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): **November 14, 2022**

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36714**	**46-2956775**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Pine Street, Suite 400 **San Francisco, California**	**94104**
(Address of principal executive offices)	(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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 Per Share	JAGX	The Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Conditions.

On November 14, 2022, Jaguar Health, Inc. (the "Company") issued a press release announcing third quarter 2022 results. A copy of this press release is furnished as Exhibit 99.1 to this report.

The information in Item 2.02 and the press release furnished as Exhibit 99.1 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 November 14, 2022.
104	Cover Page Interactive Data File (embedded with the inline XBRL document)

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/ Lisa A. Conte
Name: Lisa A. Conte
Title: President and Chief Executive Officer

Date: November 14, 2022

Exhibit 99.1

Jaguar Health Provides Company Updates and Reports 2022 Third Quarter Financials

Prescription product net revenue of approximately $3.1 million in Q3 2022 increased 8.2% over Q2 2022 and increased approximately 412% over prescription product net revenue in Q3 2021

Core initiatives:

· ***OnTarget*** *Phase 3 clinical trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD) adding international sites, targeting completion of enrollment in Q2 2023*

· *Publication of Phase 2 IIT study in peer reviewed journal* ***Breast Cancer Research and Treatment***

· *Expected presentation in December 2022 from a third-party investigator, Dr. Mohamad Miqdady, Division Chief of the Pediatric Gastroenterology, Hepatology & Nutrition Division at Sheikh Khalifa Medical City in Abu Dhabi, following initiation of proof-of-concept trial of crofelemer for short bowel syndrome (SBS) and congenital diarrheal disorders (CCD), supporting the potential for expanded patient access through programs in Europe in 2023*

· *Second conditional approval for Canalevia®, for exercise-induced diarrhea (EID), expected in Q1 2023, adding to ongoing commercial activities of Canalevia-CA1 for treatment of chemotherapy-induced diarrhea (CID) in dogs*

· *Business development activities with nondilutive funding for Jaguar's mental health Entheogen Therapeutics Initiative (ETI) program targeted for Q1 2023*

· *Jaguar's Canine Cancer: Take C.H.A.R.G.E. Registry honored by the MarCom Awards program with two Platinum awards and one Gold award*

REMINDER: *Jaguar to host investor webcast Monday, November 14th at 8:30 a.m. Eastern regarding third quarter 2022 financials and company updates; Click* ***here*** *to register for webcast*

SAN FRANCISCO, CA / November 14, 2022 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today provided Company updates and reported consolidated third-quarter 2022 financial results.

The combined net revenue for Mytesi® and the Company's other prescription product, Canalevia®-CA1, which became commercially available in April 2022, was approximately $3.1 million in the third quarter of 2022, representing an increase of 8.2% over prescription product net revenue in the second quarter of 2022, which totaled approximately $2.9 million, and an increase of approximately 412% over Mytesi net revenue in the third quarter of 2021, which totaled approximately $0.6 million.

“We are very pleased that growth in Mytesi (crofelemer) revenue continued for the fifth quarter in a row in the third quarter of 2022,” said Lisa Conte, Jaguar's president and CEO. “As previously announced, the transition we completed throughout the end of 2021 and into the beginning of 2022 to a limited distribution network of specialty pharmacies resulted in a meaningful reduction in Mytesi distribution costs as well as a higher average net price. It is wonderful to see Mytesi growth continuing following this transition and the other components of our Mytesi patient access program, including our ongoing educational and promotional activities in 2022 and the launch this past May of our telehealth initiative for Mytesi. Most importantly, we are pleased with the realization of our mission of providing relief with a novel, plant-based, first-in-class mechanism of action to patients in need – including patients for whom no alternative therapeutic options exist.”

“As I frequently state, what is really powerful about crofelemer is that it is a pipeline within a product, and we are focused on two late-stage clinical events in the next approximately 6 to 9 months that we expect to be transformational in terms of value creation and recognition for the Company. Our key near-term clinical activity is our Phase 3 pivotal **OnTarget** trial of crofelemer for our core follow-on indication of prophylaxis of cancer therapy-related diarrhea (CTD). We expect enrollment in this pivotal trial to complete in the second quarter of 2023,” Conte said. “Our second prioritized clinical program centers around our approved investigator-initiated proof-of-concept trial of crofelemer for short bowel syndrome (SBS) and congenital diarrheal disorders (CDD). SBS and CDD are devastating and often catastrophic diseases for patients, who are frequently on parenteral nutrition for as long as 20 hours a day, seven days a week. The third-party investigator is targeting a presentation following the initiation of this proof-of-concept study at next month’s World Congress of Gastroenterology – a global GI conference in Dubai. Additional investigator-initiated requests and trials and clinical data for SBS and CDD are expected to come throughout 2023. In accordance with the guidelines of specific European Union countries, publications of proof-of concept data from these trials could support early patient access to crofelemer for SBS or CDD with intestinal failure within 2023 through programs in Europe. Early access programs are revenue generating, and reimbursable for participating patients.”

2022 MILESTONES, UPDATES & ACCOMPLISHMENTS:

- **Phase 3 clinical trial of crofelemer for cancer therapy-related diarrhea (CTD) in humans:** The pivotal **OnTarget** Phase 3 clinical trial of crofelemer for prophylaxis of CTD was initiated in October 2020 and is ongoing. The Company is in the process of adding additional clinical trial sites – both in the US and outside the US – to accelerate patient enrollment. Further details about the trial can be viewed **here** on the clinicaltrials.gov website. Is it estimated that 50–80% of chemotherapy patients experience diarrhea,[1] and diarrhea has the potential to cause dehydration, potential infections, and non-adherence to treatment in cancer patients. Patients with CTD are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without CTD,[2] and the cost of care of CTD patients is estimated to be 2.9 times higher than for patients who are not experiencing CTD.[3]

- **European Medicines Agency grants Orphan Drug Designation for crofelemer for Microvillus Inclusion Disease (MVID), a second rare disease indication:** Jaguar and Napo Therapeutics, the Italian corporation established by Jaguar in Italy in 2021 that focuses on development and commercialization of crofelemer in orphan and rare diseases, thus expanding access to crofelemer to patients in Europe, announced on October 17, 2022 that the European Commission adopted the decision to grant Orphan Drug Designation (ODD) for crofelemer for the indication of microvillus inclusion disease (MVID), a rare congenital diarrheal disorder (CDD) condition, in the European Union. This is a very welcome development for crofelemer, a new molecular entity that has been granted two orphan designations by the EMA in less than one year, as crofelemer received ODD for short bowel syndrome (SBS) from the EMA in December 2021 (crofelemer received ODD in the U.S. for SBS from the FDA in 2017.) The recognition of ODD in Europe for crofelemer for MVID is a key Napo Therapeutics milestone under the company's exclusive crofelemer license agreement with Jaguar, and receipt of this new ODD supports some specific regulatory pathways for this serious form of CDD, which remains a significant unmet medical need, especially in pediatric patients.

- **December 2022: Presentation by third-party investigator Dr. Mohamad Miqdady, Division Chief of the Pediatric Gastroenterology, Hepatology & Nutrition Division at Sheikh Khalifa Medical City in Abu Dhabi in the United Arab Emirates, following initiation of proof-of-concept trial of crofelemer for short bowel syndrome (SBS) and congenital diarrheal disorders (CCD):** Jaguar is currently supporting an investigator-initiated proof-of-concept study of crofelemer in patients with SBS or CDD with intestinal failure, with a planned endpoint of reduction of requirement of weekly volume of parenteral nutrition. The investigator is targeting a presentation in December 2022 at the World Congress of Gastroenterology – a global GI conference in Dubai. Additional investigator-initiated requests and trials and clinical data are expected to come throughout 2023. In accordance with the guidelines of specific EU countries, published data from these trials could support early patient access of crofelemer for SBS or CDD with intestinal failure by mid-2023 through programs in Europe for these devastating diseases for which there is a significant unmet medical need. Participation in Early Access Programs provides a potential opportunity for meaningful revenue generation in addition to the ability to impact important morbidity, mortality, and the cost of care for chronically ill patients for whom no good therapeutic options exist. SBS affects approximately 10,000 to 20,000 people in the U.S.,[4] according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size.[5] Despite limited treatment options, the global SBS market exceeded $568 million in 2019 and is expected to reach $4.6 billion by 2027, according to a report by Vision Research Reports.

- **September 29, 2022: Jaguar subsidiary Napo Pharmaceuticals announced activation by FDA of Investigational New Drug (IND) application for NP-300, a novel drug candidate for the symptomatic relief and treatment of diarrhea from cholera and other pathogens:** The Company was very pleased to hear from the FDA that they have completed their review of this IND application and concluded that Napo Pharmaceuticals may proceed with its proposed phase 1 clinical trial for the drug. Following the completion of the phase 1 trial, the Company will be positioned to initiate the next stage of its clinical development program for cholera-related diarrhea when the Company’s development team has the requisite resources and bandwidth to initiate the additional required trials. Jaguar and Napo Pharmaceuticals are grateful for the partial financial support from the National Institute of Allergy and Infectious Diseases (NIAID) to support the NP-300 preclinical program. NP-300 is a novel oral botanical drug product that is sustainably derived from the *Croton lechleri* tree, the same source as that for crofelemer, and is planned to be developed under the FDA's Botanical Guidance. As stated on the FDA's website, crofelemer is currently one of only two drugs that have been approved under the FDA's Botanical Guidance definition of a botanical drug product. Upon completion of the requisite development activities to support the New Drug Application (NDA) and subsequent approval of NP-300 by the FDA for the symptomatic relief and treatment of diarrhea from cholera, the Company intends to pursue a Tropical Disease Priority Review Voucher to develop NP-300 for this indication under the FDA's financial incentive program. Priority review vouchers are transferable, and in past transactions by other companies have sold for values ranging from $67 million to $350 million, which provides for a potential immediate return on investment upon approval of NP-300 for the cholera-related diarrhea indication.

- **2022, Jaguar's Year of the Dog:** Launch activities remain underway for Canalevia-CA1 in the U.S. veterinary market for the treatment of chemotherapy-induced diarrhea (CID) in dogs. Dogs, as with humans, discontinue their disease modifying chemotherapy approximately 40% of the time due to diarrhea, and dogs are a predictive model of the human situation. Jaguar expects that Canalevia could additionally receive FDA conditional approval, under the name Canalevia®-CA2, for the treatment of exercise-induced diarrhea (EID) in dogs in the first quarter of 2023.

- Jaguar Animal Health sponsored the October 26, 2022 episode of **dvm360 Live!**™, a web-based, magazine-style talk show for veterinary professionals hosted by Adam Christman, DVM, MBA, to drive awareness of Canalevia-CA1 and encourage veterinary clinics to contribute canine cancer records to the *Take C.H.A.R.G.E.* initiative. Dr. Sue Ettinger, DVM, DACVIM (Oncology), also known as Dr Sue Cancer Vet®, appeared on the dvm360 Live! episode to discuss Canalevia-CA1. She was joined on the show by one of her canine patients, a Labrador mix undergoing chemotherapy for sarcoma, and the dog's owner, who discussed his pet's experience with Canalevia-CA1. Dr. Ettinger is also a member of the *Take C.H.A.R.G.E.* Scientific Advisory Board.

- In November 2022, the **MarCom Awards** program, which celebrates excellence in marketing and communication, honored *Take C.H.A.R.G.E.* with two Platinum awards and one Gold award, which drives awareness of and therefore value to the Registry. The *Take C.H.A.R.G.E.* campaign was developed by TogoRun, which is Jaguar's PR firm and one of the financial co-sponsors of *Take C.H.A.R.G.E.* TogoRun's efforts have led to more than 80 million media impressions generated to date for *Take C.H.A.R.G.E.*, with more to come.

· **Ongoing business development initiatives in 2022:**

· In June of this year, as announced, Jaguar and Filament Health signed a letter of intent to enter a collaboration agreement to develop botanical prescription drugs for specific psychoactive target indications in the U.S. Filament Health has the laboratories, manufacturing, and IP capability for natural and plant-based products that Jaguar, as a company focused on later-stage clinical development, no longer has. Jaguar brings to the table the ethnobotany expertise, the expertise of how to do drug development under FDA Botanical Guidance, which is the approval the Company has for Mytesi. The two companies together are seeking partnerships with well-funded entities to pursue regulatory approval and ultimately commercialization for novel, pharmaceutical-grade, plant-based, standardized drug candidates in the mental health space. Jaguar and Filament Health are far along in discussions, and the Company expects that a formalized business development collaboration will be established within the next several months that involves bringing in nondilutive funding to help mobilize and leverage Jaguar's proprietary library of 2,300 plants and 3,500 plant extracts for the very important initial target markets of ADHD and social anxiety disorder, two markets that have understandably expanded because of the pandemic.

· In June 2022, as announced, Jaguar entered an exclusive license and services agreement with Ontario, Canada-based SynWorld Technologies Corporation (SynWorld) for the treatment of diarrhea in dogs in the China market with Jaguar's Canalevia drug product. Per the terms of the agreement, Jaguar engaged SynWorld as a service provider to obtain regulatory approval of the product for Jaguar in China and granted SynWorld a license to commercialize and sell this product following such approval in China. As consideration for the license, Jaguar is entitled to receive 60% of any profits from sales of the product in China. If Jaguar reimburses SynWorld for the direct expense of obtaining regulatory approval in China, the profit sharing will be 80% and 20%, respectively, for Jaguar and SynWorld.

- As announced, the Company and Quadri Pharmaceuticals Store LLC (Quadri Pharma) executed an exclusive crofelemer distribution and license agreement for multiple target indications in Middle East markets on March 31, 2022. The agreement grants Quadri Pharma exclusive promotional, commercialization, and distribution rights for specified human indications of crofelemer in Bahrain, Kuwait, Qatar, Saudi Arabia, the United Arab Emirates, and Oman following regulatory approval to market crofelemer in these countries for the specified indications, including the indication currently approved in the U.S. for HIV-related diarrhea, and cancer therapy-related diarrhea. In addition, the agreement grants Quadri Pharma exclusive rights to distribute crofelemer in these countries in the future under Named Patient Programs.

- Jaguar is continuing efforts to forge additional license and business development relationships in key markets around the globe.

- **Updates about recent and currently active investigator-initiated trials of crofelemer:**

  - Investigator-initiated HALT-D trial evaluating crofelemer for preventing chemotherapy-induced diarrhea (CID) in HER2-positive breast cancer patients: As announced, the full results of this study, which were presented at the December 2021 San Antonio Breast Cancer Symposium (SABCS 2021), were published in October 2022 in the peer reviewed journal **Breast Cancer Research and Treatment**.

  - Chronic idiopathic diarrhea in non-HIV adult patients

    - Study Name: *Yield of Diagnostic Tests and Management of Crofelemer for Chronic Idiopathic Diarrhea in Non-HIV Patients: A Pilot Study*
    - Location: University of Texas Health Science Center at Houston

  - Functional diarrhea in non-HIV adult patients

    - Study Name: *A randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and efficacy of crofelemer in subjects with functional diarrhea*
    - Location: Beth Israel Deaconess Medical Center, a Harvard Medical School institution in Boston

2022 THIRD QUARTER COMPANY FINANCIAL RESULTS:

Prescription product net revenue was approximately $3.1 million in the third quarter of 2022, representing an increase of 8.2% over prescription product net revenue in the second quarter of 2022, which totaled approximately $2.9 million, and an increase of approximately 412% over prescription product net revenue in the third quarter of 2021, which totaled approximately $0.6 million.

“Mytesi total prescription volume increased approximately 3% in the third quarter of 2022 over the second quarter of 2022,” said Ian Wendt, Jaguar's Chief Commercial Officer. “As previously announced, the transition we completed this past January to a limited distribution network of specialty pharmacies resulted in a meaningful reduction in Mytesi distribution costs as well as a higher average net price. I am very pleased to report that we significantly outperformed the industry gross-to-net average in the third quarter of 2022 – as we did in the three previous quarters – for sales of our human prescription product. This improvement in our gross-to-net was largely a result of the efficiencies realized by the transition to a closed network of specialty pharmacies. This transition assists in the preparation of the Company’s U.S. commercial distribution network for potential future indication expansion of crofelemer to other populations of patients with complex medical needs, such as CTD, inflammatory bowel disease, and SBS.”

The Company believes the availability of Mytesi through specialty pharmacies represents a significant benefit to patients, as such pharmacies focus on complex and chronic conditions and offer a higher level of support for prior authorizations, appeals, adherence reminders, counseling, and home delivery options.

- **Mytesi Prescription Volume:** As stated above, Mytesi prescription volume increased approximately 3% in the third quarter of 2022 over the second quarter of 2022. Prescription volume differs from invoiced sales volume, which reflects, among other factors, varying buying patterns among specialty pharmacies in the closed network as they manage their inventory levels.

- **Prescription Product Net Product Revenue:** Prescription product net revenue during the third quarter of 2022 was approximately $3.1 million and approximately $2.9 million in the second quarter of 2022, an increase of approximately $0.2 million, or 8.2%, quarter over quarter, and an increase of approximately 412% over prescription product net revenue in the third quarter of 2021, which totaled approximately $0.6 million. The transition to a limited distribution network of specialty pharmacies, which was completed this past January, resulted in a meaningful reduction in Mytesi distribution costs and a higher average net price. As part of the process of transitioning to the closed specialty pharmacy network, the third and fourth quarters of 2021 were significantly impacted by the inventory draw-down of approximately 1,300 bottles of Mytesi across the Company's third-party logistics warehouse, wholesalers, distributors, and retail stores.

- **Neonorm™:** Revenues for the non-prescription Neonorm products and Jaguar's Animal Health business unit were minimal for the third quarters of 2022 and 2021, in accordance with the Company's primary focus on human health and prescription products.

Financial Highlights	Three Months Ended September 30,			
(in thousands, except per share amounts)	**2022**	**2021**	$ change	% change
Net product revenue	$ 3,150	$ 630	2,520	400%
Loss from operations	$ (9,896)	$ (9,529)	(367)	4%
Net loss	$ (12,520)	$ (12,192)	(328)	3%
Net loss per share, basic and diluted	$ (0.12)	$ (0.27)		

- **Cost of Product Revenue:** Total cost of product revenue for the quarter ended September 30, 2022 was the same amount at $0.6 million for the quarter ended September 30, 2021.

- **Research and Development:** The R&D expense increased by $2.6 million, from $3.3 million for the quarter ended September 30, 2021 to $5.9 million during the same quarter in 2022 primarily due to the phase 3 clinical trial of crofelemer for CTD.

- **Sales and Marketing:** The Sales and Marketing expense decreased by approximately $0.2 million, from $2.3 million for the quarter ended September 30, 2021 to $2.1 million during the same quarter in 2022. Though direct marketing fees and expenses increased due to increased patient access programs and other Mytesi marketing initiatives, personnel and related benefits decreased.

- **General and Administrative:** The G&A expense increased by $0.4 million, from $4.0 million for the quarter ended September 30, 2021, to $4.4 during the same quarter in 2022. The increase of $0.4 million was largely due to an aggregate increase of $1.1 million in personnel and related benefits, public company expenses, legal and consulting costs, offset by an aggregate decrease of $0.7 million in stock-based compensation, rent, travel and other expenses.

- **Loss from Operations:** Loss from operations increased by $0.4 million, from $9.5 million in the quarter ended September 30, 2021 to $9.9 million during the same period in 2022.

- **Net Loss:** Net loss attributable to common shareholders increased by approximately $0.3 million, from $12.2 million in the quarter ended September 30, 2021 to $12.5 million in the same period in 2022. In addition to the loss from operations:
    - Interest expense increased by $0.6 million from $2.1 million in the quarter ended September 30, 2021 to $2.7 million for the same period in 2022 primarily due to interest from the royalty and note agreements.
    - Change in fair value of financial instrument and hybrid instrument designated at Fair Value Option (“FVO") increased $0.7 million from a loss of approximately $0.6 million in the three months ended September 30, 2021 to a gain of about $0.2 million for the same period in 2022 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.
    - Other expenses increased by about $0.1 million from $20,000 in the quarter ended September 30, 2021 to approximately $0.2 million for the same period in 2022 largely due to foreign currency transactions.
- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the third quarter of 2022 and the third quarter of 2021 were a net loss of $8.5 million each, respectively.

	Three Months Ending September 30,	
(in thousands)	**2022**	**2021**
	(unaudited)	
Net loss	$ (12,520)	$ (12,192)
Adjustments:		
Interest expense	2,731	2,078
Property and equipment depreciation	15	8
Amortization of intangible assets	483	422
Share-based compensation expense	745	1,165
Income taxes	-	-
Non-GAAP EBITDA	(8,546)	(8,519)
Non-GAAP Recurring EBITDA	$ (8,546)	$ (8,519)

Note Regarding Use of Non-GAAP Measures

The Company supplements its condensed consolidated financial statements presented on a GAAP basis by providing non-GAAP EBITDA and non-GAAP recurring EBITDA, which are considered non-GAAP under applicable SEC rules. Jaguar believes that the disclosure items of these non-GAAP measures provide investors with additional information that reflects the basis upon which Company management assesses and operates the business. These non-GAAP financial measures are not in accordance with GAAP and should not be viewed in isolation or as substitutes for GAAP net sales and GAAP net loss and are not substitutes for, or superior to, measures of financial performance in conformity with GAAP.

The Company defines non-GAAP EBITDA as net loss before interest expense and other expense, depreciation of property and equipment, amortization of intangible assets, share-based compensation expense and provision for or benefit from income taxes. The Company defines non-GAAP Recurring EBITDA as non-GAAP EBITDA adjusted for certain non-recurring revenues and expenses. Company management believes that non-GAAP EBITDA and non-GAAP Recurring EBITDA are meaningful indicators of Jaguar’s performance and provide useful information to investors regarding the Company’s results of operations and financial condition.

Participation Instructions for Webcast
When: Monday, November 14, 2022, at 8:30 AM Eastern Time
Participant Registration & Access Link: **Click Here**

Replay Instructions for Webcast
Replay of the webcast on the investor relations section of Jaguar's website: (click here)

About Jaguar Health, Napo Pharmaceuticals, Napo Therapeutics & Jaguar Animal Health

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. Our crofelemer drug product candidate is the subject of the OnTarget study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe. Jaguar Animal Health is a tradename of Jaguar Health.

For more information about Jaguar Health, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.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%).

See full Prescribing Information 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.

Important Safety Information About Canalevia®-CA1

For oral use in dogs only. Not for use in humans. Keep Canalevia-CA1 (crofelemer delayed-release tablets) in a secure location out of reach of children and other animals. Consult a physician in case of accidental ingestion by humans. Do not use in dogs that have a known hypersensitivity to crofelemer. Prior to using Canalevia-CA1, rule out infectious etiologies of diarrhea. Canalevia-CA1 is a conditionally approved drug indicated for the treatment of chemotherapy-induced diarrhea in dogs. The most common adverse reactions included decreased appetite, decreased activity, dehydration, abdominal pain, and vomiting.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. **It is a violation of Federal law to use this product other than as directed in the labeling. Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-552.**

See full Prescribing Information at Canalevia.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's expectation that enrollment in the OnTarget Phase 3 clinical trial will complete in Q2 2023, the Company's expectation that the third-party investigator of the proof-of-concept trial of crofelemer for SBS and CCD will conduct a presentation about this trial at the December 2022 World Congress of Gastroenterology, the Company's expectation that additional investigator-initiated requests and trial and clinical data for SBS and CDD will come throughout 2023, the Company's expectation that, in accordance with the guidelines of specific EU countries, publications of proof-of concept data from these trials could support early patient access to crofelemer for SBS or CDD with intestinal failure within 2023 through programs in Europe, the Company's expectation that a second conditional approval for Canalevia, for EID, may be granted in Q1 2023, the Company's expectation that it will host an investor webcast on November 14, 2022, the Company's expectation that two late-stage clinical events in the next approximately 6 to 9 months may be transformational in terms of value creation and recognition for the Company, the Company's expectation that it will pursue a Tropical Disease Priority Review Voucher to develop NP-300 for the planned cholera-related indication, the Company's expectation that information from *Take C.H.A.R.G.E.* will provide the first ever national representation of the incidence and prevalence of canine cancer and help inform decisions that advance the quality of life of both dogs with cancer and their owners, Jaguar's plans to incorporate a comprehensive coding system into *Take C.H.A.R.G.E.*, the Company's expectation that data from *Take C.H.A.R.G.E.* may provide insights to help better understand cancer in humans, and the Company's expectation that a formalized business development collaboration will be established within the next several months that involves bringing in nondilutive funding to help mobilize and leverage Jaguar's proprietary library of plants and plant extracts for the initial target markets of ADHD and social anxiety disorder. 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 several 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.

[1] Gibson RJ and Stringer AM. Chemotherapy-induced diarrhoea. Curr Opin Support Palliat Care 2009; 3: 31–35

[2] Pablo C. Okhuysen, M.D., *The impact of cancer-related diarrhea on changes in cancer therapy patterns: Real world evidence*

[3] Eric Roeland, M.D., FAAHPM, *Healthcare utilization and costs associated with cancer-related diarrhea*

[4] http://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/short-bowel-disease-crohns.pdf

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