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): **March 31, 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 March 31, 2021, Jaguar Health, Inc. (the "Company") issued a press release announcing 2020 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 March 31, 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: March 31, 2021

Jaguar Health Reports 2020 Financial Results and Business Updates

Mytesi® net sales and gross sales grew 64% and 148%, respectively, in 2020 compared to 2019

SAN FRANCISCO, CA / March 31, 2021 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today reported consolidated financial results for the year ended December 31, 2020.

2020 Company Financial Results:

- **Mytesi® Net Product Revenue:** 2020 Mytesi net sales were approximately $9.3 million, and Mytesi gross (non-GAAP) sales were approximately $20.4 million, an increase of 64% and 148%, respectively, year over year. In 2020, the Company's animal product research and development efforts were intentionally minimal, and Jaguar's animal-related sales were also minimal.

Financial Highlights (in thousands**)**	**Year-Ended December 31,**			
Gross product sales	**2020**	**2019**	$ change	% change
Mytesi	$ 20,434	$ 8,249	$ 12,185	148 %
Neonorm	77	102	(25)	(25)%
Total gross product sales	20,511	8,351	12,160	146 %
Medicare rebates	(1,738)	(500)	(1,238)	248 %
Sales discounts	(7,046)	(1,451)	(5,595)	386 %
Sales returns	(273)	(120)	(153)	128 %
Wholesaler fee	(2,069)	(505)	(1,564)	310 %
Net product sales	$ 9,385	$ 5,775	$ 3,610	63 %

Financial Highlights	**Year-Ended December 31,**			
(in thousands, except per share amounts)	**2020**	**2019**	$ change	% change
Net product revenue	$ 9,385	$ 5,775	3,610	63 %
Loss from operations	$ (26,647)	$ (28,948)	2,301	-8 %
Net loss	$ (33,809)	$ (38,539)	4,730	-12 %
Net loss attributable to common shareholders	$ (38,648)	$ (44,725)	6,077	-14 %
Net loss per share, basic and diluted	$ (1.00)	$ (9.01)	8	-89 %

- **Operating Expenses:** The total operating expense for the year 2020 was $36.0 million as compared to $34.7 million for the year 2019, a 4%, or $1.3 million, increase year over year. The increase in total operating expenses was mostly due to an increase in inducement expense of $5.3 million relating to the Series B Convertible Preferred Stock and Series 3 Warrants, an Atlas trial delay penalty of $1.0 million, offset by a decrease in the last-year impairment of long-lived intangible assets of $4.0 million, and a $0.6 million decrease in the settlement of the Tempesta royalty license agreement.

- **Cost of Product Revenue:** Total cost of product revenue for the year ended December 31, 2020 and December 31, 2019 was $3.3 million compared to $3.8 million, respectively, which is a 14%, or $0.5 million, decrease year over year. Material costs decreased $0.3 million from $2.1 million for the year ended December 31, 2019 to $1.8 million in 2020 mainly consisting of a decrease of $0.2 million in Mytesi inventory sold, a year-end contractual credit of $0.1 million received from the Company's contract manufacturer, and a campaign batch cancelation fee of $78,000. Other costs decreased $0.4 million from $0.7 million for the year ended December 31, 2019 to $0.3 million mainly consisting of $0.1 million in lower write-offs of non-conforming inventory, and a decrease in equipment maintenance of $55,000.

- **Research and Development**: The R&D expense was $6.4 million for the year 2020 compared to $5.8 million for the year 2019, a 10%, or $0.6 million, increase year over year. The increase was due to other expenses of $0.9 million, which are composed primarily of consulting, formulation, and regulatory fees. The consulting expenses increased due to an increase in clinical trial consultant services, which is consistent with the increased activity in development of multiple potential follow-on indications for Mytesi, including the initiation in October 2020 of the Company's pivotal Phase 3 clinical trial of crofelemer (Mytesi) for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy ("cancer therapy-related diarrhea" (CTD)). This is offset by a decrease in clinical and contract manufacturing expenses of $0.1 million primarily due to a decrease in contract manufacturing costs for enhanced manufacturing process improvements the Company is developing to reduce the cost of revenue, and a decrease in non-cash stock-based compensation of $0.1 million primarily due to a prior year expense incurred for options granted with upfront vesting to existing employees.

- **Sales and Marketing**: The Sales and Marketing expense was $6.6 million for the year 2020 compared to $6.9 million for the year 2019, a 5%, or $0.3 million, decrease year over year. The decrease in Sales and Marketing expense was due to a decrease in personnel and related benefits of $0.9 million because of a sales force reduction in 2019, and other expenses of $0.3 million related to reduced travel because of the COVID-19 pandemic. This is offset by an increase in direct marketing and sales expenses of $0.8 million from marketing programs for Mytesi related to expanding market access through the specialty pharmacy channel.

- **Total Mytesi Prescription Volume**: Total Mytesi unit sales volume decreased 7% in the year 2020 over the year 2019. The Company believes the COVID-19 pandemic played a role in this decrease, with the pandemic causing a significant number of HIV patients to cancel physician visits or to see their physicians less frequently. This is consistent with overall pharmaceutical industry performance that showed a negative growth in total US prescriptions for all drugs and a 10% decrease in new to brand prescriptions. Additionally, pandemic-necessitated travel restrictions impacted the ability of the Company's sales personnel to detail Mytesi to physicians in 2020.

- **General and Administrative**: The G&A expense was $14.4 million for the year 2020 compared to $13.5 million for the year 2019, a 7%, or $0.9 million, increase year over year. The year-over-year increase was primarily due to the $1.0 million Atlas trial delay penalty, a $0.3 million increase in the D&O insurance premium, and an increase in legal expenses of $0.6 million, and other public company expenses. These increases were offset largely by a decrease in consulting fees of $1.2 million.

- **Loss from Operations:** For the year 2020, the loss from operations was $26.6 million compared to a loss of $28.9 million in 2019, an 8%, or $2.3 million, decrease year over year. This decrease in operating loss was due primarily to the adjustment of the Mytesi list price in April 2020.

- **Net Loss:** For the year 2020, the net loss was $33.8 million compared to a net loss of $38.5 million in 2019, a 12%, or $4.7 million, decrease year over year. The decrease in net loss was primarily due to a decrease in loss from operations of $2.3 million, a decrease of interest expense of $2.9 million, a decrease of loss on extinguishment of debt of $3.1 million, and a decrease in other income of $0.1 million, offset by increase in change in fair value of financial instruments of $3.7 million.

- **Net Loss Attributable to Common Shareholders:** For the year 2020, the net loss attributable to common shareholders was $38.6 million compared to $44.7 million for the year 2019. There were $4.8 million of deemed dividends recorded in the year 2020, as compared to $6.2 million recorded during the year 2019.

- **Non-GAAP EBITDA**: Non-GAAP EBITDA for the years 2020 and 2019 was a net loss of $26.5 million and $28 million, respectively. Excluding the impairment of indefinite-lived intangible assets, loss on extinguishment of debt, and other non-recurring expenses, non-GAAP recurring EBITDA was a loss of $24.3 million and $19.0 million for the years 2020 and 2019, respectively.

	Year-Ended December 31,	
	2020	2019
	(unaudited)	
Net loss	$ (33,809)	$ (38,539)
Adjustments:		
Interest expense	2,792	5,731
Property and equipment depreciation	41	50
Amortization of intangible assets	1,687	1,687
Share-based compensation expense	2,824	2,989
Income taxes	-	(10)
Non-GAAP EBITDA	(26,465)	(28,092)
Impairment of indefinite-lived intangible assets	-	4,000
Loss on extinguishment of debt	1,864	4,941
Campaign batch cancelation fee	78	78
Distribution fees from former distributor	227	227
Reversal of accrued royalty due to termination of royalty agreement	-	(189)
Non-GAAP Recurring EBITDA	$ (24,296)	$ (19,035)

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, which generate invoiced sales and cash flow 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 is 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.

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." 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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