# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K
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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 5, 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)
- 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 7.01 Regulation FD Disclosure.

On May 5, 2016, Jaguar Animal Health, Inc. (the "Company") expects to make a presentation concerning its business to investors and other interested parties (the "Investor Presentation"). A copy of the Investor Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Investor Presentation contained in Exhibit 99.1 is also posted on the Company's website at http://phx.corporate-ir.net/phoenix.zhtml?c=253723&p=irol-irhome.

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

Exhibit No.
99.1 Description
Investor Presentation dated May 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 5, 2016



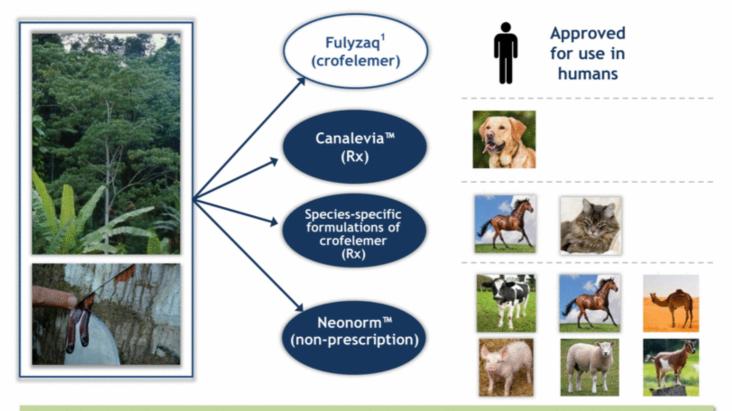
# Corporate Presentation May 2016

# **Forward-Looking Statements**

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding the anticipated timing of the commercial launch of Canalevia, and the timing of expanding the indication for Canalevia to acute diarrhea and the timing of data from planned proof of concept, field and other studies are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. 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 presentation are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this presentation 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 our control. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that we may face. Except as required by applicable law, we do not plan to publicly update or revise any forwardlooking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.



# **GI Product Development Strategy**



Intellectual property applies globally to all products across species



<sup>1</sup>Fulyzaq was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. The product is a registered trademark of and is marketed by Salix Pharmaceuticals, Inc.

## **Investment Highlights**

### First-in-Class GI Products for **Animals**

- The only FDA-approved human anti-secretory diarrhea product<sup>1</sup>
- · Significant animal and human data
- · Natural products from Croton lechleri

#### Rationale for MOA

- · Highly conserved Mechanism of Action (MOA) in all mammals
- · Clinical benefit shown in humans, calves, dogs and foals

### Recent Milestones

- Initiated pivotal clinical trial for acute diarrhea in dogs
- Submitted to FDA all major technical sections for Chemo-Induced Diarrhea (CID)
  Proof-of-concept safety & effectiveness results for treatment of gastric ulcers in horses
  Initiated study to investigate possible prophylactic & prebiotic benefits of Neonorm Calf
  Commercial launch of Neonorm Foal in US

### Anticipated **Upcoming** Milestones

- Conditional Approval in dogs for Canalevia for CID
- Complete clinical development program for acute diarrhea in dogs
- Continue SB-300 clinical development program for treatment of gastric ulcers in horses
- · Launch second-generation formulation of Neonorm Calf

### Management **Team**

- · Expertise in GI product development
- · Medicine, regulatory and commercial experience within animal health

### Commercialization

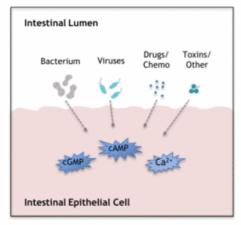
- Common educational and promotional activities focus on first-in-class MOA
- Companion and high-value animal drugs drive long-term business opportunity

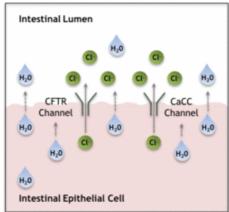


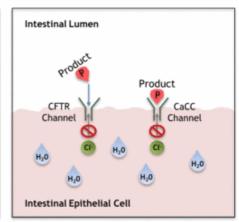
<sup>1</sup>Fulyzaq was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. The product is a registered trademark of and is marketed by Salix Pharmaceuticals, Inc.

# Common Pathway and MOA in Mammals

Canalevia and Neonorm are distinct products that act at the same last step in a physiological pathway generally present in mammals, regardless of cause







Acts locally in the gut and is minimally absorbed systemically



## Intellectual Property Portfolio

- Exclusive worldwide veterinary license to all Napo IP for all veterinary treatment uses and indications for all species of animals
  - Zero to low royalties
  - o Exclusive global veterinary license to 2,300+ medicinal plants
- Eight provisional patent applications, three pending patent applications under the Patent Cooperation Treaty, and one U.S. non-provisional patent application
- Notices of Allowance for two NP-500 patent applications
  - Jaguar's drug product candidate to treat diseases related to insulin-resistance in dogs, horses & cats
- Prebiotic benefits of polyphenols/Croton lechleri-derived products
- Rifaximin combination



# **Rx Drug Product Candidates**

Product	Sancian		Completed/Anticipated Milestones		
Candidate	Species	Indication	2015	2016	
		CID	Submitted all major technical sections for NADA	Expect NADA in 2H (with commercial launch in 1H 2017)	
Canalevia	7	Acute Diarrhea	Product development meeting with FDA, protocol concurrence     Initiate pivotal trial	2H, Complete clinical development program     Initiate filing NADA	
		Diarrhea Associated with Acute Colitis	• 2H, Safety data	1H, FDA product development meeting     Commence clinical development program	
Specific formulations of crofelemer	<b>A</b>	Ulcers	Opened INAD     2H, Completed pilot safety study	<ul> <li>Positive top-line EGUS POC data</li> <li>Mid 2016, Dose confirmation data</li> <li>2H, Initiate pivotal trial</li> </ul>	
		Acute Diarrhea		Top-line POC data	
Virend (topical)		Herpes Virus		Safety & POC data	
	9	Obesity-related Metabolic Dysfunction	IP, Notice of allowance		
Specific formulations of NP-500	<b>A</b>	Metabolic Syndrome	IP, Notice of allowance		
		Type II Diabetes	IP, Notice of allowance		



# Canalevia: Diarrhea in Dogs

- Diarrhea is one of the most common reasons for veterinary and emergency visits for dogs in the US
  - o Six million cases annually of acute and chronic watery diarrhea
- No FDA-approved anti-secretory products for dogs
  - Current treatments
    - Rehydration
    - Diet change
    - Absorbents/binding agents (Pepto-Bismol)
    - o Anti-motility agents (Imodium)
    - Antibiotics
- No current treatments directly address dehydration and watery flow



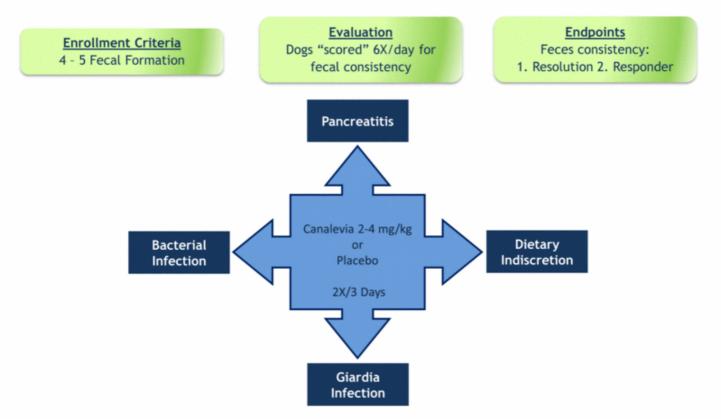


# Canalevia: Chemotherapy-Induced Diarrhea (CID) in Dogs

- · Over 230,000 dogs receive chemotherapy in the US
  - o Approximately 25% suffer from CID
- Received MUMS designation
  - o MUMS designation is similar to "orphan drug" status
- · Submitted all required major technical sections to FDA
  - · Same manufacturers as human approved NDA
- Completed pilot safety study: 25% of dogs entered study with unformed feces and resolved
- Targeted NADA: 2H, 2016



# Canalevia: Acute Diarrhea Proof of Concept Study -- 39 dogs evaluated

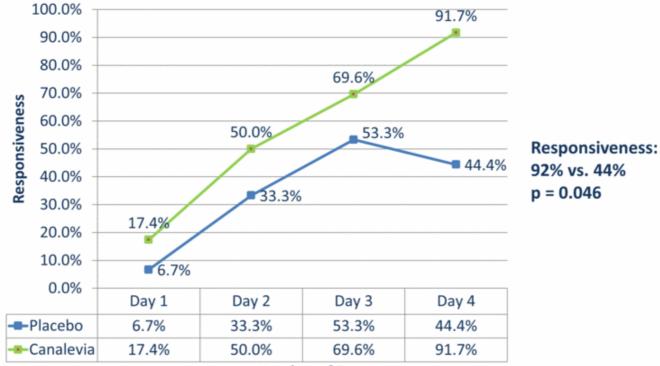


Treatment: All dogs received "standard of care" for diarrhea (oral/IV fluids for rehydration or disease-specific medications)



### Canalevia: Clinical Results

### Clinical Responsiveness of Canalevia vs. Placebo

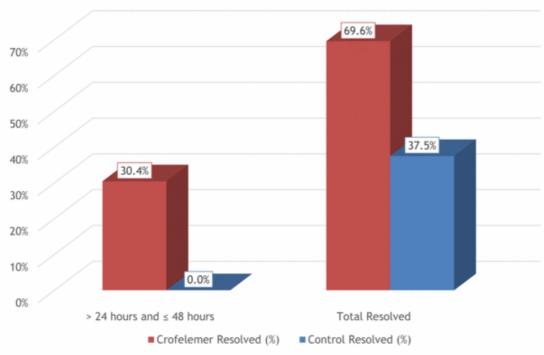


**Number of Days** 

Response in Canalevia arm is greater than placebo on all days by >10%



# Number of Dogs Achieving Resolution\* of Diarrhea



\*Resolution of diarrhea is defined as achieving a fecal score of 1 or 2 and no relapse during the study

- The difference in proportions for crofelemer and control is 32%
- The Chi-square p-value = 0.0470



# Canalevia: Pathway to Commercialization

# Expand label indication for Canalevia to acute diarrhea, regardless of cause

Development
Meeting with FDA,
Protocol
Concurrence,
2015

Pivotal efficacy initiation in 2015 Commercial launch for CID expected in 2017

Commercial launch expected in 2017







# **Equine Ulcer Opportunity (SB-300)**

- · Positive top-line EGUS POC data
- 97% of high performance horses have either gastric or colonic ulcers\*
- 63% of high performance horses have colonic ulcers\*
- 87% of high performance horses have gastric ulcers\*
- 54% of high performance horses have both colonic and gastric ulcers\*
- No marketed FDA-approved treatments for colonic ulcers in horses
- Chronic treatment cost ~\$50/day
- International synergies for market awareness and demand
- ~4 million high performance horses in US





\*Pellegrini, Franklin L., Results of a large-scale necroscopic study of equine colonic ulcers. J Equine Vet Sci 2005; v. 25, no. 3; 113-117.

# SB-300 Proof-of-Concept Study for Equine Ulcers

### Study Objective:

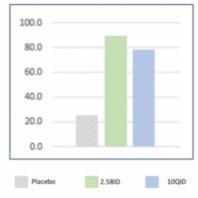
Evaluate the safety and effectiveness of SB-300 for treatment of equine gastrointestinal ulcers

#### Conclusions:

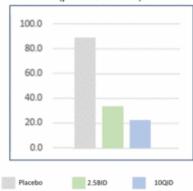
Glandular Ulcers
Resolution and improvement vs.
placebo at Day 14, with a p-value
of 0.0286



GLANDULAR: DAY 14 % of Horses with Improvement (1 Grade Decrease)



GLANDULAR: DAY 35 % of Horses with No Resolution (p-value of 0.03)



30 racehorses were randomized to one of three groups (10 horses per group). Horses in the TRT5 group received 5 grams of SB-300 divided into 2 doses per day; and those in the TRT40 group received 40 grams of SB-300 divided into 4 doses per day.

Published studies<sup>1,2</sup> with omeprazole demonstrate that between 14% and 34% of horses diagnosed with EGUS are observed with resolution or improvement of glandular ulcers when used at the manufacturer's recommended treatment duration of 28 days



\*Sykes BW, Sykes KM, Hallowell GD. A comparison of three doses of omeprazole in the treatment of equine gastric ulcer syndrome: A blinded, randomised, dose-response clinical trial. Equine Yet J. 2015;47(3):285-290. 

\*Sykes BW, Sykes KM, Hallowell GD. A comparison of two doses of omeprazole in the treatment of equine gastric ulcer syndrome: a blinded, randomised, clinical trial. Equine Yet J. 2014;46(4):416-421.

# SB-300 Proof-of-Concept Study for Equine Ulcers

### **Additional Advantages:**

- Drug testing in horses that received SB-300 did not detect any substances commonly disallowed in horse racing—enabling continued therapy
- SB-300 acts locally in the gut with minimal systemic absorption
- Feed does not appear to interfere with local availability of SB-300

- SB-300 did not alter gastric pH
- Maintaining normal gastric pH is essential for:
  - Digestion
  - Gut immunity
  - First line defense against pathogens
  - Absorption of vitamins and minerals





# **Neonorm: Non-Prescription Products**

Products Species		11-2	Anticipated Milestones		
Products	Species	Use	2015	2016	
Neonorm Calf		Improve gut health and normalize stool formation in pre- weaned dairy calves with scours	Field studies: Include evaluation of herd-wide prophylactic & prebiotic benefits. Initial results support prebiotic effect and beneficial results of Neonorm on weight gain in preweaned calves	<ul> <li>Launch second-generation formulation (administered in liquid)</li> <li>South American commercial launch</li> </ul>	
Species- specific formulations of Neonorm		Normalize fecal formation (horse foals)	<ul> <li>2H, POC positive results</li> <li>2H, Soft-launched at American Association of Equine Practitioners Trade Show</li> </ul>	• 1H, Commercial launch	
		Normalize fecal formation (adult horses & other farm/production animals)	Initiate POC studies in various species based on market research		





### A new and unique anti-diarrheal for foals

- · Commercial launch in Q1 2016
  - Premiered product at Dec. 2015 American Association of Equine Practitioners Trade Show
- There are currently no other anti-secretory products commercially available for the foal market







# **Neonorm Foal Proof-of-Concept Study**

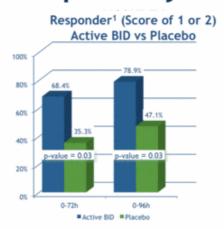
### Study Objective:

Determine the safety, tolerability, and efficacy of Neonorm Foal

#### Conclusion:

This exploratory study demonstrated the effectiveness of Neonorm Foal vs. placebo in the treatment of diarrhea amongst foals from birth to 16 weeks.







<sup>1</sup>Responder: A foal who achieved a formed stool by the end of the treatment period.

<sup>2</sup>Resolution: A foal who achieved a formed stool (1 or 2) at any point at any post-baseline assessment.

# Neonorm Calf E. coli Challenge Study\*

### Study Objective:

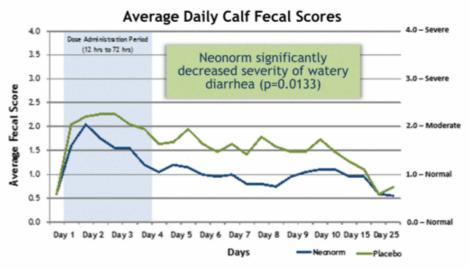
Evaluate severity and incidence of diarrhea, mortality and weight gain.

### Conclusion:

The total economic benefit from health endpoints, such as weight gain, from Neonorm could be ~\$110 per calf.







### Health and Economic Impacts

	Average Duration of Watery Diarrhea (Score ≥2)	Average Duration of Severe Watery Diarrhea (Score 3 or 4)
Neonorm Calf	3.03 days	1.10 days
Placebo	5.16 days	2.42 days

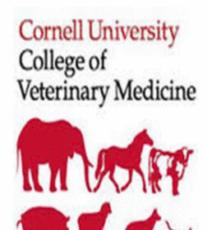
3	# of Calves	Mortality	Average Daily Weight Gain After 25 Days
Neonorm Calf	20	5% (1 calf)	15.5 pounds (281 g/day)
Placebo	19	21% (4 calves)	12.1 pounds (219 g/day)



\*Study published in American Dairy Science Association's Journal of Dairy Science, fall 2015

### Neonorm Calf: Field Studies<sup>1</sup>

- Two recently completed field studies:
  - Study conducted in association with Cornell University College of Veterinary Medicine and field study in Wisconsin further supports benefits related to supporting reductions in water loss associated with diarrhea and supporting weight gain in preweaned calves
- Recently completed Cornell study supports benefit on optimization of intestinal microbiome in calves
  - Cornell trial to investigate this potential prebiotic and prophylactic benefit
  - Second-generation formulation of Neonorm—for entire herd management—that can be administered in water and/or milk replacer



<sup>1</sup>These are results from the two field studies conducted to support Jaguar's commercial launch of Neonorm.



# **Jaguar Commercial Strategy**

- Focused direct sales force, unique Mechanism of Action
- Educational outreach to key opinion leaders and decision makers
- Complement major distribution partnerships
- Transferable as we expand from production to companion animals
- Meaningful partnerships in international markets: example, signed distribution agreement with Biogenesis Bagó, South America's largest veterinary biotechnology company

Change Ch

Biogenesis Bagó agreement covers red-shaded regions



Each dot represents 1,500 cows (Reprinted by permission; March 25, 2013 Hoard's Dairyman Magazine)



- Veterinary Medical Schools and Colleges
- Departments of Veterinary Science
- Departments of Comparative Medicine
- Other Educational Veterinary Institutions



# **US Market Opportunity**

### Canalevia Market

### **R**x

**Companion Animals** 

US Population: 74.0M Cats, 70.0M Dogs

**Total Cases** 

**Acute Cases** 

6.0M Dogs

~ 2/3

2.9M cats

~ 2/3

3.9M Performance Horses

### SB-300 Market

### Rx

**Horses** 

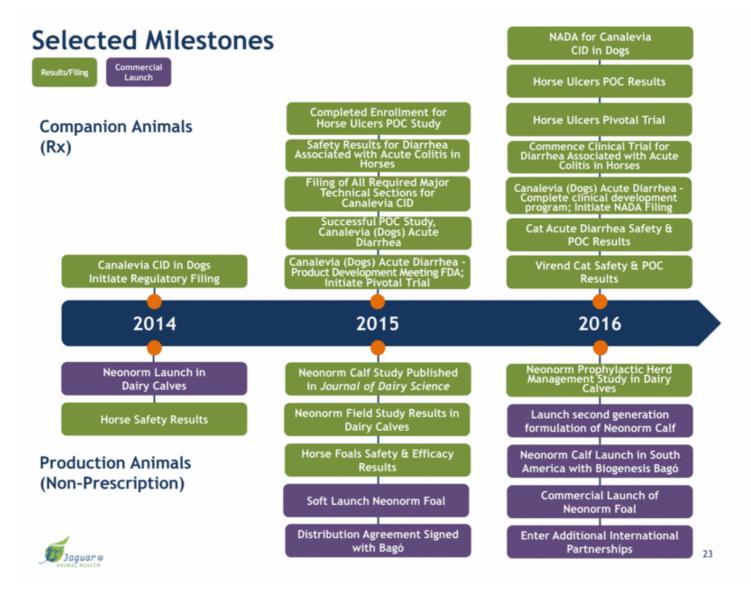
**US Population:** 

Total horses: 9.2M Race horses: 844,531 Show horses: 2.7M

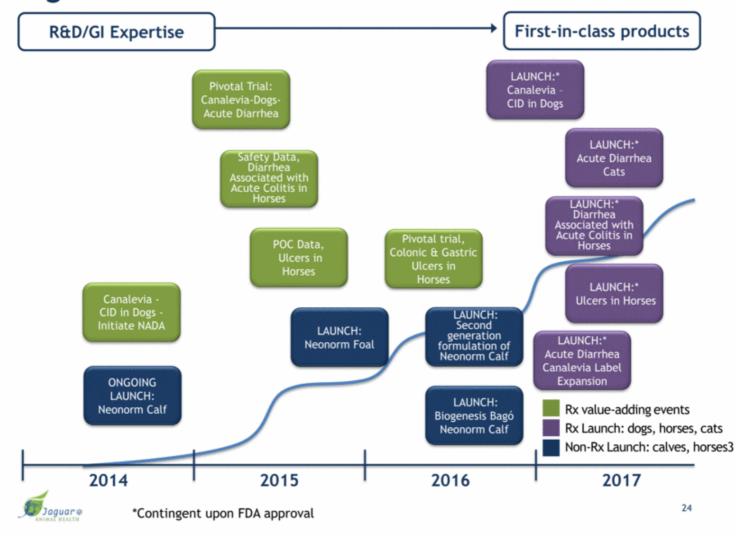
### Incidence:

54% of performance horses have both colonic and gastric ulcers and 97% of performance horses have either a gastric (87%) or a colonic (63%) ulcer\*





# **Jaguar Commercialization Horizon**



## **Investment Highlights**

### First-in-Class GI Products for **Animals**

- The only FDA-approved human anti-secretory diarrhea product<sup>1</sup>
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# **Potential Merger**

Jaguar and Napo Pharmaceuticals are engaged in discussions to review a potential merger and/or other ways to cooperate with their respective business endeavors.







# **Management Team**

Lisa Conte Founder, Chief Executive Officer & President	<ul> <li>25+ years of industry experience</li> <li>Obtained first anti-secretory human product FDA approval</li> </ul>
Karen Wright Chief Financial Officer	<ul> <li>30+ years of financial experience with biotech companies</li> <li>Former head of finance for Clene Nanomedicine</li> </ul>
Philippe Brianceau, DVM Chief Veterinary Officer	<ul> <li>20+ years of animal health experience</li> <li>Former director of global pharmaceutical project development at Merck Animal Health</li> </ul>
Michael Guy, DVM, MS, PhD Vice President & Clinical Veterinarian	<ul> <li>20+ years of pharmaceutical R&amp;D experience</li> <li>Former Director of Morris Animal Foundation's</li> <li>Canine Lifetime Health Project</li> </ul>
Brett McKusick, DVM, MS, PhD Head of Regulatory Affairs	<ul> <li>20+ years of clinical and animal health R&amp;D experience</li> <li>Former Veterinary Medical Officer, FDA CVM</li> </ul>
Steven King, PhD Executive Vice President, Ethnobotany & Supply	<ul> <li>22+ years experience surrounding supply of crofelemer</li> <li>Previously with Napo</li> </ul>
David Sesin Vice President, Project Management	<ul> <li>30+ years of chemistry-related experience in biotech fields</li> <li>Former Director of Chemistry at Bayer CropScience</li> </ul>



# **Board of Directors**

James Bochnowski Chairman	<ul> <li>Founder of Delphi Ventures, one of the first VC firms to focus exclusively on investing in life sciences companies</li> <li>Co-founded Technology Venture Investors</li> </ul>
Lisa Conte Founder, CEO & President	<ul> <li>25+ years of industry experience</li> <li>Obtained first anti-secretory human product FDA approval</li> </ul>
Jiahao Qiu Director	<ul> <li>Principal of BioVeda China Fund, a life science investment firm</li> <li>Extensive experience evaluating, managing &amp; investing in life science companies</li> </ul>
Zhi Yang, Ph.D. Director	<ul> <li>Chairman, Managing Partner and Founder of BioVeda China Fund</li> <li>Advisor to the China Health and Medical Development Foundation, under China's Ministry of Health</li> </ul>
Folkert Kamphuis Director	<ul> <li>Former Global Head of Strategic Planning at Novartis Animal Health</li> <li>20+ years in executive roles at Pfizer Animal Health/Pharmacia and Merial</li> </ul>
John Micek III Director	<ul> <li>Managing partner of Verdant Ventures</li> <li>Former managing director of Silicon Prairie Partners, LP</li> </ul>





