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): **November 16, 2020**

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** (Address of principal executive offices)		**94104** (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 November 16, 2020, Jaguar Health, Inc. (the "Company") issued a press release announcing third quarter 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 November 16, 2020.

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: November 16, 2020

Exhibit 99.1

Jaguar Health, Inc. Reports 2020 Third Quarter Financial Results

Third quarter 2020 Mytesi net sales and gross sales were approximately $2.8 million and approximately $6.3 million, respectively

Company to host investor call Monday, November 16th at 8:30 a.m. Eastern regarding third quarter 2020 financials & business updates

SAN FRANCISCO, CA / November 16, 2020 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today reported consolidated third quarter 2020 financial results.

2020 Third Quarter Company Financial Results:

- **Mytesi® Net Product Revenue:** Mytesi net sales during the third quarter of 2020 were approximately $2.8 million and $1.0 million in the third quarter 2019. This third quarter 2020 result represents approximately 280% of the same period in 2019, or an increase of $1.8 million quarter over quarter.

- **Mytesi Gross Product Revenue (Non-GAAP):** Mytesi gross sales during the third quarter of 2020 were approximately $6.3 million and $1.9 million in the third quarter of 2019. This third quarter 2020 result represents approximately 332% of the same period in 2019, or an increase of $4.4 million quarter over quarter.

  The increase in sales coincided with enhancements to the Mytesi patient access program, known as NapoCares™, of Jaguar's wholly owned subsidiary, Napo Pharmaceuticals, Inc., in the beginning of April 2020. In the third quarter of 2020, the Company's animal product commercialization efforts were intentionally minimal, and Jaguar's animal-related sales were also minimal.

Financial Highlights	**Three Months Ended September 30,**			
(in thousands, except per share amounts)	**2020**	**2019**	$ change	% change
Net product revenue	$ 2,773	$ 973	1,800	185%
Loss from operations	$ (5,375)	$ (6,727)	1,352	-20%
Net loss	$ (7,866)	$ (7,555)	(311)	4%
Net loss attributable to common shareholders	$ (8,271)	$ (11,683)	3,412	-29%
Net loss per share, basic and diluted	$ (0.21)	$ (2.00)	2	-90%

- **Operating Expenses:** The total operating expense for the third quarter of 2020 was $8.1 million as compared to $7.7 million for the third quarter of 2019, a 5%, or $0.4 million, increase year over year. The increase in total operating expenses was primarily due to an increase in general and administrative expense of $1.2 million and an increase in R&D expense of $0.2 million, offset by a decrease of $0.2 million in cost of revenues, a $0.2 million decrease in sales and marketing expenses, and settlement of the Tempesta Royalty License Agreement of $0.6 million in the third quarter of 2019.

- **Cost of Product Revenue:** Total cost of product revenue for the quarter ended September 30, 2020 was $0.8 million (28% of revenue) compared to $1.0 million (97% of revenue) for the quarter ended September 30, 2019. The third quarter 2020 figure represents a 20%, or $0.2 million, decrease quarter over quarter. The improvement in cost of product revenue was due to a non-recurring write-off of non-conforming inventory and a campaign batch cancellation fee in the third quarter of 2019.

- **Research and Development:** The R&D expense was $1.5 million for the third quarter of 2020 compared to $1.3 million for the third quarter of 2019, a $0.2 million increase quarter over quarter. The increase in R&D expense was due to an increase in clinical trial costs as the Company prepared for the initiation of its pivotal trial for cancer therapy-related diarrhea in the third quarter of 2020.

- **Sales and Marketing:** The Sales and Marketing expense was $1.5 million for the third quarter of 2020 compared to $1.7 million for the third quarter of 2019, a 12%, or $0.2 million, decrease quarter over quarter. The decrease in Sales and Marketing expense was due to a reduction in personnel and related benefits of $0.4 million in the third quarter of 2019, offset by an increase in marketing expenses of $0.2 million as the Company continues to expand the NapoCares patient access program.

- **Total Mytesi Prescription Volume:** Total Mytesi prescription volume, which is the combination of new prescriptions and refills, has maintained an essentially consistent level of activity in the third quarter of 2020 over the third quarter of 2019, according to data from IQVIA, a provider of life sciences industry analytics.

- **General and Administrative:** The G&A expense was $4.3 million for the third quarter of 2020 compared to $3.1 million for the third quarter of 2019, a 39%, or $1.2 million, increase quarter over quarter. The increase in G&A expenses was largely due to the net impact of a one-time trial delay fee of $2.5 million related to the patent purchase and license back arrangement with Atlas Sciences, LLC (“Atlas”) for Napo’s NP-500 drug product candidate, which obligated the Company to initiate a proof of concept Phase 2 study or else incur a trial delay fee of $2.5 million. The Company made the decision not to initiate the Phase 2 study and terminated its performance obligation. The Company derecognized $1.5 million in deferred revenue and the excess of the Trial Delay Fee was recognized in "General and Administrative Expenses" in the condensed consolidated statement of operations.

- **Loss from Operations:** For the third quarter of 2020, the loss from operations was $5.4 million compared to a loss of $6.7 million in the third quarter of 2019, a 24%, or $1.3 million, decrease quarter over quarter. The increase in the Mytesi sales resulted in a decrease of loss in operations.

- **Net Loss:** For the third quarter of 2020, the net loss was $7.9 million, compared to a net loss of $7.6 million in the third quarter of 2019, a 4%, or $0.3 million, increase quarter over quarter. The increase in net loss was primarily due to an increase in the fair value of financial instruments of $2.9 million offset by a decrease in interest expense of $0.8 million, a decrease in loss from operations of $1.4 million, a decrease of other income of $0.1 million, and a decrease of $0.3 million in loss of extinguishment of debt.

- **Net Loss Attributable to Common Shareholders:** For the third quarter of 2020, net loss attributable to common shareholders was $8.3 million compared to $11.7 million for the third quarter of 2019.

- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the third quarter of 2020 and the third quarter of 2019 was a net loss of $6.2 million and a net loss of $4.6 million, respectively. Excluding the loss on extinguishment of debt, and other non-recurring expenses, non-GAAP Recurring EBITDA was a loss of approximately $6.2 million and a loss of approximately $4.1 million for the third quarter of 2020 and the third quarter of 2019, respectively.

	Three Months Ended September 30,	
	2020	2019
	(unaudited)	
Net loss	$ (7,866)	$ (7,555)
Adjustments:		
Interest expense	581	1,353
Property and equipment depreciation	11	10
Amortization of intangible assets	422	422
Share-based compensation expense	675	1,110
Income taxes	—	10
Non-GAAP EBITDA	$ (6,177)	$ (4,650)
Loss on extinguishment of debt	—	337
Contract manufacturer's fee charged for canceling a Mytesi production run	—	161
Distribution fees from former distributor	—	227
Reversal of accrued royalty due to termination of royalty agreement	—	(189)
Non-GAAP Recurring EBITDA	$ (6,177)	$ (4,114)

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 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, 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.

Dial-In Instructions for Investor Call
When: Monday, November 16, 2020 at 8:30 a.m. Eastern Time
Dial-in (US Toll Free): 866-548-4713
Dial-in (International): 323-794-2093
Conference ID number: 8490376
Live webcast on the investor relations section of Jaguar's website (click here)

Replay Instructions for Investor Call
Dial-in (US Toll Free): 844-512-2921
Dial-in (International): 412-317-6671
Replay Pin Number: 8490376
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 call on November 16, 2020. 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.

Contact:
Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health

Jaguar-JAGX

# # #