
**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): **May 10, 2022**

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.)

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

94104
(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 May 10, 2022, Jaguar Health, Inc. (the “Company”) issued a press release announcing first 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 May 10, 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: May 10, 2022



Jaguar Health Provides Company Updates and Reports 2022 First Quarter Financials

Mytesi[®] net revenue of \$2.6 million increased approximately 24% over the fourth quarter of 2021 and increased approximately 112% over Mytesi net revenue in the first quarter of 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 1H 2023
- Targeted completion in 2022 & 2023 of investigator-initiated proof-of-concept studies of crofelemer for short bowel syndrome and congenital diarrheal disorders, supporting the potential for expanded patient access through programs in Europe in 2023
- Ongoing launch of Canalevia[®]-CA1, which is now commercially available for treatment of chemotherapy-induced diarrhea (CID) in dogs

REMINDER: Jaguar to host investor webcast Tuesday, May 10th at 8:30 a.m. Eastern regarding first quarter 2022 financials and company updates; Click [here](#) to register for webcast

SAN FRANCISCO, CA / May 10, 2022 / Jaguar Health, Inc. (NASDAQ: JAGX) (“Jaguar” or the “Company”) today provided company updates and reported consolidated first quarter 2022 financial results.

Mytesi net revenue was approximately \$2.6 million in the first quarter of 2022, representing an increase of approximately 24% over Mytesi net revenue in the fourth quarter of 2021, which totaled approximately \$2.1 million, and an increase of approximately 112% over Mytesi net revenue in the first quarter of 2021, which totaled approximately \$1.2 million.

“These increases in Mytesi revenue largely represent the important and continuing realization of the benefits – from both a financial perspective and the standpoint of improved patient access – from the shift Jaguar completed this past January to distributing Mytesi through a closed network of specialty pharmacies (rather than to wholesalers that resell the product to retail pharmacies). I am also pleased to announce that Canalevia-CA1 (crofelemer), our prescription product for chemotherapy-induced diarrhea (CID) in dogs, is now commercially available,” said Lisa Conte, Jaguar’s president and CEO.

“Regarding future commercial opportunities, Jaguar is focused on two important crofelemer pipeline development activities in the next 12-15 months that are expected to be value-creating: the completion of enrollment for our Phase 3 pivotal **OnTarget** trial of our core follow-on indication for crofelemer’s novel mechanism of action, prophylaxis of cancer therapy-related diarrhea (CTD) in humans; and the completion in 2022 and 2023 of investigator-initiated proof-of-concept studies of crofelemer for short bowel syndrome (SBS) and congenital diarrheal disorders (CDD), supporting the potential for expanded patient access through programs in Europe in 2023 for these devastating and catastrophic diseases and health situations for these patients, who are often on parenteral nutrition for as long as 20 hours a day, seven days a week.”



2022 MILESTONES, UPDATES & ACCOMPLISHMENTS:

“We look forward to 2022 continuing to be an exciting year, with continued development initiatives for crofelemer – our ‘pipeline within a product’; continuing efforts to forge license and business development relationships, such as the recently completed license and distribution deal with Quadri Pharma for the MENA region; our ongoing Canalevia-CA1 launch, and potential expansion of Canalevia conditional approval to exercise-induced diarrhea (EID) in dogs; and continued growth in sales of Mytesi, with the successful completion of the shift to our specialty pharmacies distribution and continued educational and promotional activities in 2022, including the recent launch of our telehealth initiative. 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,” Conte said.

- **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 patient population. Patients with CTD are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without CTD,¹ and the cost of care of CTD patients is estimated to be 2.9 times higher than for patients who are not experiencing CTD.²
 - **2022 & 2023 Milestones: Completion of investigator-initiated proof-of-concept studies of crofelemer for short bowel syndrome (SBS) and congenital diarrheal disorders (CDD) with intestinal failure:** Napo Therapeutics is supporting planned investigator-initiated studies 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 U.S. 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 good therapeutic options exist. SBS affects approximately 10,000 to 20,000 people in the U.S.,³ according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size.⁴ 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, and works by the same mechanism of action as crofelemer. 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. Priority review vouchers are transferable, and in past transactions by other companies have sold for prices ranging from \$67 million to \$350 million, which provides for a potential immediate return on investment upon approval of the product for the symptomatic relief of diarrhea from cholera.
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- **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. Canalevia-CA1 was the focus of Jaguar Animal Health's exhibit booth at April's Veterinary Cancer Society Mid-Year Conference in Puerto Vallarta, Mexico, and the Company also held a well-attended dinner event for veterinary oncologists about CID in dogs at this conference. Jaguar Animal Health will be exhibiting at the June 23-25, 2022 American College of Veterinary Internal Medicine (ACVIM) Forum in Austin, Texas. Dogs, as with humans, 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.
 - **SAVE THE DATE!** Special media event and performance in New York City on Monday, May 23rd from 12:30 to 2:30 PM Eastern to celebrate the launch of the **Jaguar Health Canine Cancer: Take C.H.A.R.G.E.** initiative. "C.H.A.R.G.E." is an acronym for Canine Health And ReGistry Exchange. The goal is to establish the first-ever U.S. canine cancer national registry and cancer care index to assess the prevalence and incidence of cancer in dogs. The mission is important, because protecting dogs from cancer begins with knowing its impact by breed, type, age, gender, and location. Data will be revealed at the event from the first nationwide Gallup survey of pet owners addressing their experience with canine cancer, as well as the registry itself that is based on the analysis of thousands of canine medical records. The data may also provide insights to help better understand cancer in humans and the importance of managing side effects in human cancer therapy.
 - **Ongoing business development initiatives in 2022:**
 - Ongoing management of the Company's relationship with Quadri Pharmaceuticals Store LLC (Quadri Pharma) following the execution on March 31, 2022 of an exclusive crofelemer distribution and license agreement with Quadri Pharma for multiple target indications in Middle East markets. As announced, 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 immediate 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: The full results of this study, which was presented at the San Antonio Breast Cancer Symposium (SABCS 2021) in December 2021, are expected to be submitted to a medical journal in 2022 for consideration for publication.
 - Chronic idiopathic diarrhea in non-HIV adult patients
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- o Study Name: *Yield of Diagnostic Tests and Management of Crofelemer for Chronic Idiopathic Diarrhea in Non-HIV Patients: A Pilot Study*
- o Location: University of Texas Health Science Center at Houston
- Functional diarrhea in non-HIV adult patients
 - o Study Name: *A randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and efficacy of crofelemer in subjects with functional diarrhea*
 - o Location: Beth Israel Deaconess Medical Center, a Harvard Medical School institution in Boston

2022 FIRST QUARTER COMPANY FINANCIAL RESULTS:

Mytesi net revenue was approximately \$2.6 million in the first quarter of 2022, representing an increase of approximately 24% over Mytesi net revenue in the fourth quarter of 2021, which totaled approximately \$2.1 million, and an increase of approximately 112% over Mytesi net revenue in the first quarter of 2021, which totaled approximately \$1.2 million.

“Mytesi total prescription volume, the metric we believe to be the best indicator of patient demand, increased 14.6% in the first quarter of 2022 over the fourth quarter of 2021,” said Ian Wendt, Jaguar’s Chief Commercial Officer. “As previously announced, the transition to a closed network of specialty pharmacies has resulted in a meaningful reduction in Mytesi distribution costs as well as 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. This transition has also allowed us to begin utilizing sales and prescription data directly provided by our network of specialty pharmacies to more accurately track prescription volume, rather than relying on a third-party provider of estimated data for this important performance metric.”

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.

- **Mytesi Prescription Volume:** As stated above, Mytesi prescription volume, the metric the Company believes to be the best indicator of growth in patient demand, increased 14.6% in the first quarter of 2022 over the fourth quarter of 2021. 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.
 - **Mytesi Net Product Revenue:** Mytesi net revenue during the first quarter of 2022 was approximately \$2.6 million and approximately \$2.1 million in the fourth quarter of 2021, an increase of approximately \$0.5 million, or approximately 24%, quarter over quarter, and an increase of approximately 112% over Mytesi net revenue in the first quarter of 2021, which totaled approximately \$1.2 million. The transition to a closed 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.
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- **Mytesi Gross Product Revenue (Non-GAAP):** Mytesi gross revenue was approximately \$3.4 million in the first quarter of 2022 and \$3.0 million in the fourth quarter of 2021, representing an increase of approximately \$0.4 million or 13.4% quarter over quarter, and a decrease of approximately 25.5% over Mytesi gross revenue in the first quarter of 2021, which totaled approximately \$4.6 million. The increase in Mytesi gross revenue in the first quarter of 2022 over the fourth quarter of 2021 is due largely to the fact that infrastructure required to complete the transition to a closed network of specialty pharmacies was not fully in place in the fourth quarter of 2021, and the loosening of Covid-related travel restrictions in the first quarter of 2022 – which allowed Mytesi sales personnel to visit more healthcare providers. The decrease in Mytesi gross revenue in the first quarter of 2022 compared to the same quarter in the prior year was due to the process of transitioning to distributing Mytesi through a closed network of specialty pharmacies instead of through wholesalers that resell the product to retail pharmacies.
- **Neonorm™:** Revenues for the non-prescription Neonorm products and Jaguar’s Animal Health business unit were minimal for the first quarters of 2022 and 2021, in accordance with the Company’s primary focus on human health and prescription products.

Financial Highlights (in thousands)	Three Months Ended March 31,			
	2022	2021	\$ change	% change
Gross product sales				
Mytesi	\$ 3,395	\$ 4,558	\$ (1,163)	-25.5%
Neonorm	20	33	(13)	-39.4%
Canalevia	44	—	44	100.0%
Total gross product sales	3,459	4,591	(1,132)	-24.7%
Medicare rebates	(504)	(1,097)	593	-54.1%
Sales discounts	(320)	(1,732)	1,412	-81.5%
Sales returns	(10)	(20)	10	-50.0%
Wholesaler fee	—	(501)	501	-100.0%
Net product sales	\$ 2,625	\$ 1,241	\$ 1,384	111.5%

Financial Highlights (in thousands, except per share amounts)	Three Months Ended March 31,			
	2022	2021	\$ change	% change
Net product revenue	\$ 2,625	\$ 1,241	1,384	111.5%
Loss from operations	\$ (11,754)	\$ (8,766)	(2,988)	34.1%
Net loss attributable to common shareholders	\$ (17,986)	\$ (12,009)	(5,977)	49.8%
Net loss per share, basic and diluted	\$ (0.40)	\$ (0.28)	(0.12)	42.9%

- **Cost of Product Revenue:** Total cost of product revenue for the quarter ended March 31, 2022 was \$0.5 million compared to \$0.6 million for the quarter ended March 31, 2021, representing a \$0.1 million decrease over the first quarter of 2021. This decrease in cost of product revenue was largely due to the decrease in distribution costs and channel rebate/discounts that resulted from the shift to the specialty pharmacies distribution model.
- **Research and Development:** The R&D expense was \$4.9 million for the first quarter of 2022 compared to \$2.4 million for the first quarter of 2021, an increase of \$2.5 million quarter over quarter. Clinical and contract manufacturing increased approximately \$0.8 million in the first quarter of 2022 compared to the same period in 2021 due largely to increased clinical trial activities related to the Company’s OnTarget Phase 3 clinical trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD) as well as development efforts for other indications, additional CMC manufacturing, expenses related to consulting and contractors, and cholera/lechlemer-related research expenses. In addition, personnel and related benefits increased to \$1.6 million in the first quarter of 2022 compared to the same period in 2021 due to an increase in headcount beginning in 2021 and other compensation. Non-cash stock-based compensation expense increased \$0.2 million in the first quarter of 2022 compared to the first quarter of 2021, primarily due to the issuance of new options and the granting of restricted stock units.



- **Sales and Marketing:** The Sales and Marketing expense was \$2.8 million for the first quarter of 2022 compared to \$2.1 million for the first quarter of 2021, an increase of approximately \$0.7 million quarter over quarter. The increase in Sales and Marketing expense was largely due to an increase in marketing programs of \$0.2 million related to the Company's transition to selling Mytesi through a closed network of specialty pharmacies, an increase of \$0.3 in personnel and related benefits due to an increase in compensation including commissions, and an increase of approximately \$0.2 million in travel due to loosening of Covid-related travel restrictions.
 - **General and Administrative:** The G&A expense was \$6.1 million for the first quarter of 2022 compared to \$3.4 million for the first quarter of 2021, an increase of \$2.7 million quarter over quarter. The increase in G&A expenses was largely due to an increase of \$1.2 million in personnel and related benefits due to increased compensation, an increase in public company expense of \$0.6 million due to investor relations activities, an increase in corporate-related activities of \$0.6 million, an increase of \$0.1 million in travel expenses due to loosening of Covid-related travel restrictions, an increase in consulting, rent, and legal expenses, and an increase in non-cash stock-based compensation of \$0.2 million due to continued vesting of option grants. These expenses were offset by a decrease of \$0.3 million in audit and accounting services due to the transition to a new accounting firm and fewer complex transactions.
 - **Loss from Operations:** For the first quarter of 2022, the loss from operations was \$11.8 million compared to a loss of \$8.8 million in the first quarter of 2021, an increase of \$3.0 million quarter over quarter.
 - **Net Loss:** For the first quarter of 2022, the net loss attributable to common shareholders was approximately \$18.0 million, compared to a net loss of \$12.0 million in the first quarter of 2021, an increase of approximately \$6.0 million quarter over quarter. In addition to the loss from operations:
 - Interest expense increased by \$2.3 million from \$1.9 million in the three months ended March 31, 2021 to \$4.2 million for the same period in 2022 primarily due to interest from the royalty and note agreements.
 - The increase in the loss on extinguishment of debt from \$753,000 in the three months ended March 31, 2021 to \$2.8 million in the same period in 2022 is due to the \$2.8 million extinguishment loss from the exchange of the outstanding balance of one of the royalty agreements for shares of the Company's common stock.
 - Change in fair value of financial instruments and hybrid instruments designated at fair value option (FVO) losses decreased \$0.4 million from a loss of \$0.6 million in the three months ended March 31, 2021 to \$0.2 million for the same period in 2022 designated at FVO.
 - Other income increased by \$0.8 million from \$10,000 in the three months ended March 31, 2021 to \$0.8 million for the same period in 2022 due to the foreign currency transactions.
 - **Non-GAAP EBITDA:** Non-GAAP EBITDA for the first quarter of 2022 and the first quarter of 2021 was a net loss of \$9.4 million and \$6.8 million, respectively.
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(in thousands)	Three Months Ending March 31,	
	2022	2021
	(unaudited)	
Net loss attributable to common shareholders	\$ (17,986)	\$ (12,009)
Adjustments:		
Interest expense	4,194	1,901
Property and equipment depreciation	131	9
Amortization of intangible assets	422	422
Share-based compensation expense	1,063	634
Non-GAAP EBITDA	(12,176)	(9,043)
Loss on extinguishment of debt	2,815	753
Series 3 warrants inducement expense	-	1,462
Non-GAAP Recurring EBITDA	\$ (9,361)	\$ (6,828)

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 select Specialty Pharmacies with Jaguar's third-party logistics warehouse, less allowances for rebates 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. 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 specialty pharmacy discounts, Medicare rebates, Medicaid rebates, 340B discounts, ADAP rebates, VA rebates, copay program costs, prompt pay discounts, and returns 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: Tuesday, May 10, 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.

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 investigator-initiated proof-of-concept studies of crofelemer for SBS and CDD will be completed in 2022 and 2023, supporting the potential for expanded patient access through programs in Europe in 2023, Jaguar’s expectation that these SBS- and CDD-related activities, as well as completion of enrollment for the Phase 3 pivotal OnTarget trial in the U.S., will be value-creating in the next 12-15 months, the Company’s expectation that Canalevia may receive conditional approval for treatment of EID in dogs in the fourth quarter of 2022, the Company’s expectation that growth in sales of Mytesi will continue, Jaguar’s expectation that ODD status in the EU for crofelemer for SBS will support Napo Therapeutics’ plans to make crofelemer available through Early Access Programs in the EU for SBS and that participation in Early Access Programs will provide 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, Jaguar’s expectation that the Company will file an IND application with the FDA for lechlemer in mid-2022 in support of the initiation of a Phase 1 lechlemer study in 2H 2022 for the symptomatic relief of diarrhea from cholera, the Company’s plans to pursue a tropical disease priority review voucher from the FDA for lechlemer for the symptomatic relief of diarrhea from cholera, the expectation that Jaguar will exhibit at the June 2022 ACVIM Forum in Austin, the expectation that a special media event and performance event will be held in New York City on May 23, 2022 to celebrate the launch of the Jaguar Health Canine Cancer: Take C.H.A.R.G.E. initiative, the expectation that data from the Take C.H.A.R.G.E. initiative may provide insights to help better understand cancer in humans and the importance of managing side effects in human cancer therapy, the expectation that the full results of the HALT-D trial will be submitted to a medical journal in 2022 for consideration for publication, and the expectation that Jaguar will host an investor webcast on May 10, 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 Eric Roeland, M.D., FAAHPM, *Healthcare utilization and costs associated with cancer-related diarrhea*

³ <http://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/short-bowel-disease-crohns.pdf>

⁴ <http://www.pharmabiz.com/NewsDetails.aspx?aid=84221&sid=2>

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