



Jaguar Health Reports 2022 Financial Results - Prescription Revenues up 179% to \$11.9 Million

March 27, 2023

- Prescription product net revenue was approximately \$11.9 million for the year ended December 31, 2022 versus approximately \$4.3 million for the year ended December 31, 2021, an increase of 178.7%.
- Prescription product net revenue of approximately \$3.3 million in Q4 2022 increased 3.4% over Q3 2022 and increased approximately 57% over prescription product net revenue in Q4 2021.
- As of March 24, 2023, the filing date of Jaguar's annual report on Form 10-K for the year 2022, the Company's cash position was approximately \$15.3 million.

Core initiatives:

- Patient enrollment in [OnTarget](#) Phase 3 clinical trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD) is now at approximately 80% and expected to complete in Q2 2023.
- Jaguar planning to support investigator-initiated proof-of-concept (POC) studies of crofelemer in 2023 for short bowel syndrome (SBS) with intestinal failure and congenital diarrheal disorders (CDD). POC targeted for 2H 2023 in support of potential early patient access in Europe, potentially in 2024.
- The Company plans to submit an Investigational New Drug (IND) application in Q2 2023 to FDA for crofelemer for microvillus inclusion disease, a rare CDD condition, for which Orphan Drug Designation has been granted by both the FDA and European Medicines Agency.

REMINDER: Jaguar to host investor webcast Monday, March 27th at 8:00 a.m. Eastern regarding 2022 financials and company updates; Click [here](#) to register for webcast.

SAN FRANCISCO, CA / ACCESSWIRE / March 27, 2023 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today provided Company updates and reported consolidated financial results for the year ended December 31, 2022.

The combined net revenue for Mytesi[®] and the Company's other crofelemer prescription product, Canalevia[®]-CA1, which became commercially available in April 2022, was approximately \$11.9 million in the year 2022, representing an increase of 178.7% over the combined net revenue in the year 2021, which totaled \$4.3 million. The combined net revenue for Mytesi and Canalevia-CA1 was approximately \$3.3 million in the fourth quarter of 2022, representing an increase of 3.4% over prescription product net revenue in the third quarter of 2022, which totaled approximately \$3.1 million, and an increase of approximately 57.0% over prescription product net revenue in the fourth quarter of 2021, which totaled approximately \$2.1 million.

"We are very pleased that growth in Mytesi revenue continued for the sixth quarter in a row in the fourth 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 continuing to grow following this transition and the successful implementation of our Mytesi patient access programs, including our ongoing disease state education and promotional activities. 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. Our key near-term clinical activity is our Phase 3 pivotal [OnTarget](#) trial of our novel botanical drug, crofelemer, for our core follow-on indication of prophylaxis of cancer therapy-related diarrhea (CTD). Our efforts over the past year to expand the OnTarget trial to new U.S. and international sites - with trial sites now active in Eastern Europe - in both Georgia and the Republic of Serbia - as well as in Argentina and Taiwan - have significantly accelerated patient enrollment. As announced, enrollment reached approximately 75% one month ago. Enrollment is now at approximately 80%, and target trial enrollment of 256 patients is expected to complete in the second quarter of 2023, which is just around the corner," Conte said.

The Company's second prioritized clinical program centers around our approved investigator-initiated proof-of-concept trial of crofelemer for short bowel syndrome with intestinal failure (SBS-IF) and for microvillus inclusion disease (MVID), a rare congenital diarrheal disorder (CDD). SBS-IF and MVID 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. Jaguar and the company it established in Europe, Napo Therapeutics, are planning to support investigator-initiated proof-of-concept studies of crofelemer in patients with SBS-IF or MVID, focused on obtaining proof-of-concept (POC) of reduction of requirements of parenteral support including parenteral nutrition and/or intravenous fluids, in 2023. In accordance with the guidelines of specific European Union countries, publications of

POC data from these trials could support early patient access to crofelemer for SBS-IF or MVID through programs in Europe. Early access programs are revenue generating, and reimbursable for participating patients.

COMPANY MILESTONES, UPDATES & ACCOMPLISHMENTS:

- As of March 24, 2022, the filing date of Jaguar's annual report on Form 10-K for the year 2022, the Company's cash position was approximately \$ 15.3 million.
- **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 diarrhea in adult cancer patients receiving targeted therapy, with or without chemotherapy, was initiated in October 2020 and is ongoing. The trial is evaluating the effectiveness of crofelemer's novel mechanism of action - the modulation of two chloride ion channels in the gastrointestinal tract - to mitigate or substantially reduce chronic cancer therapy-related diarrhea. Jaguar's expectation is that this placebo-controlled trial will provide evidence that diarrhea associated with targeted cancer therapies is chronic, not acute, and impacts the patient's ability to remain on their cancer therapy regimens at proven doses for better outcomes. Each year, according to the CDC, more than 1 million cancer patients receive chemotherapy or radiation in an outpatient oncology clinic in the U.S. Treatment can last for months to years, in both the curative and metastatic situations. Crofelemer is currently approved for a chronic use in HIV/AIDS patients, providing a potential opportunity for a paradigm shift for prophylaxis of CTD compared to the management of severe chronic diarrhea with constipating agents such as ant motility drugs, which are predominantly opioids.
- **February 2023: FDA granted Orphan Drug Designation for crofelemer for Microvillus Inclusion Disease (MVID), a second rare disease indication:** As announced, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to crofelemer for the indication of microvillus inclusion disease (MVID), a rare congenital diarrheal disorder (CDD), following review of the ODD application the Company submitted to the FDA. Crofelemer is a new molecular entity that now holds four orphan designations, as crofelemer previously received ODD for MVID from the European Medicines Agency (EMA) and for short bowel syndrome (SBS) from both the FDA and the EMA. Jaguar is planning to support investigator-initiated proof-of-concept studies of crofelemer in patients with SBS-IF or MVID, focused on obtaining proof-of-concept (POC) of reduction of requirements of parenteral support including parenteral nutrition and/or intravenous fluids, in 2023. SBS and CDD are the initial focus of Napo Therapeutics, the Italian corporation established by Jaguar in Milan, Italy in 2021 with a mission to expand crofelemer access in Europe for the treatment and management of orphan and rare disease indications. In accordance with the guidelines of specific European Union countries, publications of POC data from these trials could support early patient access to crofelemer for SBS-IF or MVID through programs in Europe, potentially in 2024. Early access programs are revenue generating, and reimbursable for participating patients.
- **Q2 2023 Milestone: Submit Investigational New Drug (IND) application to FDA for MVID:** As announced, the Company intends to submit an IND application to FDA in the second quarter of 2023 for crofelemer for this ultra-rare CDD condition.
- **January 2023: Jaguar and Filament Health, with Funding from One Small Planet, Formed Joint Venture Magdalena Biosciences to Develop Botanical Pharmaceutical Drug Candidates for Mental Health Illnesses:** The focus of U.S.-based joint venture Magdalena Biosciences, Inc. is to develop novel, natural prescription medicines derived from plants for mental health indications including attention-deficit/hyperactivity disorder (ADHD) in adults. The goal of the collaboration is to extend the botanical drug development capabilities of Jaguar and Filament in order to develop pharmaceutical-grade, standardized drug candidates for mental health disorders, and to partner with a potential future licensee to develop and commercialize these novel plant-based drugs.
- **September 2022: The Company announced activation by the FDA of IND application for NP-300, a novel drug candidate for the symptomatic relief and treatment of diarrhea from cholera and other pathogens:** The Company plans to conduct a phase 1 trial in healthy volunteers, and 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. The Company is 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.
- **Other investigator-initiated trials of crofelemer:**

- Currently ongoing: Study of 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
- Currently ongoing: Study of 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

COMPANY FINANCIAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2022:

"As previously announced, the transition we completed in January 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," Ian Wendt, Jaguar's Chief Commercial Officer, stated. "I am very pleased to report that we significantly outperformed the industry gross-to-net average in the fourth quarter of 2022 - as we did in the four 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. While Mytesi net revenue increased by 3.0% in the fourth quarter of 2022 over the third quarter of 2022, Mytesi total prescription volume decreased slightly by approximately 2% in this time period. This transition to specialty pharmacy distribution also 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:** Mytesi total prescription volume was approximately 5,947 in the year 2022. Due to the transition to a limited distribution specialty pharmacy model in 2022, the Company cannot accurately compare prescription volume from 2021 to 2022, as there are significant differences in reporting methodology from these different distribution models. In the future, the Company will be able to accurately reflect growth in prescription volume using 2022 as the new baseline. Mytesi total prescription volume decreased slightly by approximately 2% in the fourth quarter of 2022 over the third 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.
- **Net Mytesi Revenue:** Net revenue for Mytesi was approximately \$11.7 million in the year 2022, representing an increase of 174.8% over Mytesi net revenue in the year 2021, which totaled approximately \$4.3 million. Mytesi net revenue was approximately \$3.2 million in the fourth quarter of 2022, representing an increase of 3.0% over Mytesi net revenue in the third quarter of 2022, which totaled approximately \$3.1 million, and an increase of approximately 55.8% over Mytesi net revenue in the fourth quarter of 2021, which totaled approximately \$2.1 million.

The transition to a limited distribution network of specialty pharmacies, which was completed in January 2022, 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.

- **Net Canalevia®-CA1 Revenue:** Net revenue for the Company's other crofelemer prescription product, Canalevia-CA1, which became commercially available in April 2022, was approximately \$167 thousand in 2022. Canalevia-CA1 net revenue was approximately \$24 thousand in the fourth quarter of 2022, representing an increase of 100% over Canalevia-CA1 net revenue in the third quarter of 2022, which totaled approximately \$12 thousand.
- **Neonorm™:** Revenues for the non-prescription Neonorm products were minimal for the fourth quarters of 2022 and 2021, in accordance with the Company's primary focus on human health and prescription products.

Financial Highlights (in thousands)	Year Ended			
	December 31,		\$ change	% change
(in thousands, except per share amounts)	2022	2021		
Net product revenue	\$ 11,956	\$ 4,335	7,621	175.8%
Loss from operations	\$ (34,415)	\$ (40,708)	6,293	-15.5%
Net loss	\$ (48,395)	\$ (52,600)	4,205	-8.0%
Net loss per share, basic and diluted	\$ (36.18)	\$ (88.22)	52	-59.0%

- **Cost of Product Revenue:** Total cost of product revenue for the year 2022 was \$2.0 million compared to \$2.3 million for the year 2021, representing a \$0.3 million decrease year over year largely due to the reduction in distribution fees and decreased labor allocation in manufacturing.
- **Research and Development:** The R&D expense increased by \$2.6 million, from \$15.1 million for the year 2021 to \$17.7

million during the year 2022 largely due to increased clinical trial activities related to phase 3 CTD and other indications.

- **Sales and Marketing:** The Sales and Marketing expense decreased slightly by \$56 thousand from \$8.9 million for the year 2021 to about the same in 2022. Direct marketing fees and expenses increased to expand market access to Mytesi through the Specialty Pharmacy channels but this was offset by the decrease in headcount.
- **General and Administrative:** The G&A expense increased by \$0.8 million, from \$17.1 million for the year 2021 to \$17.9 during the same quarter in 2022. The increase in expenses was largely due to an aggregate increase of \$3.3 million in personnel and related benefits, public company expenses, rent, travel, and other expenses, offset by an aggregate decrease of \$2.5 million in stock-based compensation, legal fees, consulting, and audit fees.
- **Loss from Operations:** Loss from operations decreased by \$6.3 million, from \$40.7 million in the year 2021 to \$34.4 million in 2022 largely due to the aggregate improvement in net revenue of \$7.6 million, decreased cost of sales and marketing expenses of \$0.4 million, and warrant inducement expenses of \$1.6 million in 2021 and none recorded in 2022. These were offset by the aggregate increase in R&D and G&A expenses of \$3.3 million.
- **Net Loss:** Net loss attributable to common shareholders decreased by approximately \$5.1 million, from \$52.6 million in the year 2021 to \$47.5 million in 2022. In addition to the loss from operations:
 - Interest expense increased by \$4.3 million from \$8.4 million in the year 2021 to \$12.7 million in 2022 primarily due to additional interest expense incurred on royalty interest agreements primarily as result of the change in the timing of payments due to exchanges and a new royalty interest purchase agreement.
 - The loss on extinguishment of debt increased \$1.4 million from \$0.8 million for the year 2021 to \$2.2 million in 2022 due to the extinguishment loss from the exchange of the outstanding balance of a royalty agreement for shares of the Company's common stock.
 - Change in fair value of financial instrument and hybrid instrument designated at Fair Value Option ("FVO") decreased \$1.9 million from a loss of approximately \$2.0 million in the year 2021 to a loss of about \$21,000 for the year 2022 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.
 - Other income (expenses) increased \$1.7 million from approximately \$0.8 million other expense for the year 2021 to approximately \$1.0 million other income in 2022 due to write-off of extinguished liabilities as a result of legal release and reversal of long outstanding accruals with reasonable uncertainty to not be incurred.
- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the year 2022 and the year 2021 were a net loss of \$28.1 million and net loss of \$37.5 million, respectively.

(in thousands)	Year Ended	
	December 31,	
	2022	2021
Net loss	\$ (48,395)	\$ (52,595)
Adjustments:		
Interest expense	12,723	8,421
Property and equipment depreciation	171	40
Amortization of intangible assets	1,687	1,687
Stock based Compensation	3,318	3,974
Warrant Inducement Expense	-	172
Non-GAAP EBITDA	(30,496)	(38,301)
Loss on extinguishment of debt	2,187	753
Non-GAAP Recurring EBITDA	<u>\$ (28,309)</u>	<u>\$ (37,548)</u>

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, March 27, 2023, at 8:00 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 Crofelemer

Crofelemer is the only oral FDA approved drug under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals, Jaguar Health's wholly owned U.S. subsidiary, has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for Indigenous communities.

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, 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. For more information about Napo Therapeutics, visit napotherapeutics.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's expectation that patient enrollment in the OnTarget trial will complete in Q2 2023, Jaguar's expectation that the OnTarget trial will provide evidence that diarrhea associated with targeted cancer therapies is chronic, not acute, and impacts the patient's ability to remain on their cancer therapy regimens at proven doses for better outcomes, the Company's expectation that crofelemer's current approval for a chronic use in HIV/AIDS patients provides a potential opportunity for a paradigm shift for prophylaxis of CTD compared to the management of severe chronic diarrhea with constipating agents such as antimotility drugs, the expectation that Jaguar and Napo Therapeutics will support investigator-initiated proof-of-concept (POC) studies of crofelemer in 2023 for SBS with intestinal failure and congenital diarrheal disorders, the Company's expectation that publications of data from these POC trials could support early patient access to crofelemer for SBS-IF or MVID through programs in Europe, potentially in 2024, the Company's expectation that it will submit an IND application in Q2 2023 to FDA for crofelemer for MVID, the Company's expectation that it will conduct a phase 1 trial of NP-300 in healthy volunteers, the Company's expectation that NP-300 will be developed under the FDA's Botanical Guidance, the Company's expectation that it will pursue a Tropical Disease Priority Review Voucher to develop NP-300, the Company's expectation that it will in the future be able to accurately reflect growth in Mylesi prescription volume using 2022 as the new baseline, and the Company's expectation that it will host an investor webcast on March 27, 2023. 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.

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accesswire.com

<https://www.accesswire.com/745825/Jaguar-Health-Reports-2022-Financial-Results--Prescription-Revenues-up-179-to-119-Million>