & Botswana**

**San Francisco, CA (September 25, 2017):** Jaguar Health, Inc. (NASDAQ: JAGX) (Jaguar), a natural-products pharmaceuticals company focused on developing and commercializing novel, sustainably-derived gastrointestinal products for both human prescription use and veterinary use on a global basis, announced today that its wholly-owned subsidiary, Napo Pharmaceuticals, Inc. (Napo), has entered into a Termination, Asset Transfer and Transition Agreement (the Agreement) with India-based Glenmark Pharmaceuticals Ltd. (Glenmark). Glenmark is Napo's primary manufacturer of crofelemer, the active pharmaceutical ingredient (API) in Mytesi<sup>®</sup>, Jaguar's and Napo's FDA-approved human prescription drug product. The Agreement returns to Napo certain rights which Napo licensed to Glenmark in 2005 related to the development and commercialization of crofelemer for certain specified human indications in India and 140 other countries largely in developing regions. As a result of the execution of the Agreement, Jaguar, through Napo, now controls commercial rights for Mytesi<sup>®</sup> for all indications, territories and patient populations globally, and also holds commercial rights to the existing regulatory approvals for crofelemer in Brazil, Ecuador, Zimbabwe and Botswana.

Mytesi<sup>®</sup> is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Jaguar and Napo are pursuing a follow-on indication for Mytesi<sup>®</sup> in chemotherapy-induced diarrhea (CID), an important supportive care indication for patients undergoing primary or adjuvant chemotherapy for cancer treatment. Mytesi<sup>®</sup> is also in development for rare disease indications for infants and children with congenital diarrheal disorders and short bowel syndrome (SBS); for irritable bowel syndrome (IBS) (Mytesi<sup>®</sup> has demonstrated benefit to IBS-D patients in published Phase 2 studies); for supportive care for inflammatory bowel disease (IBD); and as a second-generation anti-secretory agent for use in cholera patients. Mytesi<sup>®</sup> has received orphan-drug designation for SBS.

Pursuant to Napo's settlement with Salix Pharmaceuticals, Inc. in May 2016, Napo has held global commercial rights to Mytesi<sup>®</sup> for certain proposed follow-on indications, including CID, IBS and IBD.

Crofelemer, which was developed by members of Jaguar's management team while working at Napo, is isolated and purified from the *Croton lechleri* tree, which is sustainably harvested by Jaguar. Crofelemer is also the API in Canalevia<sup>™</sup>, Jaguar's prescription drug product candidate for treatment of various types of diarrhea in dogs. As previously announced, Jaguar signed a four-year manufacturing and supply agreement with Glenmark in September 2015 for the manufacture of crofelemer.

"We highly value our relationship with Glenmark, given their expertise and long-term experience in the cGMP-compliant manufacturing of crofelemer. Although the transfer of rights covered by the Agreement for the specified emerging economies has for some time been agreed to in principle between Jaguar and Glenmark—as part of our joint negotiations on the global

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manufacturing and supply of crofelemer—we are very pleased about the signing of this new Agreement," Lisa Conte, Jaguar's president and CEO, stated. "As a result of the execution of the Agreement, Jaguar is now free to design and implement a truly global strategy to bring Mytesi<sup>®</sup> to approval for potentially millions of patients for our proposed follow-on indications, and for the corresponding opportunities for financial return that we expect will result for our various stakeholders."

Glenmark manufactures crofelemer for Jaguar and Napo at its facilities located in Ankleshwar, India, and in Aurangabad, India.

**About Glenmark Pharmaceuticals Ltd.**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2017). Glenmark is a leading player in the discovery of new molecules—both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is focused in the areas of oncology, dermatology and respiratory.

The company has significant presence in the branded generics markets across emerging economies including India. Glenmark has 16 manufacturing facilities across five countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

**About Mytesi<sup>®</sup>**

Mytesi<sup>®</sup> (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi<sup>®</sup> is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi<sup>®</sup>. 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%).

More information and complete Prescribing Information are available at Mytesi.com. Crofelemer, the active ingredient in Mytesi<sup>®</sup>, 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 Jaguar Health, Inc.

Jaguar Health, Inc. is a natural-products pharmaceuticals company focused on developing and commercializing novel, sustainably derived gastrointestinal products for both human prescription use and animals 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. Mytesi® is in development for

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multiple possible follow-on indications, including chemotherapy-induced diarrhea; orphan-drug indications for infants and children with congenital diarrheal disorders and short bowel syndrome; supportive care for inflammatory bowel disease (IBD); irritable bowel syndrome (IBS); and as a second-generation anti-secretory agent for use in cholera patients. Canalevia™ is our lead animal prescription drug candidate, intended for treatment of various forms of diarrhea in dogs. Equilevia™ is Jaguar's non-prescription product for total gut health in equine athletes. Canalevia™ and Equilevia™ contain ingredients isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm™ Calf and Neonorm™ Foal are Jaguar's lead non-prescription animal products. Mytesi®, Canalevia™, Equilevia™ and Neonorm™ are distinct products that act at the same last step in a physiological pathway generally present in mammals.

For more information about Jaguar, please visit [jaguar.health](http://jaguar.health). For more information about Napo, visit [napopharma.com](http://napopharma.com).

## Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the development of potential Mytesi® follow-on indications, and the Company's development of a global strategy to bring Mytesi® to approval for potentially millions of patients for the Company's proposed follow-on indications, and the corresponding opportunities for financial return that the Company expects will result for its various stakeholders. 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.

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