

**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): **February 20, 2017**

---

**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 February 20, 2017, Jaguar Animal Health, Inc., a Delaware corporation (the "Company"), made available on its website at [www.jaguaranimalhealth.com](http://www.jaguaranimalhealth.com) a slide presentation about the Company for investors and stockholders. The presentation includes materials regarding the previously announced intended merger between the Company and Napo Pharmaceuticals, Inc.

A copy of the investor presentation is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. The information under Item 7.01 and in Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, or otherwise subject to the liabilities thereof, nor shall it be deemed to be incorporated by reference in any filing under the Securities and Exchange Act of 1934 or under the Securities Act of 1933, except to the extent specifically provided in any such filing.

**Disclaimer on Forward-looking Statements**

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. These include statements regarding the Company's intention to merge with Napo, the estimated potential annual sales market for Mytesi™, the 2017 net sales forecast for Mytesi™, the combined company's ability to benefit from economies of scale, access efficiencies, and enhance potential value creation, the expectation that definitive merger agreement will be entered into and the merger conditions to closing will be satisfied, the anticipated timing of the commercial launches of Canalevia, Equilevia, and the second-generation formulation of Neonorm Calf, 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. 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. The Company 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 the Company's control. Except as required by applicable law, the Company 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.

**Important Information for Investors and Stockholders**

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the proposed merger between the Company and Napo, the Company will file with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-4 that will include a joint proxy statement of the Company and Napo that also constitutes a prospectus of the Company. The definitive joint proxy statement/prospectus will be delivered to the Company's and Napo's stockholders. INVESTORS AND SECURITY HOLDERS OF THE COMPANY AND NAPO ARE URGED TO READ THE DEFINITIVE JOINT PROXY STATEMENT/PROSPECTUS AND OTHER DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of the registration statement and the definitive joint proxy statement/prospectus (when available) and other documents filed with the SEC by the Company through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed with the SEC by the Company will be available free of charge on the Company's internet website at [www.jaguaranimalhealth.com](http://www.jaguaranimalhealth.com) or by contacting the Company at: Investor Relations, Jaguar Animal Health, Inc., 201 Mission Street, Suite 2375, San Francisco, California, 94105; (415)-371-8300.

### Participants in the Merger Solicitation

The Company, Napo, their respective directors and certain of their executive officers and employees may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the Company's and Napo's stockholders in connection with the proposed merger will be set forth in the joint proxy statement/prospectus when it is filed with the SEC. Information about the directors and executive officers of the Company is set forth in its annual report on Form 10-K for the fiscal year ended December 31, 2016 as filed with the SEC on February 15, 2017 and definitive proxy statement for its 2016 annual meeting of stockholders filed with the SEC on April 29, 2016. Information about the executive officers of Napo is set forth at [www.napopharma.com](http://www.napopharma.com). Additional information regarding the participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the joint proxy statement/prospectus filed with the above-referenced registration statement on Form S-4 and other relevant materials to be filed with the SEC when they become available.

2

---

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation, dated February 20, 2017.

3

---

### 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/ Karen S. Wright  
Name: Karen S. Wright  
Title: Chief Financial Officer

Date: February 21, 2017

4

---



**General Overview**  
February 2017

# Forward-Looking Statements

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding Jaguar's intention to merge with Napo, the estimated potential annual sales market for Mytesi™, the 2017 net sales forecast for Mytesi™, the combined company's ability to benefit from economies of scale, access efficiencies, and enhance potential value creation, the expectation that definitive merger agreement will be entered into and the merger conditions to closing will be satisfied, the anticipated timing of the commercial launches of Canalevia, Equilevia, and the second-generation formulation of Neornorm Calf, 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 forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

## Important Additional Information Will be Filed With the SEC

This presentation may be deemed solicitation material regarding the intended merger between Jaguar and Napo. Jaguar currently intends to file with the SEC a Registration Statement on Form S-4 that will include a proxy solicitation. Jaguar also plans to file other relevant materials with the SEC. Stockholders of Jaguar and Napo are urged to read the proxy solicitation/prospectus contained in the Registration Statement when it becomes available and any other relevant materials filed with the SEC because these materials will contain important information about the intended merger. Once available, these materials will be made available to the stockholders of Jaguar and Napo at no expense to them. The Registration Statement, proxy statement/prospectus and other relevant materials, including any documents incorporated by reference therein, once available, may be obtained free of charge at the SEC's website at [www.sec.gov](http://www.sec.gov) or from Jaguar at [www.jaguaranimalhealth.com](http://www.jaguaranimalhealth.com) or by emailing [grussell@kcsa.com](mailto:grussell@kcsa.com).

Jaguar and certain of its directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with the intended merger. Information about the executive officers and directors of Jaguar is set forth in Jaguar's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 as filed with the SEC on February 15, 2017 and Definitive Proxy Statement for the 2016 Annual Meeting of Stockholders of Jaguar filed with the SEC on April 29, 2016.

1

## Jaguar Animal Health and Napo Pharmaceuticals Have Entered a Binding Agreement of Terms to Merge

- Napo: wholly-owned subsidiary of Jaguar
- Market cap of merged company: 4 times Jaguar Animal Health (JAGX)



### Human Health FDA Approved Product: Mytesi™ (crofelemer)



Mytesi™ (crofelemer 125mg delayed-release tablets) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART).

### Animal Health

Canalevia™  
Equilevia™  
Neornorm™

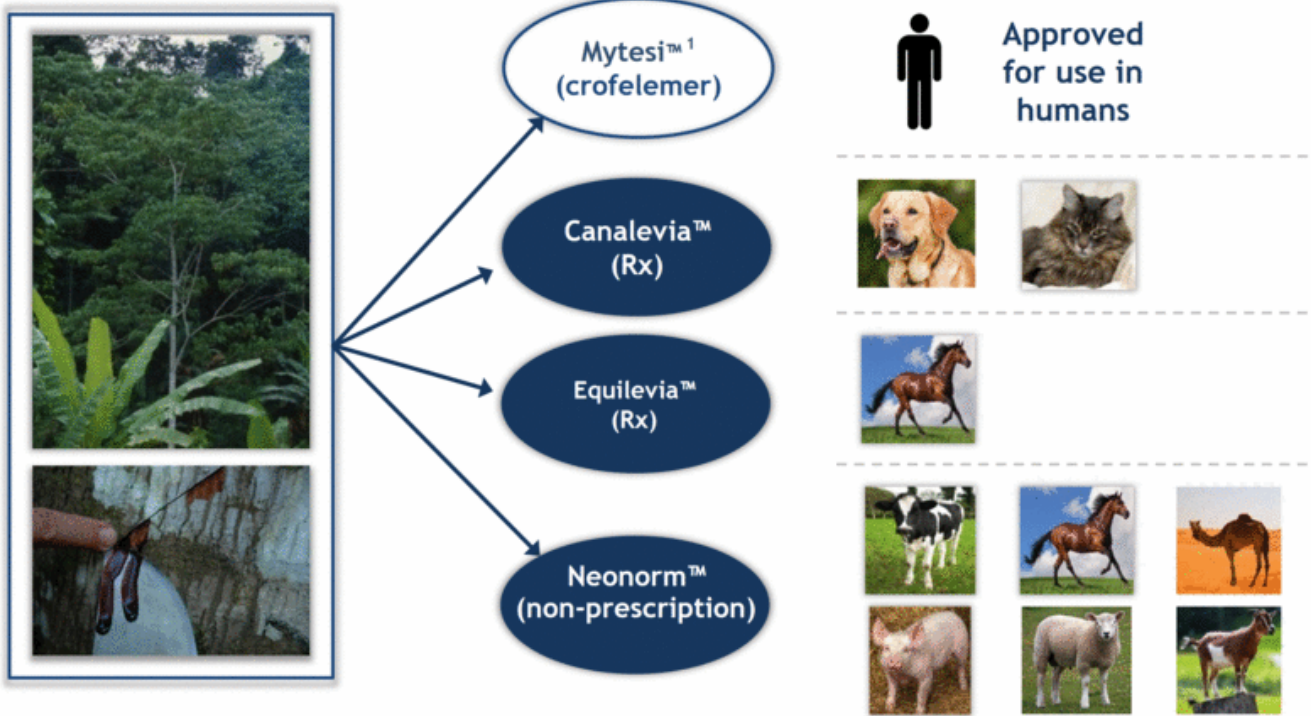


- Essentially Unencumbered Worldwide Rights
- Multiple Blockbuster Follow-on Indications

- Selected Geographical Partnerships

2

# GI Product Development Strategy



Intellectual property applies globally to all products across species

<sup>1</sup>Mytesi (formerly known as Fulyzaq) was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Mytesi is a trademark of Napo Pharmaceuticals.

# Napo Launched Mytesi™ October 2016 and Estimates Potential U.S. Market to be Approximately \$100 Million in Gross Annual Sales

- Napo anticipates deploying direct sales effort in Q2 2017 with 8 field sales representatives and telesales to promote Mytesi™ to top ART-prescribing doctors in U.S.
- Napo forecasts Mytesi™ will generate approximately **\$7 million in net sales in 2017**, with the greatest impact on prescription growth coincident with deployment of sales force and sampling program



**Mytesi** is the **ONLY** FDA-approved **diarrhea treatment** that's been studied specifically in adults with **HIV/AIDS**<sup>1</sup>

Media Outlets that Covered the Launch



<sup>1</sup>Orange Book, [www.accessdata.fda.gov/scripts/cder/ob/](http://www.accessdata.fda.gov/scripts/cder/ob/), accessed October 2016

## Total Specialty Market Opportunity of ~\$100 Million

- Initiation on a new ART still causes diarrhea 15% of the time
- >50% of the U.S. HIV population is aging, and living with the virus in their gut for 10+ years, causing chronic diarrhea
- Commercial manufacturing in place with brand new facility
- We believe the only difference between current Mytesi™ prescribers and non-prescribers is awareness. If the ~2,000 high prescribing HIV specialists prescribe at the same rate as known prescribers, market opportunity of >~\$100M in sales could be achieved.



### IMPORTANT SAFETY INFORMATION

Mytesi™ (crofelemer 125mg delayed-release tablets) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi™ is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi™. 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%). Please see complete Prescribing Information available at [Mytesi.com](http://Mytesi.com)

# Investment Highlights

Forward integration to prescription revenue generating company

- Mytesi forecasted net sales of \$7.0 mm, 2017
- Ability to track performance

Enhanced landscape of broad product pipeline

- Multiple human indications supported by Phase 2 data
- Priority review voucher opportunity
- Horizontal leverage of highly conserved mechanism of action to all mammals

Global unencumbered product rights

- Non-dilutive funding opportunities
- Geographical deals targeted for Mytesi
- Elanco terms precedent, Jaguar

Synergies of merger

- Important manufacturing economies of scale
- Efficiencies of shared skillset
- Weaving of R&D and commercial common assets

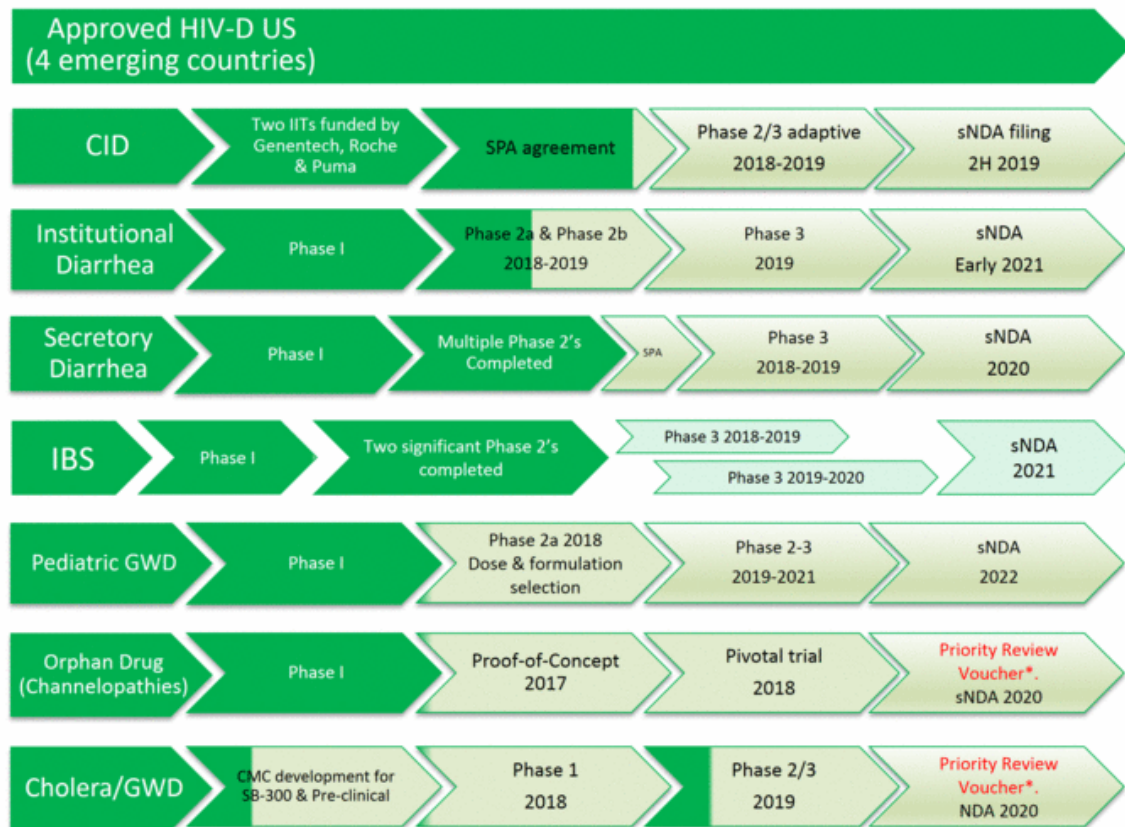
Risk-mitigated product development

- Already FDA approved commercial manufacturing facility for crofelemer
- Highly conserved MoA
- Efficacy in humans, dairy calves, dogs, pigs, horses
- Safety to support approved chronic administration

Palpable enthusiasm and mission of team

- Original discoverer and developer of successful FDA approved first in class anti-secretory agent, crofelemer
- Combined company 4 times market capitalization

# Multiple Targeted Follow-on Indications Backed by Strong Phase 2 Evidence Brings Mytesi™ to Blockbuster Potential



*Existing approval accelerates paths to market*

*\*Most recent priority review voucher sold for \$350M (sold to AbbVie)*

7

## Mytesi™ Future: Chemotherapy-induced Diarrhea (CID) A Common Problem With A Relevant Mechanism For Crofelemer

National Cancer Institute Criteria for Grading Severity of Diarrhea				
	Grade 1	Grade 2	Grade 3	Grade 4
<b>Patients without a colostomy</b>	Increase of <4 stools per day over pretreatment	Increase of 4 to 6 stools per day or nocturnal stools	Increase of ≥7 stools per day or incontinence; need for parenteral support for hydration	Physiologic consequences requiring intensive care; hemodynamic collapse

- ▶ Diarrhea is the most common adverse event reported
  - ▶ IV chemotherapy agents (especially for colorectal and gastric cancers)
  - ▶ Newer oral agents, especially epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKI's) and EGFR monoclonal antibodies (for breast, lung, and other malignancies)
  - ▶ Chronic maintenance therapy
- ▶ “All-grade” diarrhea rates are 50-80% with some combination treatments, with 10-30% grade 3-4.
  - ▶ Given frequency and severity of CID, secretory-type diarrhea and Mytesi™ mechanism of action, and inadequate current therapies, Mytesi™ will be studied in various disease states and regimens



# Two Ongoing Investigator Initiated Studies in CID

**HALT-D: Diarrhea Prevention and Prophylaxis with Crofelemer in HER2 Positive Breast Cancer Patients Receiving Trastuzumab, Pertuzumab, and Docetaxel or Paclitaxel with or without Carboplatin**



Georgetown University

**Primary objective:** To characterize the incidence and severity of diarrhea in patients receiving investigational therapy in the setting of prophylactic anti-diarrheal management.

**HALT-D: Diarrhea Prevention and Prophylaxis with Crofelemer in HER2 Positive Breast Cancer Patients Receiving Trastuzumab, Pertuzumab, and Docetaxel or Paclitaxel with or without Carboplatin**

Jennifer Gao, Ming Tan, Paula R. Pohlmann, Sandra M. Swain

National Cancer Institute, National Institutes of Health, Bethesda, MD; University of Colorado, University Hospital, Lombard Comprehensive Cancer Center, Washington, D.C.; National Cancer Institute, National Institutes of Health, Bethesda, MD

**INTRODUCTION**

- Chemotherapy induced diarrhea (CID) occurs in 40-60% of patients receiving trastuzumab, pertuzumab, and docetaxel or paclitaxel (THP) or trastuzumab, pertuzumab, carboplatin, and docetaxel (TCHP).
- Blocking EGFR causes excess chloride secretion and secondary diarrhea.
- Crofelemer (also called SP-NE3) - Proanthocyanidin oligomer isolated from the red oak (sample de droge) of the Coast Redwood tree in South America.
  - Used by local healers for treating diarrhea and GI, respiratory, and skin ailments.
  - Induces mucosal unimodal chloride efflux.
  - Sustained for every tree harvested.
  - FDA approved for diarrhea in HIV/AIDS patients on HAART.

**HYPOTHESIS**

Crofelemer will be an effective and targeted approach at preventing CID in breast cancer patients on THP or TCHP.

**OBJECTIVE/ENDPOINTS**

**Primary Objective**

- To determine the efficacy of crofelemer in preventing CID in patients with HER2 positive breast cancer on THP or TCHP.

**Primary Endpoint**

- Incidence of diarrhea of any grade for two or more consecutive days not to be definitively probably or possibly due to THP or TCHP during cycle 1 and cycle 2 of chemotherapy.

**Select Secondary Endpoints**

- Incidence and duration of diarrhea.
- Time to onset of first event of diarrhea.
- Use of anti-diarrheal medications (other than study drug).
- Quality of life FACT-D questionnaire score.

**STUDY SCHEMA**

Patients with HER2 positive breast cancer who will receive THP or TCHP.

Screening and initial eligibility assessment.

All inclusion criteria and no exclusion criteria met.

Sign informed consent form.

Randomization (THP with docetaxel vs. THP with paclitaxel vs. THP with docetaxel).

Randomization 1:1 to treatment vs. control group.

**Control Group**

THP or TCHP + placebo.

THP or TCHP + crofelemer.

**Treatment Group**

THP or TCHP + crofelemer.

**METHODS**

Design: randomized (2x2), 1:1, stratified, open-label phase II study.

Treatment group: oral crofelemer 125 mg twice daily during cycles 1-2 of chemotherapy.

Control group: no prophylaxis.

Sample size: 22 patients per group.

Accrual duration: 17-20 months.

Study duration: patients followed for total of 3 cycles of chemotherapy.

**STATISTICAL ANALYSES**

**Sample Size**

- 46 patients gives 81% power to detect a 40% absolute decrease (from 60% to 20%) in incidence of all grade diarrhea, with a two sided significance level of 0.50 based on Fisher's exact test.

**Analysis Population**

- All randomized patients who complete 2 cycles of THP or TCHP chemotherapy.

**STUDY PROGRESS**

- Protocol approved by institutional review board (IRB).
- FDA IND and clinical trials gov pending.
- Anticipated first patient enrollment: fall 2016.

**SUPPORT**

This study is supported by Genentech, Inc. The study drug (crofelemer) is provided by Napo Pharmaceuticals, Inc.

**REFERENCES**

1. Gao J, et al. Diarrhea prevention by crofelemer and placebo in HER2-positive breast cancer patients receiving trastuzumab and docetaxel or paclitaxel: a randomized, controlled trial. *Journal of Clinical Oncology*. 2015;33(16):2145-2152.
2. Gao J, et al. Diarrhea prevention by crofelemer and placebo in HER2-positive breast cancer patients receiving trastuzumab and docetaxel or paclitaxel: a randomized, controlled trial. *Journal of Clinical Oncology*. 2015;33(16):2145-2152.
3. Gao J, et al. Diarrhea prevention by crofelemer and placebo in HER2-positive breast cancer patients receiving trastuzumab and docetaxel or paclitaxel: a randomized, controlled trial. *Journal of Clinical Oncology*. 2015;33(16):2145-2152.
4. Gao J, et al. Diarrhea prevention by crofelemer and placebo in HER2-positive breast cancer patients receiving trastuzumab and docetaxel or paclitaxel: a randomized, controlled trial. *Journal of Clinical Oncology*. 2015;33(16):2145-2152.
5. Gao J, et al. Diarrhea prevention by crofelemer and placebo in HER2-positive breast cancer patients receiving trastuzumab and docetaxel or paclitaxel: a randomized, controlled trial. *Journal of Clinical Oncology*. 2015;33(16):2145-2152.

Crofelemer as salvage anti-diarrheal therapy with investigational breast cancer agent, neratinib



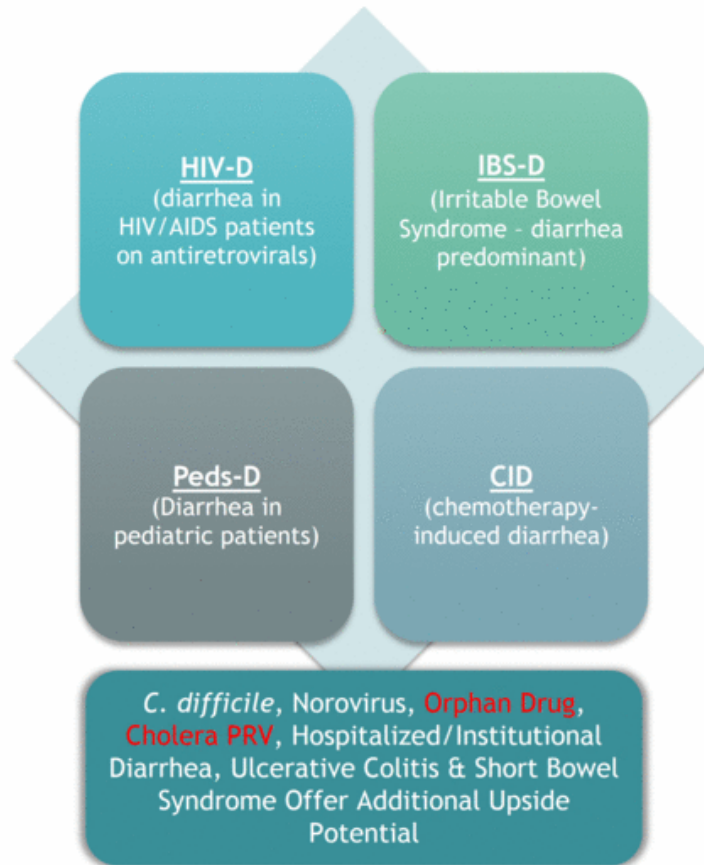
**TITLE:** An open label study to characterize the incidence and severity of diarrhea in patients with early stage HER2+ breast cancer treated with adjuvant trastuzumab and neratinib followed by neratinib monotherapy, and intensive anti-diarrhea prophylaxis.

**Primary objective:** To characterize the incidence and severity of diarrhea in patients with early stage breast cancer receiving adjuvant trastuzumab and neratinib followed by 1 year of neratinib monotherapy in the setting of prophylactic anti-diarrheal management.

**Secondary objectives:**

1. To evaluate the activity of crofelemer as a rescue anti-diarrheal medication.
2. To assess neratinib adherence, holds, delays, and early discontinuation throughout the course of study therapy, which includes patients receiving neratinib for >1 year.
3. To assess overall toxicity including constipation and cardiac toxicity with concomitant neratinib and trastuzumab.

# Mytesi™ Future: Blockbuster Opportunity



*Expanded manufacturing will lower cost of goods*

10

## Napo Seeking Geographical Partners

Middle East



South Korea



11

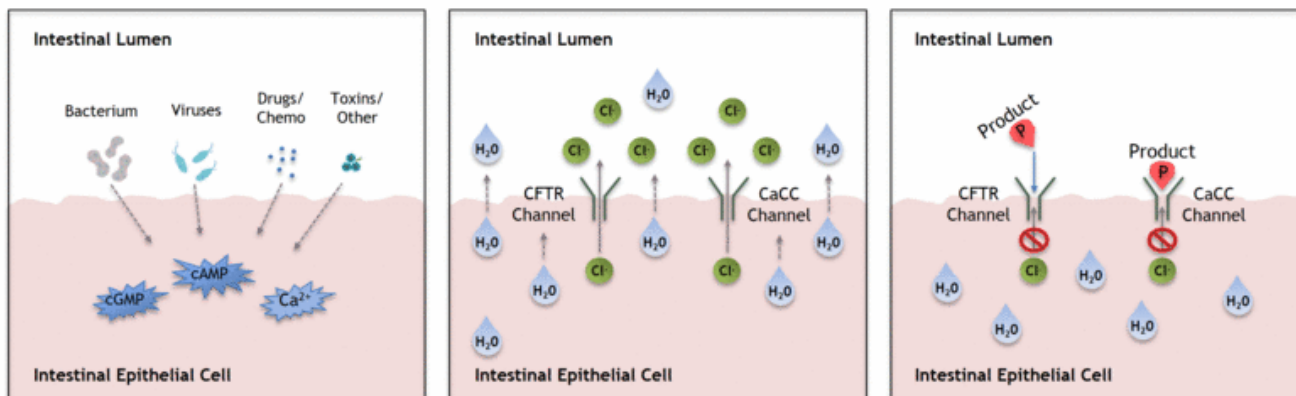
# Combination Results in Tremendous Synergies

- Centralized management
- Manufacturing economies of scale
- “Weaving” synergies of R&D
- Common messaging in commercialization



# Common Pathway and MOA in Mammals

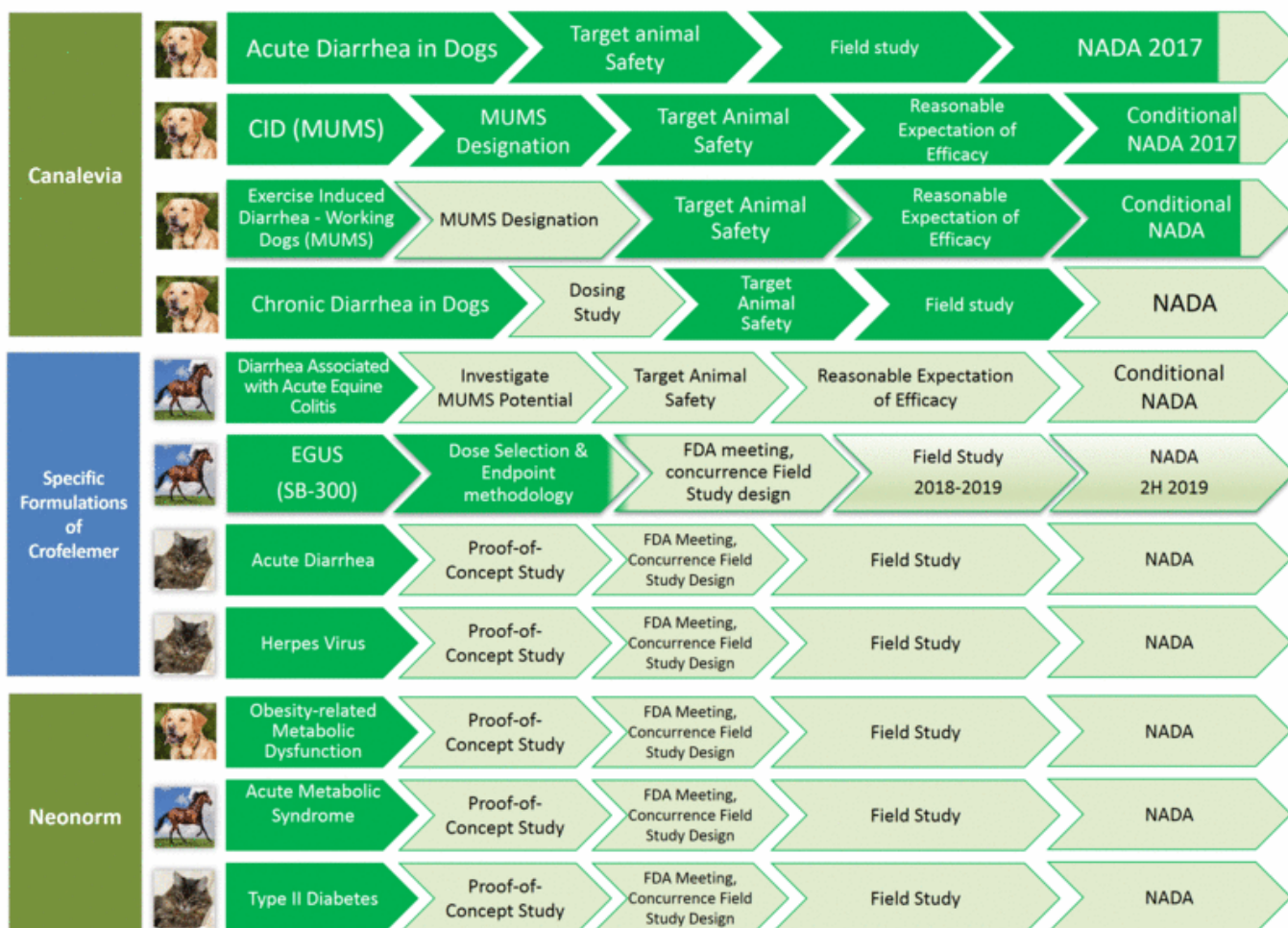
*Canalevia and Neonorm are distinct products that act at the same last step in a physiological pathway generally present in mammals, regardless of cause*



Acts locally in the gut and is minimally absorbed systemically

13

## Combined Company has Vast Pipeline of Enhanced Opportunities



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

- Received MUMS designation
  - MUMS designation is similar to “orphan drug” status
  - Termed “conditional approval” based on “reasonable expectation of efficacy”
  - Populations under 70,000 dogs
- Completed pilot safety study in CID: 25% of dogs entered study with unformed feces and resolved
- Targeted NADA: End of 2017
- Potential additional MUMS populations
  - Working sled dogs



# Jaguar and Elanco Enter Global Collaboration for Development, Co-Promotion of Canalevia™

- Elanco US Inc. is a division of Eli Lilly and Company.
- Jaguar received upfront payment and will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61M payable throughout the agreement term.
- Canalevia™ expenses have been paid retroactively by Elanco dating back to October 2016
- Jaguar retains MUMS indications and reimbursed to promote in U.S.
- Elanco offers broad distribution: 350 field reps, account managers and tech service vets call on U.S. vet clinics
- Royalties, commercial milestones, manufacturing work-up



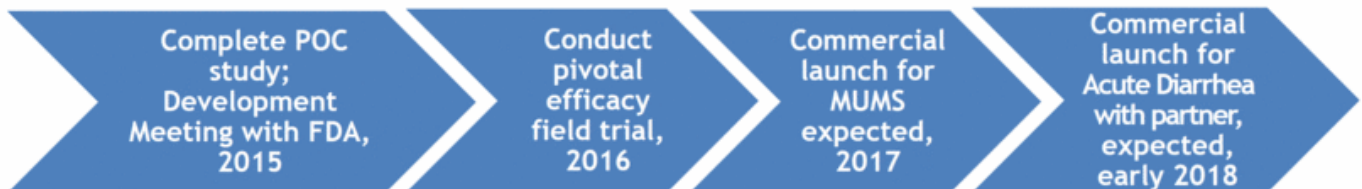
*Food and companionship enriching life.*

*At Elanco, we provide those who raise and care for animals with solutions that empower them to advance a vision of food and companionship enriching life.*

16

## Canalevia: Pathway to Commercialization

*Expand label indication for Canalevia to acute and chronic diarrhea*



Develop second-generation "chew" for ease of chronic administration



17

# Equine Athlete Ulcer Opportunity: Equilevia™

- ~4 million high performance horses in US
  - ❖ ~7 million worldwide
- 87% of high performance horses have gastric ulcers\* (squamous and glandular)
  - ❖ Glandular ulceration shown in 47-65% of Thoroughbred racehorses^
- No marketed FDA-approved treatments effective for glandular ulcers
- Chronic treatment cost omeprazole: ~\$50/day
- Positive top-line EGUS POC data



\*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.

^Sykes, B.W.; Hewetson, M.; Hepburn, R.J.; Luthersson, N.; Tamzali, Y. *European College of Equine Internal Medicine Consensus Statement—Equine Gastric Ulcer Syndrome in Adult Horses.* J Equine Vet Internal Medicine, 2015; v. 29, Issue 5; 1288–1299.

# Equilevia™ Proof-of-Concept Study for Equine Ulcers

**Distinguishing Feature:** No Withdrawal Requirement Prior to Racing; Standard Drug Testing Did Not Detect Any Commonly Disallowed Substances ; no pH change

## Study Objective:

Evaluate the safety and effectiveness of Equilevia™ for treatment of equine gastrointestinal ulcers

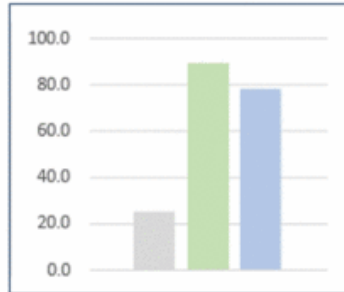
## Conclusions:

### Glandular Ulcers

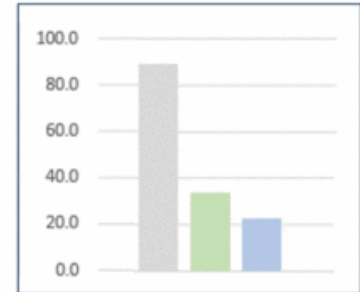
Resolution and improvement vs. placebo at Day 14, with a p-value of 0.0286



**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 Equilevia™ divided into 2 doses per day; and those in the TRT40 group received 40 grams of Equilevia™ 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

<sup>1</sup>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 Vet J.* 2015;47(3):285-290.  
<sup>2</sup>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 Vet J.* 2014;46(4):416-421.

# Equilevia™ Proof-of-Concept Study for Equine Ulcers

## Additional Advantages:

- Drug testing in horses that received Equilevia™ did not detect any substances commonly disallowed in horse racing—enabling continued therapy
- Equilevia™ acts locally in the gut with minimal systemic absorption
- Study findings suggest that feed does not interfere with local availability of Equilevia™
- Equilevia™ did not alter gastric pH
- Some research suggests that maintaining normal gastric pH is essential for:
  - ❖ Digestion
  - ❖ Gut immunity
  - ❖ First line defense against pathogens
  - ❖ Absorption of vitamins and minerals



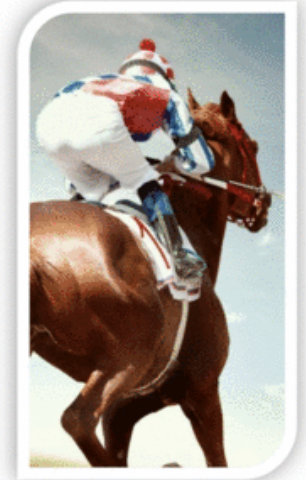


# Equilevia™ Dose Determination Study for Equine Ulcers

## Study completed; top-line results Q1 2017

### Racing Data Summary:

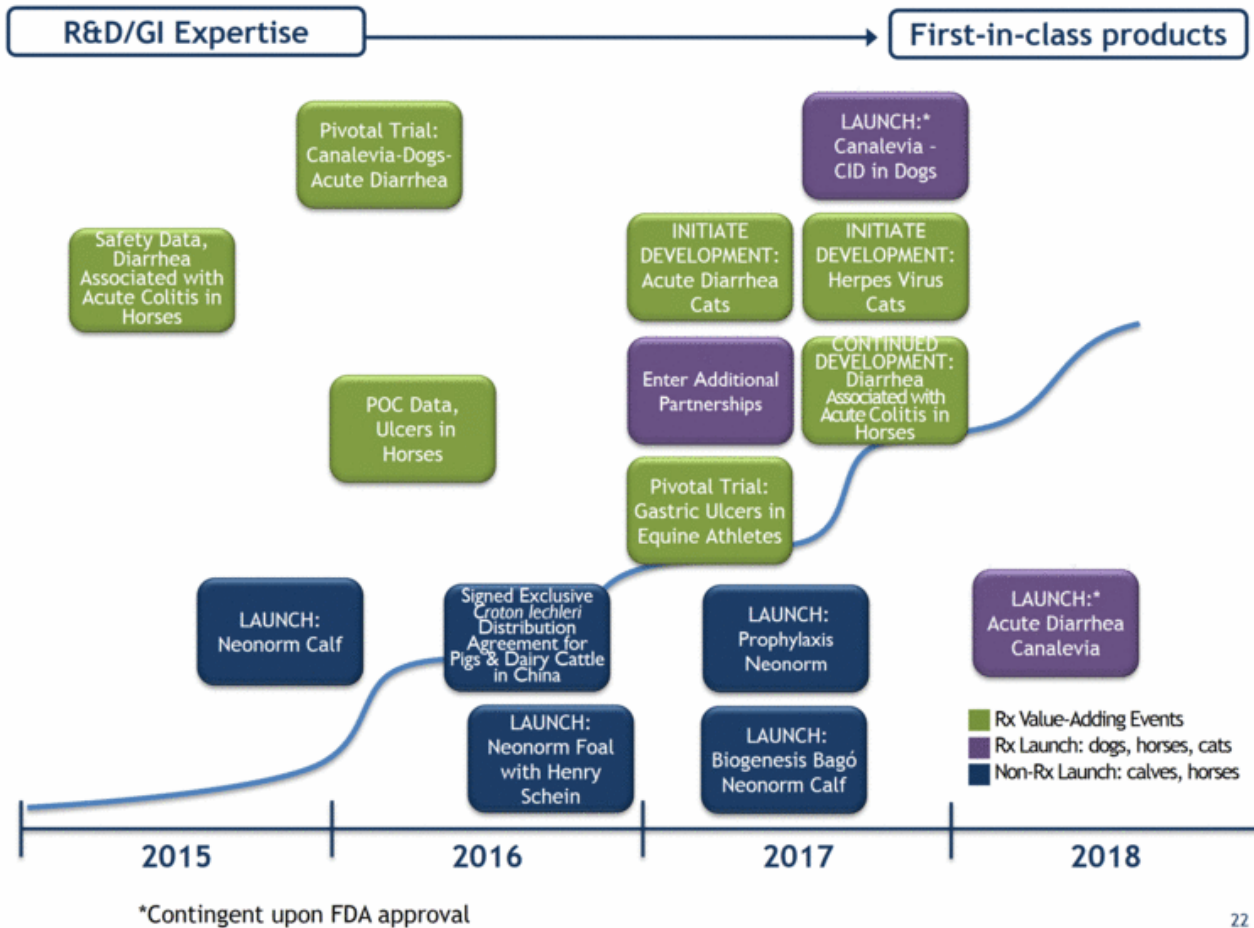
- Horses on treatment with Equilevia™ had higher average winnings as a percent of purse in races during the study treatment period compared with the period in which they raced prior to the study.
  - ❖ Horses on placebo or on the positive control (Merial's GASTROGARD® product) had a reduction in their average winnings.
- Horses on treatment with Equilevia™ had higher average total dollar winnings.
  - ❖ Horses on placebo had a reduction in total earnings, while horses on GASTROGARD® had essentially no change in earnings.
- When analyzing data according to whether or not a horse finished a race in the top 3 or in the top 5, there was also an improvement seen for horses treated with Equilevia™.
  - ❖ Horses treated with placebo had a reduction in frequency of finishing in the top 3 or in the top 5.



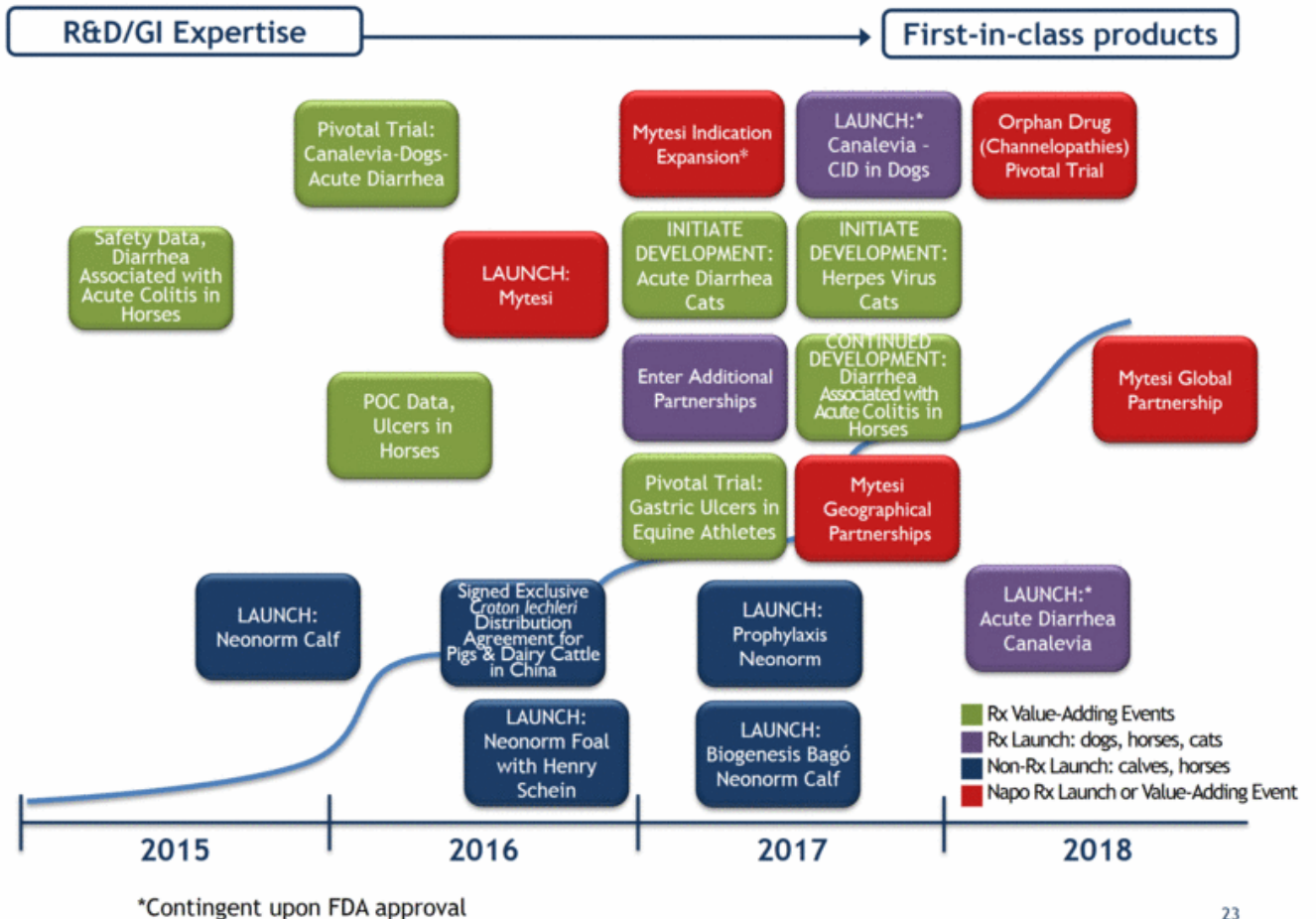
**Upcoming goal: Plan pivotal field trial development activities**  
**Targeted NADA: 2018**

*No statistically significant comparisons were generated for the aforementioned exploratory analyses.*

# Jaguar Commercialization Horizon



# Jaguar Commercialization Horizon



# Management Team of Combined Company

<b>Lisa Conte</b> Founder & CEO	<ul style="list-style-type: none"><li>• 25+ years of industry experience</li><li>• Obtained first anti-secretory human product FDA approval</li></ul>
<b>Karen Wright</b> Chief Financial Officer & Treasurer	<ul style="list-style-type: none"><li>• 30+ years of financial experience with biotech companies</li><li>• Former Head of Finance for Clene Nanomedicine</li></ul>
<b>Steven King, PhD</b> EVP, Ethnobotany & Supply	<ul style="list-style-type: none"><li>• 22+ years experience surrounding supply of crofelemer</li><li>• Previously with Napo</li></ul>
<b>Dr. Roger Waltzman</b> Chief Scientific Officer	<ul style="list-style-type: none"><li>• Human medical oncologist and experienced drug-development executive</li><li>• Former Head of Development for anti-malarials at Novartis</li></ul>
<b>Katie MacFarlane, PharmD</b> Co-EVP, Commercial Operations (Incentive-based contractor)	<ul style="list-style-type: none"><li>• 25+ years of pharmaceutical industry experience at Hoffmann-LaRoche, Parke-Davis, Pfizer, Warner Chilcott &amp; Agile Therapeutics</li></ul>
<b>Brian Zorn, PharmD</b> Co-EVP, Commercial Operations (Incentive-based contractor)	<ul style="list-style-type: none"><li>• 23 years experience in pharmaceutical marketing, advertising, and sales</li><li>• Held marketing responsibility for numerous pharma brands.</li></ul>
<b>David Upchurch</b> VP & Clinical Veterinarian	<ul style="list-style-type: none"><li>• Former Sr. Director, Chemical Manufacturing at Gilead Sciences</li></ul>
<b>Michael Guy, DVM, MS, PhD</b> VP, Supply Chain Management	<ul style="list-style-type: none"><li>• 20+ years of pharmaceutical R&amp;D experience</li><li>• Former Director of Morris Animal Foundation's Canine Lifetime Health Project</li></ul>
<b>David Sesin, PhD</b> Chief Manufacturing Officer	<ul style="list-style-type: none"><li>• Pharmaceutical scientist with extensive experience ranging from early drug discovery through final product manufacturing</li></ul>
<b>Wayne Pearl</b> Head of Quality	<ul style="list-style-type: none"><li>• President of Bio-Ops Consulting, Inc.</li><li>• 30 years with Amgen in manufacturing and operations</li></ul>
<b>Dan Tietz</b> HIV Community Advisor	<ul style="list-style-type: none"><li>• Advocate/attorney/RN with extensive experience leading advocacy, research, and education organizations</li></ul>

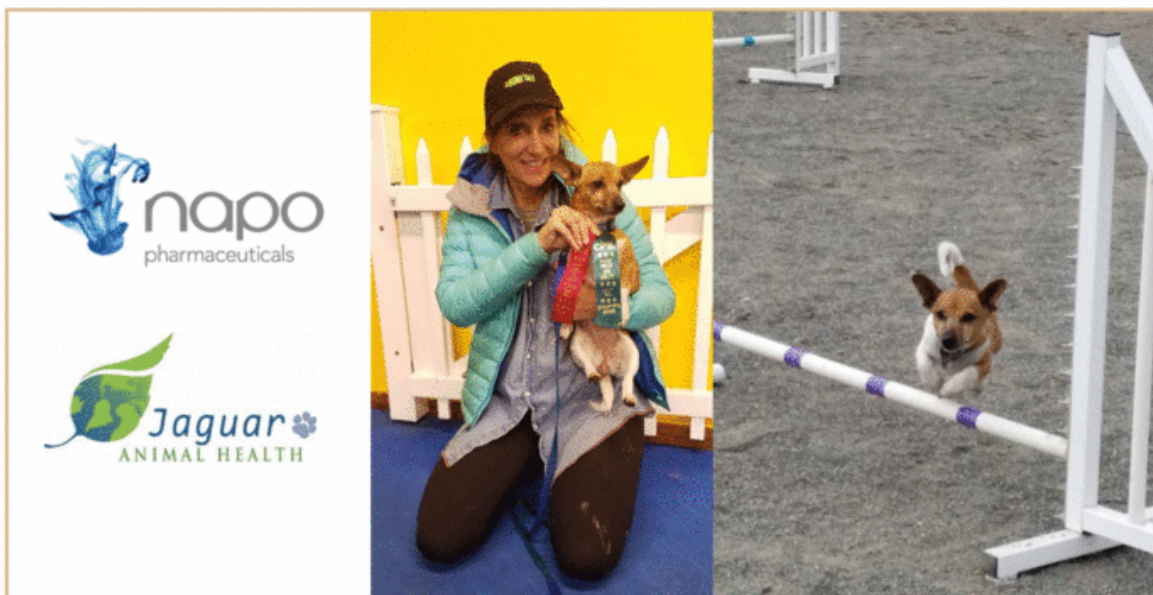
# Board of Directors of Combined Company

<b>James Bochnowski</b> Chairman	<ul style="list-style-type: none"><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>
<b>Lisa Conte</b> Founder, CEO & President	<ul style="list-style-type: none"><li>• 25+ years of industry experience</li><li>• Obtained first anti-secretory human product FDA approval</li></ul>
<b>Jiahao Qiu</b> Director	<ul style="list-style-type: none"><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>
<b>Zhi Yang</b> Director	<ul style="list-style-type: none"><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>
<b>Folkert Kamphuis</b> Director	<ul style="list-style-type: none"><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>
<b>John Micek III</b> Director	<ul style="list-style-type: none"><li>• Managing partner of Verdant Ventures</li><li>• Former Managing Director of Silicon Prairie Partners, LP</li></ul>
<b>Dr. Ari Azhir</b> Director	<ul style="list-style-type: none"><li>• Founder and CEO of two companies focused on central nervous system (CNS) therapeutics</li><li>• Successfully commercialized 20+ healthcare products</li></ul>

25

- The team that discovered and developed crofelemer
- Enthusiasm: Anyone familiar with Malcom Gladwell's book, *Outlier*, is familiar with the 10,000-hour rule to excel; our team at this combined company breaks through that barrier with 40,000 hours—20 plus years—to change the standard of care for gastrointestinal disease.

## We got it!





# In adult HIV patients on ART with non-infectious diarrhea

Mytesi™ (crofelemer) provides symptomatic relief of diarrhea so it no longer controls your day.

- The **only** anti-diarrheal studied in and FDA-approved for relief of diarrhea in HIV+ patients
- Treats diarrhea differently by normalizing the flow of water in the GI tract
- Minimally absorbed, with plasma concentrations below the level of detection
- No clinically relevant drug-drug interactions
- No effect on viral load or CD4 counts
- In clinical trials, adverse events with Mytesi were comparable to or lower than with placebo



## Indication

MYTESI™ is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

## Important Safety Information about MYTESI

MYTESI™ is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting MYTESI. 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%).

Please see complete Prescribing Information available at booth and at [MYTESI.com](http://MYTESI.com).

**References:** 1. MYTESI [package insert]. Napo Pharmaceuticals, Inc., San Francisco, CA 94105. 2. Data on File. Napo Pharmaceuticals, Inc.

NP-390-1

**Mytesi**™  
(crofelemer) 125 mg  
delayed-release tablets

**Relief, Pure and Simple**



# Equilevia™: Jaguar Drug Product Candidate in Development for Equine Gastric Ulcer Syndrome (EGUS)

Equilevia™ (formerly referred to as SB-300), is Jaguar's drug product candidate for treatment of Equine Gastric Ulcer Syndrome (EGUS). Equilevia™ is a pharmaceutical formulation of a standardized botanical extract isolated and purified from the *Croton lechleri* tree, which is sustainably harvested.

- There are ~4 million high performance horses in US and ~7 million worldwide
- 87% of high performance horses have gastric ulcers\* (squamous and glandular)
- Glandular ulceration shown in 47-65% of Thoroughbred racehorses^
- No marketed FDA-approved treatments effective for glandular ulcers
- Chronic treatment cost omeprazole: ~\$50/day
- Positive top-line EGUS POC data

**Upcoming Goal: Field Study 2018-2019**

**NADA: 2H 2019**



## Equilevia™ Dose Determination Study for Equine Ulcers Study Completed; Top-line Results Q1 2017

### Racing Data Summary:

- Horses on treatment with Equilevia™ had higher average winnings as a percent of purse in races during the study treatment period compared with the period in which they raced prior to the study.
  - Horses on placebo or on the positive control (Merial's GASTROGARD® product) had a reduction in their average winnings.
- Horses on treatment with Equilevia™ had higher average total dollar winnings.
  - Horses on placebo had a reduction in total earnings, while horses on GASTROGARD® had essentially no change in earnings.
- When analyzing data according to whether or not a horse finished a race in the top 3 or in the top 5, there was also an improvement seen for horses treated with Equilevia™.
  - Horses treated with placebo had a reduction in frequency of finishing in the top 3 or in the top 5.

No statistically significant comparisons were generated for the aforementioned exploratory analyses.

\*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.

^Sykes, B.W.; Hewetson, M.; Hepburn, R.J.; Luthersson, N.; Tamzali, Y. *European College of Equine Internal Medicine Consensus Statement—Equine Gastric Ulcer Syndrome in Adult Horses.* J Equine Vet Internal Medicine, 2015; v. 29, Issue 5; 1288–1299.



# Equilevia™ Proof-of-Concept Study for Equine Ulcers

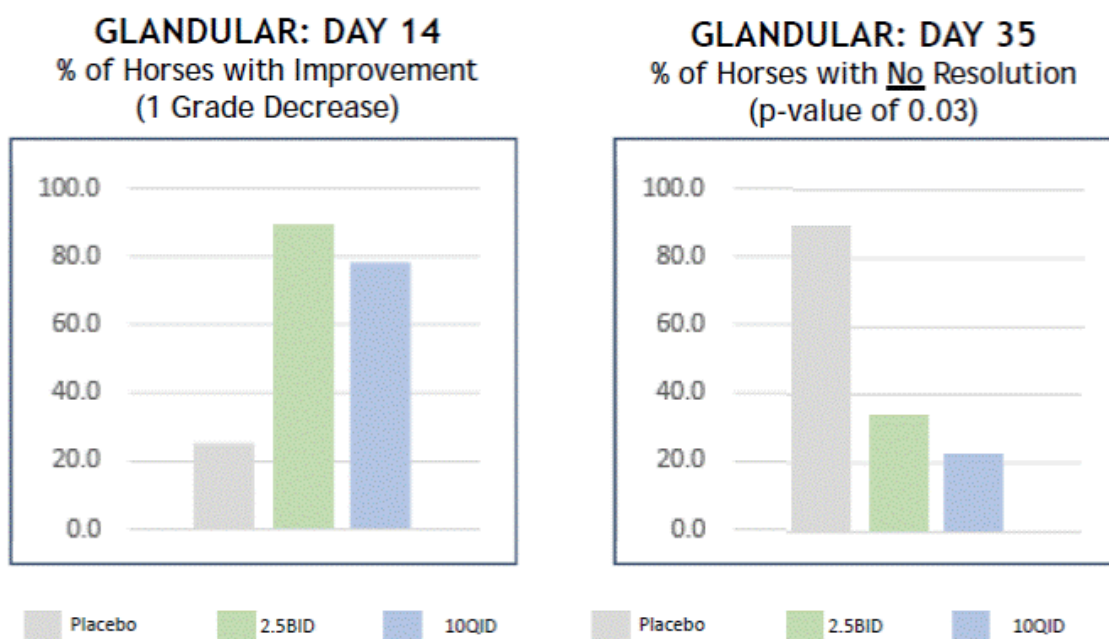
## Study Objective:

Evaluate the safety and effectiveness of Equilevia™ for treatment of equine gastrointestinal ulcers

## Conclusions:

### Glandular Ulcers

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



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

## Additional Advantages:

- Drug testing in horses that received Equilevia™ did not detect any substances commonly disallowed in horse racing—enabling continued therapy
- Equilevia™ acts locally in the gut with minimal systemic absorption
- Study findings suggest that feed does not interfere with local availability of Equilevia™
- Equilevia™ did not alter gastric pH
- Some research suggests that maintaining normal gastric pH is essential for:
  - ❖ Digestion
  - ❖ Gut immunity
  - ❖ First line defense against pathogens
  - ❖ Absorption of vitamins and minerals

<sup>1</sup>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 Vet J.* 2015;47(3):285-290.

<sup>2</sup>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 Vet J.* 2014;46(4):416-421.





## An Advanced New Product That Inhibits\* Fluid Loss at the Cellular Level

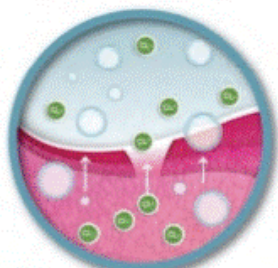
Neonorm™ is an advanced non-drug product that operates at the cellular level to inhibit the flow of fluids into the intestines—the location where vital fluids leave the body during diarrhea or scours. It is not an electrolyte or a nutritional supplement.

### A Rich History of Medicinal Use

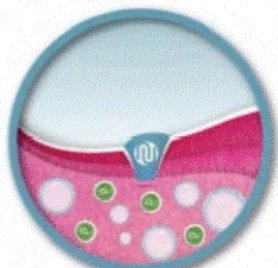
The standardized botanical extract in Neonorm™ is sustainably derived from the Amazonian tree species, *Croton lechleri*, and has a rich history of medicinal use by indigenous peoples in the Northwestern Amazon rainforests of South America.



Viruses and bacteria stimulate a reaction in the gut lining cells.



This causes a salt imbalance, driving excess water into the intestines, resulting in diarrhea.



Neonorm normalizes water flow from the gut lining cells.

\*Figure 1: Schematic of Neonorm inhibition of fluid loss



### The Mechanism of Action is Well Documented

Neonorm acts as a chloride channel blocker, normalizing water flow into the intestines.



### Acts Directly on Electrolyte Imbalances, the Root Cause of Secretory Diarrhea



A Natural, Plant-Based Product Comprised of a standardized botanical extract derived from the *Croton lechleri* tree.



Get Right to the Heart of the Problem Normalizes water flow into the intestines and can help reduce the severity of the diarrhea.



\*Effect of crofelemer extract on severity and consistency of experimentally induced enterotoxigenic *Escherichia coli* diarrhea in newborn Holstein calves. Teixeira, A.G.V. et al. Journal of Dairy Science, Volume 98, Issue 11, 8035 – 8043.



### The Problem:

Dehydration from scours, diarrhea, or other digestive problems poses a significant threat to the health and future productivity of newborn calves, and significantly increases the expenses and labor required to care for the animals. Current products cannot help calves retain fluids quickly enough to avoid severe dehydration—the ultimate goal in managing scours.

### The Solution:

Neonorm Calf is a new product to help dairies and calf farms proactively retain fluid in calves—helping the animals avoid debilitating, dangerous levels of dehydration.

### Clinically Proven

A study evaluating the effect of Neonorm Calf on diarrhea in newborn calves was published in *Journal of Dairy Science*, the official, peer-reviewed journal of the American Dairy Science Association, in 2015<sup>1</sup>. The study was conducted by researchers from Cornell University College of Veterinary Medicine (Cornell).

### Coming Soon: Powder Formulation for Prophylactic, Herd-wide Management

A Cornell study evaluating the prophylactic use of Neonorm for the prevention of naturally occurring diarrhea in newborn Holstein calves was published in *Journal of Dairy Science* in early 2017. **Jaguar plans to launch the prophylactic formulation of Neonorm™ Calf in 2017 in powder form for administration in liquid for use in herd-wide management.**



### Learn More:



(415) 371-8310



[jaguaranimalhealth.com/neonorm](http://jaguaranimalhealth.com/neonorm)



### Tackles Foal Diarrhea At The Source

Neonorm Foal acts on the root cause of secretory diarrhea, electrolyte imbalance at the gut level. Neonorm Foal is not a symptomatic absorbent, electrolyte or antibiotic. It is a clinically tested, first-in-class product.

"Neonorm is an EXCELLENT product. I'm relying on it for foals with diarrhea, as do a number of my colleagues—with positive results."



Pedro De Pedro, DVM, MS,  
DACVIM-LAM  
Ross University School of  
Veterinary Medicine

"I am pretty cautious about recommending any product but this one definitely gets five stars. I ordered Neonorm Foal just as our new filly was born. Sure enough, she came down with a bad case of foal diarrhea. Initially, I tried the usual vet recommendations and nothing seemed to work. Then, the Neonorm Foal product arrived in the mail. She started to get better after the first dose and now with the third dose the diarrhea is gone. I've never had a foal diarrhea product work this fast or this well. I will definitely keep this in supply for every foaling season."

~ John Kreider, Foal Owner



[jaguaranimalhealth.com/blog](http://jaguaranimalhealth.com/blog)



[facebook.com/jaguaranimalhealth](https://facebook.com/jaguaranimalhealth)

Jaguar Animal Health, Inc., 201 Mission Street, Suite 2375, San Francisco, CA 94105

<sup>1</sup>Effect of crotefemer extract on severity and consistency of experimentally induced enterotoxigenic *Escherichia coli* diarrhea in newborn Holstein calves. Teixeira, A.G.V. et al. *Journal of Dairy Science*, Volume 98, Issue 11, 8035–8043.



