Jaguar Health Reports First Quarter 2024 Financial Results

May 14, 2024

The combined net Q1 2024 revenue of approximately $2.4 million for prescription and non-prescription products increased approximately 20% versus net Q1 2023 revenue of $2.0 million and increased approximately 4% versus net Q4 2023 revenue of $2.3 million

Top line results expected to be imminent for company's phase 3 OnTarget trial of crofelemer for preventative treatment of cancer therapy-related diarrhea

Jaguar planning to begin commercial launch in Q3 2024 for Gelclair®, the company's third prescription product

REMINDER: Jaguar to host investor webcast Tuesday, May 14th at 8:30 a.m. Eastern regarding Q1 2024 financials and company updates; Click here to register for webcast

SAN FRANCISCO, CA / ACCESSWIRE / May 14, 2024 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today reported consolidated first-quarter 2024 financial results and provided Company updates.

The combined net revenue for the Company's crofelemer prescription products, Mytesi® and Canalevia®-CA1, and the Company's non-prescription products was approximately $2.4 million in the first quarter of 2024, representing an increase of approximately 20% over the combined net revenue in the first quarter of 2023, which totaled approximately $2.0 million, and an increase of approximately 4% over the combined net revenue in the fourth quarter of 2023, which totaled approximately $2.3 million.

Lisa Conte, Jaguar's president and CEO, said, "Our paramount near-term clinical activity is our phase 3 pivotal **OnTarget** trial of crofelemer for the follow-on indication of the preventative treatment of cancer therapy-related diarrhea (CTD), an indication we also refer to as chemotherapy-induced overactive bowel (CIOB) - which includes symptoms such as unpredictable and/or chronic debilitating diarrhea and GI urgency. Top line results from this pivotal study are expected to be imminent."

As announced, Jaguar signed an exclusive 5-year in-license agreement in April 2024 for the FDA-approved oral mucositis prescription product, Gelclair, for the U.S. market. Jaguar is planning to begin the commercial launch in Q3 2024 for Gelclair.

"Gelclair is an FDA-approved prescription product and can be commercialized without any clinical development costs for Jaguar," added Conte. "We are expanding our footprint beyond HIV-related supportive care to include cancer-related supportive care, and the in-license of Gelclair is a first building block while we await the results from our pivotal Phase 3 OnTarget trial of crofelemer for CTD. We live in the age of targeted therapies, and thanks to these amazing drugs cancer patients are living longer - 5, 10, 20 years. Targeted therapies often lead to more severe side effects, however, and patients want to live, not just survive."

Jaguar, with strong leadership and participation from Jaguar family companies Napo Pharmaceuticals and Napo Therapeutics, is supporting investigator-initiated proof-of-concept studies of crofelemer for the rare disease indications of microvillus inclusion disease (MVID) and short bowel syndrome (SBS) with intestinal failure in the US, EU and Middle East/North Africa (MENA) regions, with results expected in 2024. In accordance with the guidelines of specific EU countries, published data from clinical investigations in such rare diseases could support early patient access to crofelemer for these debilitating conditions in those countries.

2024 FIRST QUARTER COMPANY FINANCIAL RESULTS:

Net Mytesi and Canalevia-CA1 Revenue: The combined net revenue for these two prescription products was approximately $2.34 million in the first quarter of 2024, representing an increase of approximately 20% over the combined net revenue in the first quarter of 2023, which totaled approximately $2.0 million, and an increase of approximately 2% over the combined net revenue in the fourth quarter of 2023, which totaled approximately $2.29 million.

Mytesi Prescription Volume: Mytesi prescription volume decreased in the first quarter of 2024 compared to the fourth quarter of 2023 by 7%, which occurs each year as commercial and Medicare insurance deductibles reset and result in higher copays for patients in Q1. Prescriptions decreased slightly by 2.5% in the first quarter of 2024 compared to the first quarter of 2023. 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.

Neonorm ™: Revenues for the non-prescription Neonorm products were minimal for the first quarters of 2024 and 2023.

Three Months Ended

Financial Highlights	March 31,			
(in thousands, except per share amounts)	2024	2023	$ change	% change
Net product revenue	$ 2,351	$ 1,972	379	20 %
Loss from operations	$ (8,215)	$ (9,845)	1,630	-17 %
Net loss attributable to common shareholders	$ (9,226)	$ (12,202)	2,976	-24 %
Net loss per share, basic and diluted	$ (0.06)	$ (2.39)	2	-97 %

Cost of Product Revenue: Total cost of product revenue increased by approximately $85,000, from $0.3 million for the quarter ended March 31, 2023 compared to $0.43 million for the quarter ended March 31, 2024.

Research and Development: The R&D expense decreased by $0.5 million, from $4.8 million for the quarter ended March 31, 2023 to $4.3 million during the same quarter in 2024, primarily due to the winding down of activities related to the phase 3 OnTarget clinical trial, regulatory activities for the trial, and the Company's initiatives for rare disease product development.

Sales and Marketing: The Sales and Marketing expense decreased by approximately $0.5 million, from $1.8 million for the quarter ended March 31, 2023 to $1.4 million during the same quarter in 2024. Direct marketing fees and expenses decreased due to continued savings associated with the utilization of a more cost-effective patient support services vendor, other Mytesi marketing initiatives, as well as decreased stock-based compensation, and commission expenses.

General and Administrative: The G&A expense decreased by $0.4 million, from $4.8 million for the quarter ended March 31, 2023, to $4.4 million during the same quarter in 2024, largely due to decreases in personnel and benefits, legal expenses, public company expenses, and other expenses. However, this decrease is offset by an increase in consulting, lease expenses, audit, tax and accounting services, and travel expenses.

Loss from Operations: Loss from operations decreased by $1.6 million, from $9.9 million in the quarter ended March 31, 2023 to $8.2 million during the same period in 2024.

Net Loss: Net loss attributable to common shareholders decreased by approximately $2.9 million, from $12.2 million in the quarter ended March 31, 2023 to $9.2 million in the same period in 2024. In addition to the loss from operations:

Interest expense decreased by $1.6 million from $0.6 million in the quarter ended March 31, 2024 to $2.2 million for the same period in 2023, primarily due to certain debt instruments being accounted for using the fair value option. The lower interest expense was offset with a higher loss on change in fair value of debt instruments.

Change in fair value of financial instrument and hybrid instrument designated at FVO increased by $1.6 million from a loss of $2.0 million in the three months ended March 31, 2024 to a loss of $0.4 million for the same period in 2023 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.

Gain on extinguishment of debt increased by $1.2 million three months ended March 31, 2024 to a gain of none for the same period in 2023.

Non-GAAP Recurring EBITDA: Non-GAAP recurring EBITDA for the first quarter of 2024 and the first quarter of 2023 were a net loss of $7.5 million and $9.0 million, respectively.

	Three Months Ending March 31,	
(in thousands)	2024	2023
	(unaudited)	
Net loss attributable to common shareholders:	$ (9,226)	$ (12,202)
Adjustments:		
Interest expense	611	2,181
Property and equipment depreciation	17	20
Amortization of intangible assets	484	484
Share-based compensation expense	581	480
Income taxes	-	-
Non-GAAP EBITDA	(7,533)	(9,037)
Non-GAAP Recurring EBITDA	$ (7,533)	$ (9,037)

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: Tuesday, May 14, 2024, 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 Crofelemer
Crofelemer is the only oral FDA-approved prescription 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, a Jaguar family company, 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 the Jaguar Health Family of Companies
Jaguar Health, Inc. (Jaguar) is a commercial stage pharmaceuticals company focused on developing novel proprietary prescription medicines sustainably derived from plants from rainforest areas for people and animals with gastrointestinal distress, specifically associated with overactive bowel, which includes symptoms such as chronic debilitating diarrhea, urgency, bowel incontinence, and cramping pain. Jaguar family company Napo Pharmaceuticals (Napo) focuses on developing innovative, patient-centric therapeutic solutions for essential supportive care and the management of neglected side effects across complicated disease states. Napo's goal is to redefine what is possible in supportive care, providing hope and improving outcomes for patients worldwide. Napo's crofelemer drug product candidate is the subject of the OnTarget study, a pivotal Phase 3 clinical trial for preventive treatment of chemotherapy-induced overactive bowel (CIOB) in adults with cancer on targeted therapy. Jaguar family company Napo Therapeutics is an Italian corporation Jaguar established in Milan, Italy in 2021 focused on expanding crofelemer access in Europe and specifically for orphan and/or rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp. that emerged from Jaguar's Entheogen Therapeutics Initiative (ETI), is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about:
Jaguar Health, visit https://jaguar.health

Napo Pharmaceuticals, visit www.napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Visit Jaguar on LinkedIn: https://www.linkedin.com/company/jaguar-health/

Visit Jaguar on X: https://twitter.com/Jaguar_Health

Visit Jaguar on Instagram: https://www.instagram.com/jaguarhealthcommunity/

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.

About Gelclair®

INDICATIONS
GELCLAIR® has a mechanical action indicated for the management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiation therapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. Also, indicated for diffuse aphthous ulcers.

IMPORTANT SAFETY INFORMATION
Do not use GELCLAIR if there is a known or suspected hypersensitivity to any of its ingredients.

No adverse effects have been reported in clinical trials, although postmarketing reports have included infrequent complaints of burning sensation in the mouth.

If GELCLAIR is swallowed accidentally, no adverse effects are anticipated.

If no improvement is seen within 7 days, a physician should be consulted.

You are encouraged to report negative side effects of prescription medical products to the FDA.

Visit www.fda.gov/safety/medwatch, call 1-855-273-0468 or fill-in the form at this link.

Please see full Prescribing Information at: https://gelclair.com/assets/Gelclair_PI_Decemeber_2021.pdf

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 Jaguar's expectation that it will host an investor webcast May 14, 2024, the Company's expectation that results from the OnTarget study are imminent, the Company's expectation that it will begin the commercial launch in Q3 2024 for Gelclair, the Company's expectation that results from investigator-initiated and IND proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure will be available in 2024, and the Company's expectation, that in accordance with the guidelines of specific EU countries, published data from clinical investigations of crofelemer in MVID and SBS could support early patient access to crofelemer for these conditions in those countries. 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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SOURCE: Jaguar Health, Inc.