Jaguar Health Reports Third Quarter 2023 Financial Results

November 14, 2023

Net revenue increased 5% in Q3 2023 versus Q2 2023

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

REMINDER: Jaguar to host investor webcast Tuesday, November 14th at 8:30 a.m. Eastern regarding Q3 2023 financials and company updates; Click here to register for webcast

SAN FRANCISCO, CA / ACCESSWIRE / November 14, 2023 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today reported consolidated third-quarter 2023 financial results and provided Company updates.

The combined net revenue for Mytesi® (crofelemer) and the Company's crofelemer prescription product for treatment of chemotherapy-induced diarrhea in dogs, Canalevia®-CA1 was $2.8 million in the third quarter of 2023, representing an increase of 5% compared to prescription product net revenue in the second quarter of 2023, which totaled approximately $2.7 million, and a decrease of approximately 11% over prescription product net revenue in the third quarter of 2022, which totaled approximately $3.1 million. The loss from operations decreased by $1.1 million, from $9.9 million in the quarter ended September 30, 2022 to $8.8 million during the same period in 2023.

Lisa Conte, Jaguar's president and CEO, said, "Our paramount near-term clinical activity is our Phase 3 pivotal **OnTarget** trial of Mytesi for the follow-on indication of the preventative treatment of cancer therapy-related diarrhea, 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 before Thanksgiving. With success, our goal is to achieve approval for this expanded indication of Mytesi in 2024."

More than 1.9 million people are expected to be diagnosed with cancer in 2023 in the U.S., according to the American Cancer Society. A third-party study authored by Dr. Pablo Okhuysen, who is also the national principal investigator for the Company's OnTarget study, indicates that patients with cancer therapy-related diarrhea are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without cancer therapy-related diarrhea. A third-party study authored by Dr. Eric Roeland, a member of Napo's scientific advisory board, shows that it costs about three times as much to take care of a cancer patient with diarrhea compared to a patient without diarrhea, due to increased pharmacy and office visit costs, hospitalization, and other heightened expenses.

Jaguar is supporting investigator-initiated and investigator IND 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 from the end of 2023 and into 2024. In accordance with the guidelines of specific EU countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID for these debilitating conditions.

MVID, an ultra-rare pediatric congenital diarrheal disorder (CDD), and SBS with intestinal failure are Jaguar's two prioritized rare disease investigative indications for a novel formulation of crofelemer. MVID is a catastrophic medical situation for pediatric patients, and there are currently no approved drug treatments. The Company's Investigational New Drug application for crofelemer for the treatment of MVID was activated by the U.S. Food and Drug Administration (FDA) August 7, 2023.

Crofelemer has been granted Orphan Drug Designation (ODD) by the FDA and the European Medicines Agency (EMA) for both MVID and SBS with intestinal failure. The ODD programs in the U.S. and European Union qualify sponsors to receive potential incentives to develop therapies for the diagnosis, prevention, or treatment of rare diseases or conditions.

2023 THIRD QUARTER COMPANY FINANCIAL RESULTS:

- **Net Mytesi and Canalevia-CA1 Revenue:** The combined prescription net revenue for Mytesi and Canalevia-CA1 was $2.8 million in the third quarter of 2023, representing an increase of 5% compared to the combined net revenue in the second quarter of 2023, which totaled approximately $2.7 million, and a decrease of approximately 11% over the combined net revenue in the third quarter of 2022, which totaled approximately $3.1 million.
- **Mytesi Prescription Volume:** Mytesi prescription volume remained unchanged in the third quarter of 2023 compared to the second quarter of 2023, and decreased approximately 7.5% in the third quarter of 2023 compared to 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.

- **Neonorm ™:** Revenues for the non-prescription Neonorm products for calves and foals and Jaguar's Animal Health business unit were minimal for the third quarters of 2023 and 2022, in accordance with the Company's primary focus on human health and prescription products.

Financial Highlights	Three Months Ended September 30,			
(in thousands, except per share amounts)	2023	2022	$ change	% change
Net product revenue	$ 2,813	$ 3,150	(337)	-11 %
Loss from operations	$ (8,787)	$ (9,896)	1,109	-11 %
Net loss attributable to common stockholders	$ (7,778)	$ (12,520)	4,742	-38 %
Net loss per share, basic and diluted	$ (0.38)	$ (8.83)	8.45	-96 %

- **Cost of Product Revenue:** Total cost of product revenue decreased by approximately $99,000, from $613,000 for the quarter ended September 30, 2022 to $514,000 for the quarter ended September 30, 2023, as a consequence of sales volume.
- **Research and Development:** The R&D expense increased by $0.1 million, from $5.9 million for the quarter ended September 30, 2022 to $6.0 million during the same quarter in 2023 primarily due to activities related to the Phase 3 OnTarget clinical trial, regulatory activities for the trial and other initiatives.
- **Sales and Marketing:** The Sales and Marketing expense decreased by approximately $0.6 million, from $2.1 million for the quarter ended September 30, 2022 to $1.5 million during the same quarter in 2023. Direct marketing fees and expenses decreased due to 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 $0.9 million, from $4.4 million for the quarter ended September 30, 2022, to $3.5 million during the same quarter in 2023 largely due to decreased public company expenses, stock-based compensation, and legal services.
- **Loss from Operations:** Loss from operations decreased by $1.1 million, from $9.9 million in the quarter ended September 30, 2022 to $8.8 million during the same period in 2023.
- **Net Loss:** Net loss attributable to common shareholders decreased by approximately $4.7 million, from $12.6 million in the quarter ended September 30, 2022 to $7.8 million in the same period in 2023. In addition to the loss from operations:
  - Interest expense decreased by $2.2 million from $2.7 million in the quarter ended September 30, 2022 to $0.5 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 decreased by $2.4 million from a gain of $176,000 in the three months ended September 30, 2022 to a loss of $2.2 million for the same period in 2023 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.
  - Other expenses decreased by about $88,000, from $158,000 for the quarter ended September 30, 2022 to $70,000 during the same period in 2023 largely due to foreign currency transactions.
- **Non-GAAP Recurring EBITDA:** Non-GAAP recurring EBITDA for the third quarter of 2023 and the third quarter of 2022 were a net loss of $6.2 million and $8.5 million, respectively.

(in thousands)	Three Months Ending September 30,	
	2023	2022
	(unaudited)	
Net loss attributable to common stockholders	$ (7,778)	$ (12,520)
Adjustments:		
Interest expense	500	2,731
Property and equipment depreciation	19	15
Amortization of intangible assets	484	483
Share-based compensation expense	529	745

Income taxes	-	-
Non-GAAP EBITDA	(6,246)	(8,546)
Non-GAAP Recurring EBITDA	$ (6,246)	$ (8,546)

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, November 14, 2023, 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 focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the OnTarget study, an ongoing 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.

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 on November 14, 2023, the Company's expectation that top line results from the OnTarget study will be available before Thanksgiving 2023, the Company's goal of achieving approval for Mytesi for cancer therapy-related diarrhea in 2024 the Company's expectation that data from proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure will be available before the end of 2023 and in 2024, and the Company's expectation that published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID. 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.