

**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): **May 13, 2016**

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 7.01 Regulation FD Disclosure.

On May 13, 2016, Jaguar Animal Health, Inc. (the "Company") mailed its annual report to shareholders and the accompanying letter from the Company's CEO and President (the "Letter to Shareholders") to its shareholders. A copy of the Letter to Shareholders is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Letter to Shareholders, dated May 2, 2016.

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/ Karen S. Wright

Name: Karen S. Wright

Title: Chief Financial Officer

Date: May 13, 2016



DEAR FELLOW STOCKHOLDERS,

Fiscal year 2015 was a year of important progress for Jaguar Animal Health. Since the completion of our initial public offering in May 2015, we have delivered on multiple clinical, product development and operational milestones. I am both delighted by these achievements and grateful for the continued support of our employees and stockholders. Jaguar's product results have demonstrated that we are delivering on our business premise and strategic plan.

LOW RISK PRODUCT DEVELOPMENT

Our expanding line of gastrointestinal products is progressing through different phases of clinical development in various animal species. This is based on the FDA-approved first-in-class anti-diarrheal for humans, crofelemer. As we announced this past December, the pivotal clinical field study to evaluate the safety and effectiveness of crofelemer, under the trade name Canalevia—our lead prescription drug product candidate for acute diarrhea in dogs, is underway. This trial is progressing with protocol concurrence with the FDA.

Jaguar received Minor Use in a Major Species (MUMS) designation for Canalevia for Chemotherapy-Induced Diarrhea (CID) in dogs, which provides an opportunity to shorten the timeframe to commercialization. If we receive conditional approval from the FDA, we anticipate achieving our first new animal drug application in the second half of 2016. Launching for CID will aid in introducing this novel anti-secretory medicine to the companion animal veterinary community prior to the expected launch, in 2017, of Canalevia for the broader indication of acute diarrhea. Accordingly, we anticipate Canalevia marketing efforts will initially focus on veterinary oncologists, to be followed by targeted marketing to veterinary clinics and dog owners.

Canalevia utilizes the same mechanism of action as our core non-prescription drug products—Neonorm Calf and Neonorm Foal—and of Fulyzaq, a human drug approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Each of these products normalizes ion and water flow into the intestinal lumen. Because this is a physiological pathway generally present in mammals, we have validated our low risk strategy of extending the clinical success in humans to preweaned dairy calves, foals, and dogs; and we believe these clinical benefits will continue to be confirmed in other mammalian species.

According to the American Veterinary Medical Association, there were approximately 70 million dogs in the U.S. in 2012. Diarrhea is one of the most common reasons for veterinary visits for dogs and the second most common reason for visits to the veterinary emergency room, yet there are currently no FDA-approved anti-secretory agents to treat acute diarrhea or CID in dogs. As we stated last July in our press release about the completion of Jaguar's pilot safety study of Canalevia in dogs suffering from CID, we estimate that more than 230,000 dogs receive chemotherapy treatment for cancer each year in the U.S., with over 25% suffering from CID.

A HEIGHTED FOCUS ON THE EQUINE MARKET

The reception among users of Neonorm Foal, the anti-diarrheal product we launched for newborn horses early this year with a nationwide campaign offering samples, has been overwhelmingly positive. The clinically-proven performance of Neonorm Foal, in combination with our heightened understanding of market needs within the global equine space, is driving our increased focus on equine product development. Data from the American Horse Council states that there are an estimated 9.2 million horses in the U.S. alone, a population that includes nearly 845,000 race horses, more than 2.7 million show horses, and more than 3.9 million recreational horses. The positive reception to Neonorm Foal by early users is helping establish the Jaguar brand among horse owners, horse breeders and equine veterinarians—the expected future customers of the equine drug product candidates in our pipeline.

We are very encouraged by the results of our recently completed proof-of-concept study to evaluate the safety and effectiveness of SB-300, our investigational new animal drug for treatment of Equine Gastric Ulcer Syndrome. According to a third-party study, as many as 55% of performance horses have both colonic and gastric ulcers, and 97% of performance horses have either a gastric (87%) or a colonic (63%) ulcer.¹ Gastric ulcers can occur in both squamous and glandular regions of the horse's stomach. In particular, we believe there are no adequate solutions for treatment of glandular ulcers. As previously reported, SB-300 showed powerful results in a proof-of-concept study for glandular ulcers. Results of Jaguar studies also show that SB-300 may offer horse owners additional advantages: The product candidate does not negatively impact gastric pH levels, and standard drug testing of race horses that received SB-300 did not detect any substances commonly disallowed by racing authorities. Jaguar is continuing this program, with ongoing studies to confirm commercial dosing and formulation, and with a plan to initiate a pivotal field trial in 2016.

Jaguar initiated a pilot safety study in December of last year to evaluate use of crofelemer for treatment of diarrhea associated with acute colitis in horses. Crofelemer is an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. Colitis can affect thousands of horses in the U.S. each year, placing the animals at risk of severe morbidity and mortality. We believe treatment of acute colitis in high-value racing and performance horses represents a premium market opportunity for Jaguar.

ADVANTAGES OF COMMERCIALIZING PRODUCTS IN THE ANIMAL HEALTH SPACE

Product commercialization in the animal health space is a less complex process than in the human drug world. Lack of comprehensive reimbursement organization permits companies like Jaguar to commercialize products directly to veterinarians, with aligned animal health and financial incentives. Additionally, because the markets for Jaguar's products are geographically focused, we believe this makes them practical for a small company to target.

BENEFITS OF COMMERCIALIZING NEONORM: A LEARNING OPPORTUNITY FOR THE MARKET AND JAGUAR

As with Neonorm Foal, user feedback regarding Neonorm Calf has been very positive. Commercialization of these two non-prescription drug products has provided numerous benefits that we intend to leverage during our expected introductions of revenue-generating prescription drug products into the U.S. marketplace and beyond. The process has allowed us to build out a top-notch clinical development team, fine-tune internal processes, forge important

commercial manufacturing relationships, and develop commercial infrastructure with leading distributors like Vedco, Animart and Biogenesis Bagó. Our efforts have also permitted Jaguar to create relationships with thought-leaders in the veterinary community and begin the education process to the market regarding the novel mechanism of action of our anti-secretory products.

A ROBUST PIPELINE

We expect to have proof-of-concept results later this year for our drug product candidate for acute diarrhea in cats. We are also developing products such as Virend for feline herpes, and NP-500 for Type II diabetes and metabolic syndrome. Both of these product candidates have been through Phase 2 human clinical testing by third parties.

A WORLD-CLASS TEAM

I am also pleased to report that Jaguar has built an outstanding team of highly motivated and extremely experienced animal health professionals. In preparation for the expected launch of Canalevia, we intend to expand our commercial team, which will be based out of our San Francisco headquarters.

The progress Jaguar has made in our first year as a public company would not have been possible without the dedication of our employees and the support of our partners, customers and stockholders, and for that I thank each and every one of you. Together, let us look forward to the further realization of Jaguar's goals and translation of these expected achievements to company value recognition in 2016 and beyond.

Sincerely,



Lisa A. Conte
Chief Executive Officer & President
May 2, 2016

Forward-Looking Statements

Certain statements in this Stockholders Letter constitute "forward-looking statements." These include statements regarding Jaguar's belief that, if the Company receives conditional approval from the FDA for Canalevia, Jaguar will achieve its first new animal drug application in the second half of 2016, the Company's belief that launching Canalevia for CID will aid in introducing this novel anti-secretory medicine to the companion animal veterinary community prior to the expected launch, in 2017, of Canalevia for the broader indication of acute diarrhea, Jaguar's intention that Canalevia marketing efforts will initially focus on veterinary oncologists, to be followed by targeted marketing to veterinary clinics and dog owners, the Company's belief that the clinical benefits of its anti-secretory products will continue to be confirmed in other mammalian species, Jaguar's plans to initiate a pivotal field trial in 2016 for SB-300, Jaguar's belief that treatment of acute colitis in high-value racing and performance horses represents a premium market opportunity for the Company, Jaguar's belief that the geographically focused nature of the markets for its products makes them practical for a small company to target, the Company's belief that commercialization of Neonorm Foal and Neonorm Calf has provided numerous benefits that Jaguar will be able to leverage during the Company's expected introductions of revenue-generating prescription drug products into the U.S. marketplace and beyond, Jaguar's intention to have proof-of-concept results later this year for Felevia, the Company's intention to expand its commercial team, and Jaguar's belief that it will achieve further realization of its goals and that these expected achievements will be translated to Company value recognition in 2016 and beyond. 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.

¹Pellegrini FL. Results of a large-scale necroscopic study of equine colonic ulcers. *J Equine Vet Sci.* 2005;25(3):113-117.
