

**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): **October 8, 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):

- 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))

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

On October 8, 2015, Jaguar Animal Health, Inc. ("Jaguar") and Patheon Pharmaceuticals Inc., a wholly owned subsidiary of Patheon Inc., ("Patheon") entered into a formulation development and manufacturing agreement (the "Agreement"). Under the Agreement, Patheon will provide crofelemer tablets for Jaguar for use in animals. The Agreement contains standard 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 estimated duration of the Agreement is up to 36 months.

On October 15, 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 with the Securities and Exchange Commission (the "Commission") no later than as an exhibit to Jaguar's Annual Report on Form 10-K for the fiscal year ending December 31, 2015, portions of which will be subject to a FOIA Confidential Treatment Request to the 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.

99.1 Jaguar Animal Health, Inc. Press Release dated October 15, 2015.

**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: October 15, 2015



## Jaguar Animal Health Signs Crofelemer Formulation Development and Manufacturing Contract with Patheon

### Contract Secured in Preparation for Pivotal Trial & Expected Launch of Jaguar's Prescription Drug Candidate, Canalevia, for Acute Diarrhea in Dogs

#### Jaguar to Leverage Patheon's Experience Manufacturing FDA-approved, Human-specific Formulation of Crofelemer

**San Francisco, CA (October 15, 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 crofelemer formulation development and manufacturing contract with Patheon, a leading global provider of drug development and delivery solutions to the global pharmaceutical and biopharma industries. Crofelemer is an active pharmaceutical ingredient (API) in Canalevia™, Jaguar's prescription drug product candidate for the treatment of various forms of acute diarrhea in dogs.

Under the terms of the contract, Patheon will provide enteric-coated crofelemer tablets for Jaguar for use in animals. The tablets will be used in Jaguar's pivotal efficacy trial for Canalevia™, scheduled to begin in the fourth quarter of this year. Jaguar expects to use safety and effectiveness data from this trial in support of the initiation of the filing of a new animal drug application (NADA) with the FDA for Canalevia™ in 2016 for the indication of acute diarrhea in dogs. A Jaguar proof-of-concept study completed earlier this year provided statistically significant results indicating that Canalevia™ is superior to a placebo for the treatment of acute diarrhea in dogs.

Crofelemer is isolated and purified from the *Croton lechleri* tree, which is sustainably harvested by Jaguar. Jaguar is also developing formulations of Canalevia™ for cats and horses.

Patheon is the manufacturer of Fulyzaq®(1), a human-specific, enteric-coated formulation of crofelemer that was approved by the 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), where the drug was initially developed. In 2014 Jaguar entered into a license agreement with Napo which, among other things, assigned to Jaguar Napo's rights of reference to the information included in the FDA-approved human new drug application of crofelemer to support Jaguar's regulatory submissions for global veterinary purposes.

As Jaguar announced this past August, it has submitted to the FDA all required major technical sections towards a conditional NADA for Canalevia™ for dogs suffering from chemotherapy-induced diarrhea (CID), a minor use in a major species (MUMS). MUMS is an FDA drug designation, similar to the orphan drug designation in humans, which is typically limited to the use of a drug to treat disease that occurs infrequently or in a small number of animals. FDA encourages sponsors to seek MUMS designation and conditional approval of qualifying drugs to address unmet medical needs in the veterinary industry. Jaguar is preparing for the expected commercial launch of Canalevia™ for CID in the first half of 2016.



"Our contract with Patheon is a key component of our carefully-crafted formulation and manufacturing plan for Canalevia™," stated Lisa Conte, Jaguar's president and CEO. "The Chemistry, Manufacturing and Controls section of our NADA for Canalevia™ for CID leverages the fact that we will be utilizing the same cGMP-compliant manufacturers that produce the crofelemer product approved for human use, and we plan to take the same approach with our Canalevia™ NADA for acute canine diarrhea. This plan was discussed during our meeting with the FDA's Center for Veterinary Medicine earlier this year."

The Company announced last month that it recently signed a manufacturing and supply agreement with a leading, India-based pharmaceutical company, and Jaguar intends to use this firm as its primary manufacturer of the crofelemer API for animal health use.

#### About Patheon

Patheon is a leading global provider of outsourced pharmaceutical development and manufacturing services. With approximately 8,700 employees worldwide, Patheon provides a comprehensive, integrated and highly customizable set of solutions to help customers of all sizes satisfy complex development and manufacturing needs at any stage of the pharmaceutical development cycle.

#### 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™ is Jaguar's lead prescription drug product candidate for the treatment of various forms of diarrhea in dogs. Neonorm™ 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™ is a standardized botanical extract derived from the *Croton lechleri* tree. Canalevia™ and Neonorm™ 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 FDA and intends to develop species-specific formulations of Neonorm™ in six additional target species, and formulations of Canalevia™ for cats, horses and dogs.

For more information, please visit [www.jaguaranimalhealth.com](http://www.jaguaranimalhealth.com).

## Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the expected launch of Canalevia™ for acute diarrhea in dogs, the initiation of Jaguar’s pivotal efficacy trial for Canalevia™ in the fourth quarter of this year, Jaguar’s expectation of using safety and effectiveness data from the pivotal trial in support of the initiation of the filing of an NADA with the FDA for Canalevia™ in 2016 for the indication of acute diarrhea in dogs, Jaguar’s expected commercial launch of Canalevia™ for CID in the first half of 2016, the Company’s intention to leverage, in the Chemistry, Manufacturing and Controls section of its NADA for Canalevia™ for acute diarrhea in dogs, its plan to utilize the same cGMP-compliant manufacturers that produce the crofelemer product approved for human use, Jaguar’s intention to use the India-based pharmaceutical firm as its primary manufacturer of the crofelemer API for animal health use, the Company’s intention to develop species-specific

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formulations of Neonorm™ in six additional target species, and Jaguar’s planned development of formulations of Canalevia™ for cats, horses, and dogs. 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.

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(1)Fulyzaq® is a registered trademark of and is marketed by Salix Pharmaceuticals, Inc.

Source: Jaguar Animal Health, Inc.

### Contact:

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