Jaguar Health, Inc. Reports 2021 Second Quarter Financial Results

August 13, 2021

Second quarter 2021 Mytesi® net and gross sales were approximately $0.4 million and approximately $4.9 million

Company transitioning to primarily selling Mytesi directly through selected specialty pharmacies as part of Company's market access strategy

Company to host investor webcast Friday, August 13th at 8:00 a.m. Eastern regarding second quarter 2021 financials & business updates; Webcast registration link appears below

SAN FRANCISCO, CA / ACCESSWIRE / August 13, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today reported consolidated second quarter 2021 financial results.

2021 Second Quarter Company Financial Results:

- **Mytesi Prescription Volume:** Mytesi prescription volume, the metric the Company believes to be the best indicator of patient demand, increased 4.3% in the second quarter of 2021 over the first quarter of 2021, and new Mytesi prescriptions increased 2.8% during the same time period. Mytesi prescription volume declined 9% in the second quarter of 2021 over the second quarter of 2020. The Company believes COVID-19 pandemic-necessitated travel restrictions played a role in this decline, with the pandemic resulting in fewer patient visits to health care providers, fewer opportunities to diagnose new Mytesi patients, and fewer prescription refills. Prescription volume, an indicator of patient demand, can differ from invoiced sales volume, which reflects, among other factors, varying buying patterns among wholesalers and specialty pharmacies as they manage their inventory levels.
- **Mytesi Net Product Revenue:** Mytesi net revenue during the second quarter of 2021 was approximately $0.4 million and $3.2 million in the second quarter of 2020, a decrease of $2.8 million quarter over quarter. A key component of the Company's market access strategy - an initiative intended to help remove access barriers for people living with HIV to start and stay on Mytesi - involves the Company's plan to transition a substantial amount of Mytesi volume to selected specialty pharmacies by the end of 2021. The ongoing process of transitioning to primarily selling Mytesi directly through specialty pharmacies (rather than to wholesalers that resell the product to retail pharmacies) is expected to significantly decrease distribution costs and have a positive impact on net product revenue on a moving forward basis. In the second quarter of 2021, sales discounts and rebates from various government programs included an approximately $0.8 million true-up charge from the state of California related to several quarters. The Company believes this true-up charge is non-recurring and due in part to the impact of the COVID-19 pandemic on state administrative functions.
- **Mytesi Gross Product Revenue (Non-GAAP):** Mytesi gross revenue during the second quarter of 2021 was approximately $4.9 million, and $6.3 million in the second quarter of 2020, representing a decrease of approximately $1.4 million quarter over quarter. This decrease is largely due to the limited-term effects of the Company's ongoing efforts to transition to primarily selling Mytesi directly through select specialty pharmacies rather than to wholesalers that resell the product to retail pharmacies, because, over time, wholesalers will draw down on, and eventually deplete, their Mytesi inventories - supplies that largely contain product that wholesalers purchased prior to the second quarter of 2021.
- **Mytesi Volume Through Specialty Pharmacies:** Sales volume distributed through the recently established, and expanding, pool of third-party specialty pharmacies through which the Company distributes Mytesi was approximately 17% of total sales volume in the second quarter of 2021 compared to approximately 14% in the first quarter of 2021. 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.
- **Neonorm ™:** Neonorm product revenues were minimal for the second quarters of 2021 and 2020, in accordance with the Company's primary focus on human health products.

Financial Highlights (in thousands)	Three Months Ended June 30,			
Gross product sales	2021	2020	$ change	% change
Mytesi	$ 4,922	$ 6,288	$ (1,366)	-22%
Neonorm	6	14	(8)	-57%
Total gross product sales	4,928	6,302	(1,374)	-22%
Medicare rebates	(1,354)	(592)	(762)	129%
Sales discounts	(2,600)	(1,828)	(772)	42%
Sales returns	(48)	(78)	30	-38%
Wholesaler fee	(541)	(637)	96	-15%
Net product sales	$ 385	$ 3,167	$ (2,782)	-88%

Financial Highlights	Three Months Ended June 30,			
(in thousands, except per share amounts)	2021	2020	$ change	% change
Net product revenue	$ 385	$ 3,167	(2,782)	-88%
Loss from operations	$ (11,580)	$ (8,451)	(3,129)	37%
Net loss	$ (14,081)	$ (10,597)	(3,484)	33%
Net loss per share, basic and diluted	$ (0.10)	$ (0.44)	0.46	-82%

- **Cost of Product Revenue:** Total cost of product revenue for the quarter ended June 30, 2021 was $0.7 million compared to $1.0 million for the quarter ended June 30, 2020, representing a $0.3 million decrease over the second quarter of 2020. This decrease in cost of product revenue was largely due to the decrease in sales.
- **Research and Development:** The R&D expense was $3.9 million for the second quarter of 2021 compared to $1.4 million for the second quarter of 2020, an increase of $2.5 million quarter over quarter. Clinical and contract manufacturing increased $1.0 million in the second quarter of 2021 compared to the same period in 2020 due to increased clinical trial activities related to cancer therapy-related diarrhea (CTD) and other planned indications. In addition, personnel and related benefits increased to $0.9 million in the second quarter of 2021 compared to the same period in 2021 due to compensation and additional headcount. Stock-based compensation expense increased $0.2 million in the second quarter of 2021 compared to the second quarter of 2020 due to option grants and restricted stock units granted in the second quarter of 2021. Other expenses consisting of consulting, formulation and regulatory fees increased $0.4 million in the second quarter of 2021 compared to the same period in 2020, which is consistent with the increased activity in development of multiple potential follow-on indications for crofelemer.
- **Sales and Marketing:** The Sales and Marketing expense was $2.2 million for the second quarter of 2021 compared to $1.7 million for the second quarter of 2021, an increase of $0.5 million quarter over quarter. The increase in Sales and Marketing expense was largely due to an increase in costs of initiatives associated with the Company's Mytesi market access strategy.
- **General and Administrative:** The G&A expense was $5.1 million for the second quarter of 2021 compared to $3.8 million for the second quarter of 2020, an increase of $1.3 million quarter over quarter. The increase in G&A expenses was largely due to an increase of $1.0 million in public company expense incurred related to the activities of the annual shareholders meeting.
- **Inducement Expenses on Warrants:** The inducement expense was $0.2 million for the second quarter of 2021 and $3.7 million for the same period of 2020. In April 2021, in consideration for a March 2020 ELOC amendment, the Company issued a common stock purchase warrant exercisable for 100,000 shares of common stock with an exercise price per share of $1.87. In May 2020, inducement expense was associated with a 2020 modification of the exercise price of certain warrants and the issuance of cashless warrants associated with their exercise. No cashless warrants remain outstanding as of June 30, 2021.
- **Loss from Operations:** For the second quarter of 2021, the loss from operations was $11.6 million compared to a loss of $8.5 million in the second quarter of 2020, the loss increased $3.1 million, quarter over quarter.
- **Net Loss:** For the second quarter of 2021, the net loss was $14.1 million, compared to a net loss of $9.2 million in the second quarter of 2020, an increase of $4.9 million quarter over quarter. In addition to the loss from operations:

- Interest expense increased by $1.5 million from $0.5 million in the three months ended June 30, 2020 to $2.0 million for the same period in 2021 primarily due to the royalty interest agreements.
- Change in fair value of financial instruments and hybrid instruments designated at fair value option ("FVO") losses increased $0.1 million from a loss of $0.4 million in the three months ended June 30, 2020 to a loss of $0.5 million for the same period in 2021 designated at FVO.
- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the second quarter of 2021 and the second quarter of 2020 was a net loss of $10.6 million and a net loss of $7.6 million, respectively. Excluding the loss on extinguishment of debt, and other non-recurring expenses, non-GAAP recurring EBITDA was a loss of approximately $10.6 million and a loss of approximately $3.9 million for the second quarter of 2021 and the second quarter of 2020, respectively.

(in thousands)	Three Months Ending June 30, 2021	2020
	(unaudited)	
Net loss	$ (14,081)	(9,238)
Adjustments:		
Interest expense	2,009	479
Property and equipment depreciation	8	11
Amortization of intangible assets	422	422
Share-based compensation expense	1,032	749
Income taxes	-	-
Non-GAAP EBITDA	(10,610)	(7,577)
Impairment of indefinite-lived intangible assets	-	-
Loss on extinguishment of debt	-	-
Series 3 warrants inducement expense	-	-
Series B convertible preferred stock inducement expense	-	3,696
Non-GAAP Recurring EBITDA	$ (10,610)	$ (3,881)

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 wholesalers with Jaguar's third-party logistics warehouse, less allowances for rebates, chargebacks, 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. The Company believes that the presentation of gross sales provides a closer to real-time useful measure of our operating performance. 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 Medicare, ADAP 340B chargebacks, returns, and wholesale distribution fees 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: Friday, August 13, 2021, 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 Jaguar Health, Inc., Napo Pharmaceuticals, Inc. & Napo EU S.p.A.

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, specifically chronic, debilitating diarrhea. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy and the only oral plant-based prescription medicine approved under FDA Botanical Guidance. Napo EU S.p.A., the wholly owned Italian subsidiary of Napo Pharmaceuticals, focuses on expanding crofelemer access in Europe and is the named target of Dragon SPAC S.p.A., which closed its financing in July 2021 for gross proceeds of approximately 8,830,000 euros.

For more information about Jaguar, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.com. For more information about Napo EU, visit www.napoeu.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.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Jaguar will host an investor webcast on August 13, 2021, the Company's expectation that the ongoing process of transitioning to primarily selling Mytesi directly through specialty pharmacies will decrease distribution costs and have a positive impact on net product revenue on a moving forward basis, and the Company's belief that the $0.8 million true-up charge in the second quarter of 2021 is non-recurring. 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.

Contact:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health
Jaguar-JAGX

SOURCE: Jaguar Health, Inc.