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): **March 11, 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 March 11, 2022, Jaguar Health, Inc. (the "Company") issued a press release announcing 2021 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 March 11, 2022.

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: March 11, 2022

Exhibit 99.1

Jaguar Health Provides Company Updates and Reports 2021 Financials

Core 2022 development initiatives:

- *Ongoing operation of Company's **OnTarget** Phase 3 clinical trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD)*

- *Initiation and completion in 2H 2022 of investigator-initiated proof-of-concept study of crofelemer for short bowel syndrome with intestinal failure (SBS-IF)*

FDA conditional approval of Canalevia™-CA1 for treatment of chemotherapy-induced diarrhea (CID) in dogs

Fourth quarter 2021 Mytesi net revenue was approximately $2.1 million versus approximately $0.6 million in the third quarter of 2021, an increase of 230%

***REMINDER:** Jaguar to host investor webcast Monday, March 14th at 8:30 a.m. Eastern regarding 2021 financials and company updates; Click **here** to register for webcast*

SAN FRANCISCO, CA / March 11, 2022 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today provided company updates and reported consolidated financial results for the year ended December 31, 2021.

"2021 was a year of transition and progress for Jaguar's plant-based drug pipeline for human health," said Lisa Conte, the Company's president and CEO, "as we continued enrollment in our OnTarget Phase 3 clinical trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD) and advanced this key pipeline initiative with the presentation at December's San Antonio Breast Cancer Symposium of Phase 2 crofelemer data for prophylaxis in chemotherapy-related diarrhea; received Orphan Drug Designation in the European Union for crofelemer for short bowel syndrome; formed Napo Therapeutics in Milan, Italy, which was subsequently funded as a result of the merger of Napo Therapeutics with Milan-based Dragon SPAC S.p.A. and for which Jaguar Health is the majority shareholder; and completed a license agreement with Napo Therapeutics for exclusive rights to crofelemer and lechlemer in Europe. In December we also excitingly and importantly received FDA conditional approval for Canalevia-CA1 (crofelemer) for treatment of chemotherapy-induced diarrhea (CID) in dogs."

2022 UPDATES, YEAR-TO-DATE ACCOMPLISHMENTS, AND MILESTONES:

"We look forward to 2022 being an exciting year with the continued development of crofelemer – our 'pipeline within a product'; continuing efforts to forge license and business development relationships; our continuing Canalevia-CA1 launch and continued sales of Mytesi®; and, most importantly, providing relief with a novel first-in-class mechanism of action to patients in need – including patients for whom no alternative therapeutic options exist," Conte said.

Core 2022 Initiatives & Milestones:

- **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. A significant proportion of patients undergoing cancer therapy experience diarrhea, and diarrhea has the potential to cause dehydration, potential infections, and non-adherence to treatment in this population. Patients with CTD are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without CTD.[1]

- **2H 2022 Milestone: Initiation and completion of an investigator-initiated proof-of-concept study of crofelemer for short bowel syndrome with intestinal failure (SBS-IF):** Napo Therapeutics is supporting this investigator-initiated study of crofelemer in patients with short bowel syndrome (SBS) or congenital diarrheal disorders (CDD) with intestinal failure, with a planned primary endpoint of reduction of weekly volume of parenteral nutrition. On December 13, 2021, the European Medicines Agency (EMA) granted orphan-drug designation (ODD) for crofelemer for SBS in the European Union, and crofelemer has received ODD in the US for SBS. The EMA is committed to enabling early patient access to new medicines, particularly those that target an unmet medical need, and ODD status in the EU is expected to support Napo Therapeutics' plans to make crofelemer available through Early Access Programs in the EU for SBS. 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 therapeutic options exist. SBS affects approximately 10,000 to 20,000 people in the U.S.[2], according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size.[3] 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.

- **Mid-2022 Milestone: Filing of an Investigational New Drug (IND) application with the FDA for NP-300 (lechlemer) in support of the initiation of a Phase 1 lechlemer study in 2H 2022 for the symptomatic relief of diarrhea from cholera:** Lechlemer is the company's drug product candidate for symptomatic relief of diarrhea from cholera. It is a standardized and proprietary botanical drug product that is sustainably derived from the same source as crofelemer – the *Croton lechleri* tree. In support of the planned IND application filing for lechlemer, the Company received comprehensive animal toxicity preclinical services supported by the National Institute of Allergy and Infectious Diseases for four preclinical studies. The Company intends to pursue a tropical disease priority review voucher under the FDA's financial incentive program to develop drugs for tropical diseases such as cholera.

- **2022: Jaguar's year of the dog:** Launch activities remain underway for Canalevia-CA1 in the US veterinary market for the treatment of CID in dogs and included CID Treatment Forums on January 16th and March 6th for veterinarians, veterinary oncologists, and members of the media during the Veterinary Meeting & Expo (VMX) Conference in Orlando and the Western Veterinary Conference (WVC) in Las Vegas. Dogs, as with humans, must go off their disease modifying chemotherapy approximately 40% of the time due to diarrhea, and dogs are a predictive model of the human situation. As announced, 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 fourth quarter of 2022.

- **Investigator-initiated trials of crofelemer that are ongoing in 2022:**

  - 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

“As of March 11, 2022, the filing date of Jaguar’s annual report on Form 10-K for the year 2021, the Company’s cash position was approximately $18.5 million, and the Company had a public float exceeding $75 million. Therefore, the Company remains “shelf eligible,” said Conte. “There are benefits of having a shelf registration statement on Form S-3 in place, rather than a registration statement on S-1. At present, we have continuing flexibility to issue registered shares quickly and opportunistically, including in connection with potential future business transactions such as asset acquisitions, purchases of product, payments for services, and license deals, and we are pleased with the flexibility the ATM financing program provides.”

COMPANY FINANCIAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2021:

“Fourth quarter 2021 Mytesi net revenue was approximately $2.1 million versus approximately $0.6 million in the third quarter of 2021. This increase of 230%, or $1.5 million, largely represents the important realization of the benefits – from both a financial perspective and the standpoint of improved patient access – from Jaguar’s shift to distributing Mytesi through a closed network of specialty pharmacies,” said Conte. “The process of transitioning to a closed network of specialty pharmacies resulted in a one-time, short-term underrepresentation of Mytesi utilization. As anticipated, Mytesi revenue, primarily in the third and fourth quarters of 2021, was impacted by this transition as wholesalers in the retail distribution channel drew down their inventory of typically more than two-month’s volume. Our closed network of specialty pharmacies typically orders on a just-in-time inventory business model.”

“I am pleased to report that the Company completed the process of transitioning its Mytesi volume to a closed network of specialty pharmacies (rather than to wholesalers that resell the product to retail pharmacies) this past January,” said Ian Wendt, Jaguar’s Chief Commercial Officer, “and that no significant Mytesi inventory is left in the retail distribution channel. Mytesi new prescription volume, the metric we believe to be the best indicator of growth in patient demand, increased 10.4% in the fourth quarter of 2021 over the third quarter of 2021, and increased by 2.1% in the year 2021 over the year 2020. The transition to a closed network of specialty pharmacies has resulted in a meaningful reduction in Mytesi distribution costs and a higher average net price and 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 and SBS.”

- **Mytesi Prescription Volume:** As stated above, Mytesi new prescription volume, the metric the Company believes to be the best indicator of growth in patient demand, increased 10.4% in the fourth quarter of 2021 over the third quarter of 2021, and increased 2.1% in the year 2021 over the year 2020. Prescription volume differs from invoiced sales volume, which reflects, among other factors, varying buying patterns among wholesalers in the retail channel and specialty pharmacies in the closed network as they manage their inventory levels.

- **Mytesi Net Product Revenue:** Mytesi net revenue during the fourth quarter of 2021 was approximately $2.1 million and approximately $0.6 million in the third quarter of 2021, an increase of $1.5 million, or 230%, quarter over quarter. The transition to a closed network of specialty pharmacies has resulted in a meaningful reduction in Mytesi distribution costs and a higher average net price. Mytesi net revenue for the year 2021 was approximately $4.3 million and approximately $9.4 million for the year 2020, a decrease of approximately $5.1 million year over year. 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.

- **Mytesi Gross Product Revenue (Non-GAAP):** Mytesi gross revenue was approximately $3.0 million and $3.2 million during the fourth and third quarter of 2021, respectively, representing a decrease of $0.2 million quarter over quarter. Mytesi gross revenue for the year 2021 was approximately $15.7 million and approximately $20.4 million for the year 2020, a decrease of $4.7 million year over year. As described above, 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; and the transition to distribution through the closed specialty pharmacy network improved the Mytesi net-to-gross revenue ratio.

- **Mytesi Volume Through Specialty Pharmacies:** Mytesi sales volume distributed through the recently established, and expanding, closed network of third-party specialty pharmacies was 100% of total sales in the fourth quarter of 2021 compared to approximately 38% in the third quarter of 2021. 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 counseling, and home delivery options, and prepares the Company's U.S. distribution network for the anticipated future indication expansion of crofelemer to other populations of patients with complex medical needs.

- **Neonorm™:** Neonorm non-prescription product revenues were minimal for the year 2021 and the year 2020, in accordance with the Company's primary focus on human health and prescription products.

Financial Highlights (in thousands)	Year Ended December 31, 2021	2020	$ change	% change
Gross product sales				
Mytesi	$ 15,657	$ 20,434	$ (4,777)	-23.4%
Neonorm	62	77	(15)	-19.5%
Total gross product sales	15,719	20,511	(4,792)	-23.4%
Medicare rebates	(3,484)	(1,738)	(1,746)	100.5%
Sales discounts	(6,268)	(7,046)	778	-11.0%
Sales returns	(104)	(273)	169	-61.9%
Wholesaler fee	(1,528)	(2,069)	541	-26.1%
Net product sales	$ 4,335	$ 9,385	$ (5,050)	-53.8%

Financial Highlights (in thousands, except per share amounts)	Year Ended December 31, 2021	2020	$ change	% change
Net product revenue	$ 4,335	$ 9,385	(5,050)	-53.8%
Loss from operations	$ (40,708)	$ (26,647)	(14,061)	52.8%
Net loss	$ (52,600)	$ (33,809)	(18,791)	55.6%
Net loss per share, basic and diluted	$ (1.18)	$ (3.00)	2	-60.7%

- **Cost of Product Revenue:** Total cost of product revenue for the year 2021 was $2.3 million compared to $3.3 million for the year 2020, representing a $1.0 million decrease year over year. This decrease in cost of product revenue was largely due to the decrease in sales.

- **Research and Development:** The R&D expense was $15.1 million for the year 2021 compared to $6.4 million for the year 2020, an increase of $8.7 million year over year. Clinical and contract manufacturing expenses increased $4.6 million from $1.7 million for the year ended December 31, 2020, to $6.3 million in 2021 largely due to increased clinical trial activities related to the start-up of CTD and other indications, additional CMC manufacturing, expenses related to consulting and contractors, and cholera/lechlemer research expenses. In addition, personnel and related benefits increased $2.2 million from $1.8 million for the year 2020 to $4.0 million for the year 2021 due to compensation and additional headcount. Non-cash stock-based compensation expense increased $0.6 million from $0.7 million for the year 2020 to $1.3 million for the year 2021, primarily due to new options and restricted stock units granted in April 2021. Other expenses consisting of consulting, formulation, and regulatory fees increased $3.5 million for the year 2021 compared to $2.2 million for the year 2020, which is consistent with the increased activity in development of multiple potential follow-on indications for crofelemer.

- **Sales and Marketing:** The Sales and Marketing expense was $8.9 million for the year 2021 compared to $6.6 million for the year 2020, an increase of $2.3 million year over year. The increase in Sales and Marketing expense was largely due to an increase in marketing programs for Mytesi related to the expanding market access through specialty pharmacy channels.

- **General and Administrative:** The G&A expense was $17.1 million for the year 2021 compared to $14.4 million for the year 2020, an increase of $2.7 million year over year. The increase in G&A expenses was largely due to an increase of $1.5 million in personnel and related benefits due to increased resources, an increase in non-cash stock-based compensation of $0.5 million due to continued vesting of option grants, and an increase in public company expense of $1.1 million due to investor relations and expenses related to Jaguar's 2021 Annual Meeting of Shareholders. In addition, an increase of $0.3 million in audit, tax and accounting services was due to out-of-scope services, and an increase of $0.2 million in travel expenses due to loosening of Covid restrictions. These expenses were offset by decreases of $0.4 million in rent and lease as a result of the transfer to a lower-cost facility and the occupancy of less space, a decrease of $0.2 million in legal fees, and a decrease of $0.3 million in other expenditures largely due to decreased consulting expenses.

- **Loss from Operations:** For the year 2021, the loss from operations was $40.7 million compared to a loss of $26.6 million for the year 2020, an increase of $14.1 million year over year.

- **Net Loss:** For the year 2021, the net loss was $52.6 million, compared to a net loss of $38.6 million for the year 2020, an increase of $14.0 million year over year. In addition to the loss from operations:
    - Interest expense increased by $5.6 million from $2.8 million for the year 2020 to $8.4 million for the year 2021 primarily due to royalty interest agreements.
    - Change in fair value of financial instruments and hybrid instruments designated at fair value option ("FVO") losses decreased $0.8 million from a loss of $2.7 million for the year 2020 to $1.9 million for the year 2021 designated at FVO.

- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the year 2021 and the year 2020 was a net loss of $37.5 million and $24.3 million, respectively.

(in thousands)	Year Ended December 31, 2021	2020
	(unaudited)	
Net loss	$ (52,595)	$ (33,809)
Adjustments:		
Interest expense	8,421	2,792
Property and equipment depreciation	40	41
Amortization of intangible assets	1,687	1,687
Share-based compensation expense	3,974	2,824
Income taxes	-	-
Non-GAAP EBITDA	(38,473)	(26,465)
Impairment of indefinite-lived intangible assets	-	78
Warrant inducement expense	172	
Loss on extinguishment of debt	753	1,864
Distribution fees from former distributor	-	227
Non-GAAP recurring EBITDA	$ (37,548)	$ (24,296)

Note Regarding Use of Non-GAAP Measures

The Company supplements its condensed consolidated financial statements presented on a GAAP basis by providing gross sales, 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.

Gross sales percentages issued by the Company are based on gross sales figures that represent Mytesi orders placed by wholesalers with Jaguar's third-party logistics warehouse, less allowances for rebates, chargebacks, and discounts, which generate the cash flows for Napo Pharmaceuticals, Inc. ("Napo"), Jaguar's wholly owned subsidiary. Gross sales are used internally by management as an indicator of and to monitor operating performance, including sales performance of Mytesi, salesperson performance, and product growth or declines. The Company believes that the presentation of gross sales provides a closer to real-time useful measure of our operating performance. Gross sales are not a measure that is recognized under accounting principles generally accepted in the United States of America ("GAAP") and should not be considered as an alternative to net sales, which is determined in accordance with GAAP, and should not be used alone as an indicator of operating performance in place of net sales. Additionally, gross sales may not be comparable to similarly titled measures used by other companies, as gross sales have been defined by the Company's internal reporting practices. In addition, gross sales may not be realized in the form of cash receipts as promotional payments and allowances may be deducted from payments received from certain customers. Mytesi gross sales are reduced by Medicare, ADAP 340B chargebacks, returns, and wholesale distribution fees based on historical trends to determine net sales.

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

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 Animal Health is a tradename of Jaguar Health. 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.

For more information about Jaguar Health, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.com. For more information about Napo Therapeutics, visit www.napotherapeutics.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.**

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's expectation that an investigator-initiated proof-of-concept study of crofelemer for SBS-IF will be initiated and completed in 2H 2022, the expectation that the Company will file an IND application with the FDA in mid-2022 for lechlemer in support of the initiation of a Phase 1 lechlemer study in 2H 2022 for the symptomatic relief of diarrhea from cholera, the expectation that the Company will pursue a tropical disease priority review voucher under the FDA's financial incentive program to develop drugs for tropical diseases such as cholera, the expectation that Canalevia-CA2 may receive FDA conditional approval for the treatment of EID in dogs in the fourth quarter of 2022, and the expectation that Jaguar will host an investor webcast on March 14, 2022. 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] Pablo C. Okhuysen, M.D., *The impact of cancer-related diarrhea on changes in cancer therapy patterns: Real world evidence*

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

[3] http://www.pharmabiz.com/NewsDetails.aspx?aid=84221&sid=2

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