UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **May 17, 2021**

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36714**	**46-2956775**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Pine Street, Suite 400 **San Francisco, California**	**94104**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(415) 371-8300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 Per Share	JAGX	The Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Conditions.

On May 17, 2021, Jaguar Health, Inc. (the "Company") issued a press release announcing first quarter 2021 results. A copy of this press release is furnished as Exhibit 99.1 to this report.

The information in Item 2.02 and the press release furnished as Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, or incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 17, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

JAGUAR HEALTH, INC.

By: /s/ Lisa A. Conte
Name: Lisa A. Conte
Title: President and Chief Executive Officer

Date: May 17, 2021

Exhibit 99.1

Jaguar Health, Inc. Reports 2021 First Quarter Financial Results

First quarter 2021 Mytesi gross sales and net sales were approximately $4.6 million and approximately $1.2 million, increases of 250% and 43%, respectively

Company to host investor webcast Monday, May 17th at 8:30 a.m. Eastern regarding first quarter 2021 financials & business updates

SAN FRANCISCO, CA / May 17, 2021 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today reported consolidated first quarter 2021 financial results.

2021 First Quarter Company Financial Results:

- **Mytesi® Net Product Revenue:** Mytesi net sales during the first quarter of 2021 were approximately $1.2 million and $0.9 million in the first quarter of 2020. This first quarter 2021 result represents an increase of approximately 43% of the same period in 2020, or $0.3 million quarter over quarter. The increase in sales of Mytesi is due to the combined effect of the price adjustment in Wholesaler Acquisition Cost ("WAC") implemented by the Company in April 2020 and a 6% increase in the number of bottles sold in the first quarter of 2021 over the same period in 2020. The increase in sales discounts and rebates is due to the WAC price adjustment which caused higher government rebates from Medicaid and public health services programs.

- **Mytesi Gross Product Revenue (Non-GAAP):** Mytesi gross sales during the first quarter of 2021 were approximately $4.6 million and $1.3 million in the first quarter of 2020. This first quarter 2021 result represents an increase of approximately 250% of the same period in 2020, or approximatively $3.3 million quarter over quarter. The increase in sales of Mytesi is due to the combined effect of the price adjustment in WAC implemented in April 2020 and a 6% increase in the number of bottles sold in the first quarter of 2021 over the same period in 2020.

- **Total Mytesi Prescription Volume:** Total Mytesi unit sales volume increased by approximately 6% in the first quarter of 2021 over the first quarter of 2020. U.S. prescriptions for Mytesi decreased slightly by 2% in the first quarter of 2021 as compared to the first quarter of 2020. Prescription volume is the best estimate of patient demand while unit sales volume may reflect varying buying patterns among wholesalers as they manage their inventory levels. This can result in differences between these two metrics. The Company believes the COVID-19 pandemic played a role in the slight decline in prescription volume, with the pandemic resulting in fewer patient visits to their health care providers and subsequently fewer opportunities to diagnose new Mytesi patients. This is consistent with overall pharmaceutical industry performance that showed a negative growth in total U.S. prescriptions for all drugs and decreases in new to brand prescriptions. Additionally, pandemic-necessitated travel restrictions negatively impacted the ability of the Company's sales personnel to promote Mytesi to physicians in the first quarter of 2021.

- **Neonorm™:** In the first quarter of 2021, the Company's animal product commercialization efforts were intentionally minimal, and Jaguar's animal-related sales were essentially the same as the first quarter of 2020.

Financial Highlights (in thousands)	Three Months Ended March 31,			
Gross product sales	**2021**	**2020**	$ change	% change
Mytesi	$ 4,558	$ 1,304	$ 3,254	250%
Neonorm	33	34	(1)	-3%
Total gross product sales	4,591	1,338	3,253	243%
Medicare rebates	(1,097)	(68)	(1,029)	1513%
Sales discounts	(1,732)	(261)	(1,471)	564%
Sales returns	(20)	(18)	(2)	11%
Wholesaler fee	(501)	(122)	(379)	311%
Net product sales	$ 1,241	$ 869	$ 372	43%

Financial Highlights	Three Months Ended March 31,			
(in thousands, except per share amounts)	**2021**	**2020**	$ change	% change
Net product revenue	$ 1,241	$ 869	372	43%
Loss from operations	$ (8,766)	$ (7,654)	(1,112)	15%
Net loss	$ (12,009)	$ (7,936)	(4,073)	51%
Net loss per share, basic and diluted	$ (0.10)	$ (0.56)	0.46	-82%

- **Cost of Product Revenue:** Total cost of product revenue for the quarter ended March 31, 2021 was $0.6 million (47% of net revenue) compared to $0.7 million (78% of net revenue) for the quarter ended March 31, 2020. The first quarter 2021 represents a 14%, or $0.1 million, decrease over the same period in 2020. The decrease in cost of product revenue was largely due to a non-recurring write-off of non-conforming inventory in the first quarter of 2020.

- **Research and Development:** The R&D expense was $2.4 million for the first quarter of 2021 compared to $1.6 million for the first quarter of 2020, a $0.8 million increase quarter over quarter, due primarily to increased activity in development of multiple potential crofelemer follow-on indications largely from the start-up of the phase 3 cancer therapy-related diarrhea clinical trial for Mytesi.

- **Sales and Marketing:** The Sales and Marketing expense was $2.1 million for the first quarter of 2021 compared to $1.5 million for the first quarter of 2021, an increase of 46%, or $0.7 million, quarter over quarter. The increase in Sales and Marketing expense was due to an increase of patient access programs and Mytesi marketing initiatives of $0.5 million. Other expense also increased by $0.1 million due to additional marketing consultants.

- **General and Administrative:** The G&A expense was $3.4 million for the first quarter of 2021 compared to $3.1 million for the first quarter of 2020, an increase of 8%, or $0.3 million, quarter over quarter. The increase in G&A expenses was largely due to an increase in audit, tax, and accounting services of $0.5 million attributable to the increased audit fees related to complex debt and equity transactions. In addition, personnel and related benefits increased by $0.1 million due to additional resources. Moreover, D&O insurance premiums increased by $0.2 million. This is offset by decreases in legal expense of $0.3 million, decrease in rent expense of $0.2 million, and third-party consulting of $0.1 million.

- **Inducement Expense on Warrant Exercise and Preferred Stock Amendment Agreement:** The inducement expense was $1.5 million for the first quarter of 2021 compared to $1.6 million for the first quarter of 2020, a decrease of 11%, or $ 0.2 million, quarter over quarter. In March 2020 and in May 2020, there was an inducement to reduce the conversion price of the Series B Convertible Preferred Stock and under the Modification of the 2019 Bridge Warrants, there was an inducement offer to issue Series 3 Warrants in a cashless exercise as an inducement to exercise the Bridge Warrants, respectively. The modification of the conversion price was qualitatively considered an extinguishment and the Company recorded an expense of $1.6 million and derecognized the Series B Convertible Preferred shares in the first quarter of 2020. The exercise and inducement activity in Q1, 2021 resulted in an expense of $1.5 million, as compared to the exercise and inducement activity in Q1, 2020 of $1.6 million. As of March 31, 2021, all Series 3 Warrants associated with the May 2020 Modification of the 2019 Bridge Warrants have been issued in a cashless exercise.

- **Loss from Operations:** For the first quarter of 2021, the loss from operations was $8.8 million compared to a loss of $7.7 million in the first quarter of 2020, a loss increase of 15%, or $1.1 million, quarter over quarter.

- **Net Loss:** For the first quarter of 2021, the net loss was $12.0 million, compared to a net loss of $7.9 million in the first quarter of 2020, an increase of 51.3%, or $4.1 million, quarter over quarter. In addition to the loss from operations:

    - Interest expense increased by $1.7 million from $199,000 in the three months ended March 31, 2020 to $1.9 million for the same period in 2021 primarily due to interest expense incurred on royalty interest agreements and Exchange Note 2.
    - Change in fair value of financial instrument and hybrid instruments designated at fair value option (“FVO”) losses increased $598,000 from a loss of $1,000 in the three months ended March 31, 2020 to a loss of $599,000 for the same period in 2021 designated at FVO.

- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the first quarter of 2021 and the first quarter of 2020 was a net loss of $9.0 million and a net loss of $6.5 million, respectively. Excluding the loss on extinguishment of debt, and other non-recurring expenses, non-GAAP Recurring EBITDA was a loss of approximately $6.8 million and a loss of approximately $4.9 million for the first quarter of 2021 and the first quarter of 2020, respectively.

	Month Ending March 31,	
(in thousands)	**2021**	**2020**
	(unaudited)	
Net loss	$ (12,009)	(7,936)
Adjustments:		
Interest expense	1,901	199
Property and equipment depreciation	9	10
Amortization of intangible assets	422	422
Share-based compensation expense	634	760
Income taxes	-	-
Non-GAAP EBITDA	(9,043)	(6,545)
Impairment of indefinite-lived intangible assets	-	
Loss on extinguishment of debt	753	-
Series 3 warrants inducement expense	1,462	-
Series B convertible preferred stock inducement expense	-	1,647
Non-GAAP Recurring EBITDA	$ (6,828)	$ (4,898)

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. 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: Monday, May 17, 2021, at 8:30 AM Eastern Time
Participant Registration & Access Link: **Click Here**

Replay Instructions for Webcast
Dial-in (US Toll Free): 844-512-2921
Dial-in (International): 412-317-6671
Replay Pin Number: 5530970
Replay of the webcast on the investor relations section of Jaguar's website (click here)

About Jaguar Health, Inc. and Napo Pharmaceuticals, Inc.

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.

For more information about Jaguar, please visit https://jaguar.health. For more information about Napo, visit www.napopharma.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 May 17, 2021. 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.

Source: Jaguar Health, Inc.

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