Jaguar Health Reports Second Quarter 2023 Financial Results

August 14, 2023

Net revenue increased 36% in Q2 2023 versus Q1 2023

Top line results expected late October 2023 for company's phase 3 OnTarget trial of crofelemer for preventative treatment of cancer therapy-related diarrhea

Jaguar is supporting investigator-initiated proof-of-concept studies of crofelemer for the rare disease indications of short bowel syndrome and microvillus inclusion disease in the EU and Middle East/North Africa regions, with results expected before the end of 2023 and in 2024

REMINDER: Jaguar to host investor webcast Monday, August 14th at 8:30 a.m. Eastern regarding Q2 2023 financials and company updates; Click here to register for webcast

SAN FRANCISCO, CA / ACCESSWIRE / August 14, 2023 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today reported consolidated second-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, which became commercially available in April 2022, was approximately $2.7 million in the second quarter of 2023, representing an increase of 36% compared to prescription product net revenue in the first quarter of 2023, which totaled approximately $2.0 million, and a decrease of approximately 8% over prescription product net revenue in the second quarter of 2022, which totaled approximately $2.9 million. The loss from operations increased by $1.6 million, from $6.4 million in the quarter ended June 30, 2022 to $8.1 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 chemotherapy-induced overactive bowel (CIOB) - which includes symptoms such as chronic debilitating diarrhea, GI urgency, and GI incontinence. We have completed patient enrollment for OnTarget - a key step on our journey to making crofelemer available to treat the neglected comorbidity of CIOB - and top line results from this pivotal study are expected in late October 2023. With success, we expect to expand the indication of Mytesi in 2024."

Jaguar is supporting investigator-initiated and investigator IND proof-of-concept studies of crofelemer for 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 before the end of 2023 and in 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, potentially in 2024, 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 SECOND QUARTER COMPANY FINANCIAL RESULTS:

- **Net Mytesi Revenue:** Net revenue for Mytesi was approximately $2.6 million in the second quarter of 2023, representing an increase of 36% compared to Mytesi net revenue in the first quarter of 2023, which totaled approximately $2.0 million, and a decrease of approximately 7.0% over Mytesi net revenue in the second quarter of 2022, which totaled approximately $2.8 million.
- **Mytesi Prescription Volume:** Mytesi prescription volume increased approximately 4.0% in the second quarter of 2023 compared to the first quarter of 2023, and decreased approximately 4.5% in the second quarter of 2023 compared to the second 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 Canalevia-CA1 Revenue:** Net revenue for the Company's crofelemer prescription product for treatment of

chemotherapy-induced diarrhea in dogs, Canalevia-CA1, which became commercially available in April 2022, was approximately $39,100 in the second quarter of 2023, representing an increase of 40% over Canalevia-CA1 net revenue in the first quarter of 2023, which totaled approximately $27,820.

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

Financial Highlights	Three Months Ended June 30,			
(in thousands, except per share amounts)	2023	2022	$ change	% change
Net product revenue	$ 2,676	$ 2,921	(245)	-8 %
Loss from operations	$ (8,102)	$ (6,479)	(1,623)	25 %
Net loss attributable to shareholders	$ (12,150)	$ (9,367)	(2,783)	30 %
Net loss per share, basic	$ (0.69)	$ (0.12)	(0.57)	475 %
Net loss per share, diluted	$ (0.42)	$ (0.12)	(0.30)	250 %

- **Cost of Product Revenue:** Total cost of product revenue increased by approximately $35,000, from $456,000 for the quarter ended June 30, 2022 to $491,000 for the quarter ended June 30, 2023. This was due to increased direct labor from quality assurance personnel in Q2 2023 compared to Q2 2022.
- **Research and Development:** The R&D expense increased by $1.8 million, from $2.5 million for the quarter ended June 30, 2022 to $4.3 million during the same quarter in 2023 primarily due to an increase related to the Phase 3 clinical trial and regulatory initiatives for OnTarget trial and other initiatives.
- **Sales and Marketing:** The Sales and Marketing expense decreased by approximately $0.5 million, from $2.1 million for the quarter ended June 30, 2022 to $1.6 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 increased by $0.1 million, from $4.3 million for the quarter ended June 30, 2022, to $4.4 million during the same quarter in 2023. The increase of $0.1 million was largely due to increased travel expenses as travel restrictions from the pandemic have abated.
- **Loss from Operations:** Loss from operations increased by $1.6 million, from $6.5 million in the quarter ended June 30, 2022 to $8.1 million during the same period in 2023.
- **Net Loss:** Net loss attributable to common shareholders increased by approximately $2.8 million, from $9.4 million in the quarter ended June 30, 2022 to $12.2 million in the same period in 2023. In addition to the loss from operations:
- Interest expense increased by $1.0 million from $2.5 million in the quarter ended June 30, 2022 to $3.5 million for the same period in 2023 primarily due to interest from the royalty and note agreements.
- Change in fair value of financial instrument and hybrid instrument designated at Fair Value Option ("FVO") decreased $1.5 million from a gain of approximately $0.8 million for the three months ended June 30, 2022 to a loss of about $0.7 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 $1.1 million from the quarter ended June 30, 2022 to the same period in 2023 largely due to foreign currency transactions.
- **Non-GAAP Recurring EBITDA:** Non-GAAP recurring EBITDA for the second quarter of 2023 and the second quarter of 2022 were a net loss of $7.8 million and $5.3 million, respectively.

(in thousands)	Three Months Ending June 30, 2023	2022
	(unaudited)	
Net loss attributable to common shareholders	$ (12,150)	$ (9,367)
Adjustments:		
Interest expense	3,453	2,536
Property and equipment depreciation	20	10

Amortization of intangible assets	484	422
Share-based compensation expense	529	1,113
Income taxes	-	-
Non-GAAP EBITDA	(7,665)	(5,286)
Impairment of indefinite-lived intangible assets		
Loss on extinguishment of debt	-	-
Non-GAAP Recurring EBITDA	$ (7,665)	$ (5,286)

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, August 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. Jaguar family company Napo Pharmaceuticals 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 GI distress, specifically overactive bowel, which includes symptoms such as chronic debilitating diarrhea, GI urgency, and GI incontinence. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the OnTarget study, an ongoing pivotal Phase 3 clinical trial for preventative 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 rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp., is focused on developing novel prescription medicines derived from plants for mental health indications.

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. For more information about Magdalena Biosciences, visit magdalenabiosciences.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 Jaguar's expectation that it will host an investor webcast on August 14, 2023, the Company's expectation that top line results from the OnTarget study will be available in late October 2023, the Company's expectation that, with success, the indication of Mytesi will be expanded 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 Company's expectation that published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID, potentially in 2024. 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.