

**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): **January 22, 2018**

JAGUAR 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Conditions.

On January 22, 2018, Jaguar Health, Inc. ("Jaguar" or the "Company") issued a press release announcing updates regarding commercial, educational and product development programs and 2017 results for Mytesi® since Jaguar's merger with Napo. Mytesi® (crofelemer) is the first-in-class, FDA-approved anti-secretory human prescription drug product of Jaguar's wholly-owned subsidiary, Napo Pharmaceuticals, Inc. ("Napo"). A copy of the press release is furnished as Exhibit 99.1 to this report.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 22, 2018.

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 HEALTH, INC.

By: /s/ Karen S. Wright
Name: Karen S. Wright
Title: Chief Financial Officer

Date: January 22, 2018



Jaguar Health Provides Updates Regarding Commercial, Educational & Product Development Programs and 2017 Results for Mytesi Since Merger (August—December 2017)

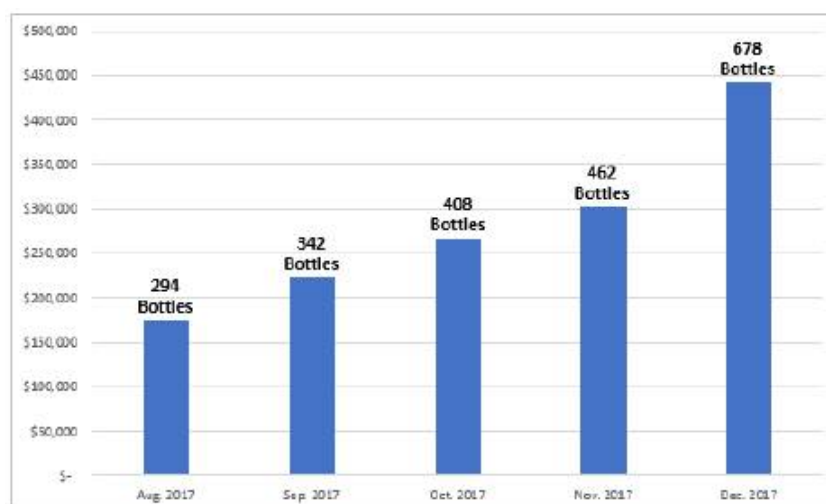
Mytesi Sales Increased 17.71% Each Month Over the Prior Month

San Francisco, CA (January 22, 2017): Jaguar Health, Inc. (NASDAQ: JAGX) (Jaguar or the Company), a commercial stage natural-products pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products for both human prescription use and animals on a global basis, today provided the following updates regarding commercial, educational and product development programs and 2017 results.

Mytesi® Sales Update (August 2017 — December of 2017)

Effective July 31, 2017, Jaguar merged with Napo Pharmaceuticals, Inc. (Napo) and acquired its first-in-class, FDA-approved anti-secretory human prescription drug product, Mytesi® (crofelemer). For the period August 1, 2017 through December 31, 2017, preliminary sales of Mytesi® were approximately \$1.40 million. During the aforementioned period, Mytesi® sales increased more than 78% relative to average monthly Mytesi® sales that took place from January through July of 2017, which is before marketing efforts were deployed in the combined Company and the deployment in the fourth quarter of Napo's team of nine dedicated sales reps. On average during the August 1, 2017 through December 31, 2017 period, sales increased 17.71% each month over the prior month.

Mytesi® Sales to Wholesalers: August-December 2017



Six of Napo's nine highly trained Mytesi® sales representatives are former long-term employees of the HIV portfolio business of drugmaker Bristol-Myers Squibb, while the remainder of the team possess extensive experience in drug sales to both HIV healthcare providers and gastroenterologists.

“Napo has identified a total high-potential prescriber base of 3,500 high-volume ART prescribers (HIV specialists) and 1,500 gastroenterologists who see the highest number of people living with HIV. The Napo sales force is located in the U.S. geographies with the highest potential, and is targeting the prescribers with the highest potential to drive Mytesi® business. From September 1, 2017 through November 30, 2017, there was an increase of 86% in new Mytesi® prescribers among gastroenterologists and 8% in HIV specialists, coincident with the deployment of our direct sales force,” Lisa Conte, Jaguar's President and CEO, stated. “According to data provided by IQVIA, the number of Mytesi® prescriptions written by physicians increased an average of 9.5% each month over the prior month during the August 1, 2017 through December 31, 2017 period. Additionally, patient redemptions of our Mytesi® Copay Savings Card increased an average of 7% each month over the prior month during the same period.”

Sales is a measure that is recognized under accounting principles generally accepted in the United States of America (“GAAP”), in accordance with new 2018 revenue recognition rules, still under review by the Company and its auditors. As a result, the preliminary Mytesi® sales figures provided herein are subject to revision until the Company reports final fourth quarter fiscal 2017 results no later than March 30, 2018.

Commercialized directly by Napo in the U.S., Mytesi® is the only antidiarrheal studied in and U.S. FDA-approved for the symptomatic relief of noninfectious diarrhea in adults living with HIV/AIDS on antiretroviral therapy (ART). Mytesi® is a prescription treatment for diarrhea that works differently, by acting locally in the GI tract to normalize the flow of water. Mytesi® does not have drug-drug interactions with ART and does not affect GI motility.

Napo Launches Health Care Practitioner and Patient Advocate Speaker Bureau — Plans to Conduct More Than 1,400 Educational Events in 2018

Napo recently completed the training of 29 health care practitioners (HCPs) and ten patient advocates to serve as members of the Napo Speakers Bureau. Medical education presentations led by participating HCPs—a group that includes HIV/AIDS specialists, infectious disease specialists, gastroenterologists, colorectal surgeons, and nurse practitioners—will focus on the prevalence and pathophysiology of gastrointestinal consequences of HIV infection and on the latest treatment options for HIV-related diarrhea. Presentations given by patient advocate members will provide information to people living with HIV (PLWH) about the prevalence of diarrhea in PLWH and offer guidance about talking to HCPs regarding diarrhea-related concerns.

As part of Napo's medical and patient education program, the Mytesi® direct sales force are planning more than 1,400 live and virtual educational events for 2018. Live events will largely take place in the following key geographies covered by the Mytesi® sales team: Miami/South Florida, Los Angeles/Palm Springs, New York, Houston, Chicago/St. Louis, Indianapolis, Kansas City, Alabama, Atlanta, San Francisco, DC, Pennsylvania, New Jersey, Delaware, Maryland, Mississippi and Louisiana.

“Since the merger of Jaguar and Napo, we have both initiated and dramatically expanded Mytesi®-related commercial, educational and development initiatives, including the creation of our direct sales force and our scientific advisory board, the roll-out of direct-to-consumer advertising campaigns, publication-focused efforts, government affairs activities regarding neglected comorbidities of HIV, and the launch of the Napo Speaker Bureau,” Conte commented. “Mytesi® sales and the awareness of a novel first-in-class approach to managing diarrhea tested specifically in the HIV population are clearly benefiting from the programs we’ve put in place—in addition to the efforts of our recently expanded team of experienced HIV sales representatives.”

Napo Accepts Request to Support Investigator-Initiated Trial of Crofelemer

Napo has accepted a request for support submitted by Dr. Mohamad Miqdady, Chief of Pediatric Gastroenterology, Hepatology and Nutrition at Sheikh Khalifa Medical City (SKMC) in Abu Dhabi, for an investigator-initiated trial of crofelemer, the active pharmaceutical ingredient in Mytesi®, for congenital diarrheal disorders (CDDs) in children.

CDDs are a group of rare, chronic intestinal channel diseases, occurring exclusively in early infancy, that are characterized by severe, lifelong diarrhea and a lifelong need for nutritional intake either parenterally or with a feeding tube. CDDs are related to specific genetic defects inherited as autosomal recessive traits. The incidence of CDDs is prevalent in regions where consanguineous marriages (related by blood) is part of the culture. CDDs are directly associated with serious secondary conditions including dehydration, metabolic acidosis, and failure to thrive, prompting the need for immediate therapy to prevent death and limit lifelong disability.

SKMC is the Abu Dhabi public health system's flagship institution and the largest hospital in the United Arab Emirates (UAE), consisting of a 586-bed tertiary hospital, 14 outpatient specialty clinics, and the Abu Dhabi Blood Bank, all of which are accredited by Joint Commission International, the oldest and largest healthcare standards-setting and accrediting body in the United States. Dr. Miqdady is American Board certified in Pediatric Gastroenterology, Hepatology and Nutrition, and he is a member of Napo's Scientific Advisory Board.

Napo intends to submit documentation in the first half of 2018 to the US Food and Drug Administration (FDA) for the planned formulation of crofelemer appropriate for feeding tube administration to support this investigation.

As announced on June 5, 2017, Napo has received orphan drug designation from the FDA for short bowel syndrome (SBS). The Orphan Drug Act provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. Orphan designation qualifies the sponsor of the drug for various development incentives, including extended exclusivity, tax credits for qualified clinical testing, and relief of filing fees.

Investigator-Initiated Trials of Crofelemer in Cancer Therapy-related Diarrhea (CTD)

As previously announced, an investigator-initiated trial titled *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* is currently underway in conjunction with Georgetown University. The primary objective of the study is to characterize the incidence and severity of diarrhea in patients receiving investigational therapy in the setting of prophylactic anti-diarrheal management.

As also previously announced, a second study, titled *An Open-Label Study to Characterize the Incidence and Severity of Diarrhea in Patients with Early-Stage HER2+ Breast Cancer Treated with Neratinib and Intensive Loperamide Prophylaxis*, is currently underway in conjunction with the University of California, San Francisco. The study is designed to evaluate crofelemer as a salvage anti-diarrheal therapy used with the investigational breast cancer agent neratinib. The primary objective is to characterize the incidence and severity of diarrhea in patients with early-stage breast cancer receiving adjuvant trastuzumab and neratinib followed by one year of neratinib monotherapy in the setting of prophylactic anti-diarrheal management.

“Diarrhea continues to be an area of concern for patients undergoing cancer treatment. Novel targeted agents, such as epidermal growth factor receptor antibodies and tyrosine kinase inhibitors (TKIs), may block natural chloride secretion regulation pathways in the normal gastrointestinal mucosa, thereby leading to secretory diarrhea,” Conte commented. “We recognize the importance of future development activities on supportive care for patients being treated with these cancer-related therapies, analogous to the supportive care of managing diarrhea in people living with HIV/AIDS.”

Animal Health Updates

While Jaguar's commercial and development efforts have evolved to focus primarily on Mytesi® and human pipeline indications since its merger with Napo, the Company is continuing animal health initiatives related to Canalevia™, its drug product candidate for treatment of various types of diarrhea in dogs, and Equilevia™, its non-prescription, personalized, premium product for total gut health in equine athletes.

As previously announced, Jaguar has received MUMS (Minor Use and Minor Species) designation status from the FDA for Canalevia™ for the indication of chemotherapy-induced diarrhea in dogs. Jaguar has completed clinical and manufacturing activity for Canalevia™ for this indication. MUMS designation is modeled on the orphan-drug designation for human drug development and offers possible financial incentives to encourage MUMS drug development, such as the availability of grants to help with the cost of developing the MUMS drug.

As announced last month, Jaguar has entered into a collaboration agreement with Seed Mena Businessmen Services LLC (SEED) for Equilevia™. Based in Dubai in the UAE, SEED is affiliated with Seed Group, a diversified group of companies under the umbrella of The Private Office of His Royal Highness Sheikh Saeed Bin Ahmed Al Maktoum establishing strategic partnerships with multinational companies from around the globe in an aim to leverage Seed Group's network to support potential business expansion in the MENA (Middle East and North Africa) region. The UAE has become a global leader in horse racing, equine endurance competitions, and other equine athletic activities. Gut health is of critical importance in competitive horses, as conditions such as ulcers can meaningfully impair equine athlete performance, and colic can lead to the death of an otherwise healthy horse in a matter of hours. According to a

third-party 2005 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

Net sales in 2017 for Jaguar's non-prescription Neonorm™ Foal and Neonorm™ Calf products totaled approximately \$422,000. Collaboration revenue totaled approximately \$2.9M. Jaguar continues to maintain a relationship with the Company's dairy market distributor in addition to selling Neonorm™ directly to end users through neonorm.com.

About Mytesi®

Mytesi® (crofelemer) 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%).

More information and complete Prescribing Information are available at Mytesi.com. Crofelemer, the active ingredient in Mytesi®, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage natural-products pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products for both human prescription use and animals on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's plan to conduct more than 1,400 educational events in 2018, the investigator-initiated trial of crofelemer for CDDs, the Company's intention to submit documentation in the first half of 2018 to the FDA for the planned formulation of crofelemer to support this investigation, the Company's belief that crofelemer may have considerable potential to help manage the severe diarrhea and dehydration symptomatic of CDDs, and the Company's plans to focus upcoming resources on the development of potentially important supportive care for patients being treated with cancer-related therapies. 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.

Source: Jaguar Health, Inc.

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