# 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, 2015

# JAGUAR ANIMAL 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):

- 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))

#### Item 1.01 Entry into a Material Definitive Agreement

On September 22, 2015, Jaguar Animal Health, Inc. ("Jaguar") and Glenmark Pharmaceuticals Ltd. ("Glenmark") entered into a manufacturing and supply agreement (the "Agreement"). Under the Agreement, Glenmark will serve as Jaguar's manufacturer of crofelemer for animal health use. The Agreement contains provisions regarding the rights and responsibilities of the parties with respect to manufacturing specifications, forecasting and ordering, delivery arrangements, payment terms, confidentiality and indemnification, as well as other customary provisions. The term of the Agreement is four years.

On September 28, 2015, Jaguar issued a press release announcing the Agreement. Jaguar is furnishing a copy of the press release, which is attached as Exhibit 99.1 to this Form 8-K.

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 Jaguar's Quarterly Report on Form 10-Q for the fiscal period ending September 30, 2015, 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, for certain portions of the Agreement. The omitted material will be included in the request for confidential treatment.

## Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number

Description

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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 ANIMAL HEALTH, INC.

By: /s/ John A. Kallassy

Name: John A. Kallassy

Title: Executive Vice President, Chief Financial Officer, Chief

Operating Officer and Treasurer

Date: September 28, 2015



#### Jaguar Animal Health Signs Crofelemer Manufacturing & Supply Agreement with Glenmark Pharmaceuticals Ltd.

San Francisco, CA (September 28, 2015): Jaguar Animal Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, announced today that it has signed a four-year manufacturing and supply agreement with Glenmark Pharmaceuticals Ltd. ("Glenmark"). With the execution of the agreement, Jaguar intends to use Glenmark as its primary manufacturer of crofelemer for animal health use.

Crofelemer is an active pharmaceutical ingredient ("API") isolated and purified from the *Croton lechleri* tree, which is sustainably harvested by Jaguar. Crofelemer is the API in Canalevia<sup>™</sup>, Jaguar's lead prescription drug product candidate for the treatment of various forms of watery diarrhea in dogs. Jaguar is also developing formulations of Canalevia<sup>™</sup> for cats and horses.

A human-specific formulation of crofelemer, Fulyzaq®(1), was approved by the U.S. FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of Jaguar's management team developed crofelemer while working at Napo Pharmaceuticals, Inc. ("Napo"), and Glenmark is the current manufacturer of crofelemer for Fulyzaq. In 2014 Jaguar entered into a license agreement with Napo granting Jaguar a Right of Reference to the entirety of the information included in the U.S. FDA-approved human new drug application of crofelemer.

As Jaguar announced this past August, it has submitted to the U.S. FDA all required major technical sections of its New Animal Drug Application ("NADA") for Canalevia™. "Given Glenmark's long-term experience in the manufacture of crofelemer, we expect this relationship to allow us to bring Canalevia™ to market in the most efficient, rapid and cost-effective manner possible," explained Lisa Conte, Jaguar's president and CEO. "The Chemistry, Manufacturing and Controls section of our Canalevia™ NADA leverages the fact that we will be utilizing the same cGMP-compliant manufacturer that produces the crofelemer product approved for human use. This plan is in line with our expectations, which were discussed during our meeting with the U.S. FDA's Center for Veterinary Medicine earlier this year."

"Our agreement with Glenmark supplements our previously announced manufacturing agreement with Milan, Italy-based Indena S.p.A. for Neonorm $^{\text{\tiny M}}$ , the standardized botanical extract in our non-prescription products, Neonorm $^{\text{\tiny M}}$  Calf and Neonorm $^{\text{\tiny M}}$  Foal Plus. We intend to eventually use Indena as an alternative supplier for crofelemer," stated Conte.

#### About Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals Ltd. is a research-driven, global, integrated pharmaceutical company and ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues. Glenmark is a leading player in the discovery of new NCE and NBE molecules. Glenmark has several molecules in various stages of clinical development and is primarily focused on the areas of inflammation, pain and oncology. The company has significant presence in branded formulations across emerging economies including India. Glenmark also has a significant presence in the generic pharmaceuticals markets in the U.S. and Europe.

#### About Indena S.p.A.

Indena S.p.A. is dedicated to the identification, development and production of high-quality active principles derived from plants, for use in the pharmaceutical, health food and personal care industries. Headquartered in Milan and founded in 1921, Indena has five production sites, five international branches throughout the world, manages distribution operations in more than 70 countries, and employs more than 800 staff.

#### About Jaguar Animal Health, Inc.

Jaguar Animal Health, Inc. is an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals. Canalevia<sup>™</sup> is Jaguar's lead prescription drug product candidate for the treatment of various forms of watery diarrhea in dogs. Neonorm<sup>™</sup> Calf is the Company's lead non-prescription product. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm<sup>™</sup> is a standardized botanical extract derived from the *Croton lechleri* tree. Canalevia and Neonorm<sup>™</sup> are distinct products that act at the same last step in a physiological pathway generally present in mammals. Jaguar has filed nine Investigational New Animal Drug applications, or INADs, with the U.S. FDA and intends to develop species-specific formulations of Neonorm<sup>™</sup> in six additional target species, and formulations of Canalevia for cats, horses and dogs.

For more information, please visit www.jaguaranimalhealth.com.

#### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's planned development of formulations of Canalevia™ for cats and horses, the Company's expectation that its relationship with Glenmark will allow Jaguar to bring Canalevia™ to market in the most efficient, rapid and cost-effective manner possible, and Jaguar's intention to eventually use Indena S.p.A. as an alternative supplier for crofelemer. 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.

(1) Fulyzaq $^{\$}$  is a registered trademark of and is marketed by Salix Pharmaceuticals, Inc.

Source: Jaguar Animal Health, Inc.

#### **Contact:**

Garth Russell KCSA Strategic Communications P: 212-896-1250 grussell@kcsa.com Jaguar-JAGX