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 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):

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

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

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

o 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 17, 2021, Jaguar Health, Inc. (the "Company") issued a press release announcing third 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 November 17, 2021.
104	Cover Page Interactive Data File (embedded with the inline XBRL document)

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 18, 2021

Exhibit 99.1

Jaguar Health Reports 2021 Third Quarter Financial Results

Mytesi® prescription volume increased 7.6% in Q3 2021 over Q2 2021

Third quarter 2021 Mytesi net and gross sales were approximately $0.6 million and approximately $3.2 million

Company expects to complete transition to selling Mytesi through closed specialty pharmacy network by end of 2021 as part of Company's market access strategy

Upcoming December 2021 milestones: Presentation of Phase 2 HALT-D study results at San Antonio Breast Cancer Symposium & launch of Canalevia™-CA1 for chemotherapy-induced diarrhea in dogs

***REMINDER:** Jaguar to host investor webcast today (Wednesday, November 17th) at 8:30 a.m. Eastern regarding third quarter 2021 financials & business updates; Click **here** to register for webcast*

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

Mytesi (crofelemer) prescription volume, the metric the Company believes to be the best indicator of patient demand, increased 7.6% in the third quarter of 2021 over the second quarter of 2021, and new Mytesi prescriptions increased 9.0% during the same period. Mytesi total prescription volume remained the same in the third quarter of 2021 over the third quarter of 2020 and new Mytesi prescriptions increased by 10.5% during the same period. Prescription volume differs from invoiced sales volume.

As previously announced, the Company is in the process of transitioning a substantial amount of Mytesi volume to a closed network of specialty pharmacies (rather than to wholesalers that resell the product to retail pharmacies) by the end of 2021. This transition results in an underrepresentation of Mytesi utilization, as revenue related to wholesaler inventory has already been recognized by Jaguar, and that inventory has now been brought down. A key component of the Company's market access strategy, this initiative is intended to help remove access barriers for patients receiving Mytesi, and includes services such as a higher level of support for prior authorizations, appeals, adherence counseling, and home delivery options. While patients often visit retail pharmacies for short-term or uncomplicated medical needs, specialty pharmacies focus on serving patients with complex and chronic medical conditions like HIV. The transition to a closed network of specialty pharmacies is expected to result in a meaningful reduction in Mytesi distribution costs and prepares the Company's U.S. commercial distribution network for future indication expansion of crofelemer to other populations of patients with complex medical needs.

Clinical & Product Development Updates:

- As announced, the results from the Phase 2 HALT-D study have been accepted for presentation at the San Antonio Breast Cancer Symposium (SABCS) in December 2021. The HALT-D study was sponsored by Georgetown University and funded by Genentech, a member of the Roche Group, and is completely independent from the ongoing pivotal Phase 3 clinical trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy that was initiated in October 2020 by Jaguar. Enrollment in the crofelemer Phase 3 trial is ongoing.

    - **SABCS Poster Session:** Poster Session #5
    - **Poster Session Title:** *HALT-D: A Randomized Open Label Phase 2 Study of Crofelemer for the Prevention of Chemotherapy Induced Diarrhea (CID) in Patients with Breast Cancer receiving trastuzumab, pertuzumab, and a taxane*
    - **Date & Time:** Friday, December 10, 2021 from 7:00 a.m. – 8:30 a.m. Central Time
    - **Location:** Hall 1, Henry B. Gonzalez Convention Center, San Antonio, TX
    - **Principle Investigator:** Paula R. Pohlmann, MD, PhD, Medical Oncologist

- The Company is planning for the conditional approval and launch of Canalevia™-CA1, Jaguar's oral plant-based prescription drug candidate for the treatment of chemotherapy-induced diarrhea (CID) in dogs, in late December 2021. As announced, Jaguar completed the filing of the New Animal Drug Application (NADA) to request the U.S. Food and Drug Administration's conditional approval to market Canalevia-CA1.

- As announced on November 1, 2021, the merger of Jaguar's Italian subsidiary Napo EU S.p.A. and Dragon SPAC S.p.A. has closed. Jaguar maintains a meaningful majority equity interest in the combined entity, which has retained the name Napo EU S.p.A. "With key management for Napo EU in place, we look forward to collaborating with and growing the Napo EU team in Italy in support of Napo EU's very important mission to expand access to crofelemer in Europe (excluding Russia) for multiple unmet gastrointestinal medical needs in the region – beginning with Napo EU's initial focus on short bowel syndrome with intestinal failure – a target indication representing another key shot on goal for crofelemer," said Conte, who is also a Napo EU board member.

- As announced on September 15, 2021, Napo EU submitted an Orphan Drug Designation (ODD) application for crofelemer for short bowel syndrome (SBS) for review by the European Medicines Agency (EMA). On November 5th, the EMA's Committee for Orphan Medicinal Products provided a positive opinion for the ODD of crofelemer in the EU for this indication. The committee's recommendation has been sent to the European Commission, which is expected to result in a final decision within the next 30 days. Crofelemer previously received ODD in the U.S. from the FDA for SBS.

2021 Third Quarter Company Financial Results:

- **Mytesi Prescription Volume:** As stated above, Mytesi prescription volume, the metric the Company believes to be the best indicator of patient demand, increased 7.6% in the third quarter of 2021 over the second quarter of 2021, and new Mytesi prescriptions increased 9.0% during the same period. Mytesi total prescription volume remained the same in the third quarter of 2021 over the third quarter of 2020 and new Mytesi prescriptions increased by 10.5% during the same period. Prescription volume differs 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 third quarter of 2021 was approximately $0.6 million and approximately $0.4 million in the second quarter of 2021, an increase of $0.2 million quarter over quarter. Mytesi net revenue decreased by $2.2 million in the third quarter of 2021 versus the third quarter of 2020. As part of the process of transitioning to the closed specialty pharmacy network, the third quarter of 2021 was significantly impacted by the one-time inventory draw-down of approximately 1,300 bottles of Mytesi across the Company's third-party logistics warehouse, wholesalers, distributors, and retail stores. The Company expects essentially a full transition to Mytesi prescriptions being dispensed through specialty pharmacies by the end of 2021.

- **Mytesi Gross Product Revenue (Non-GAAP):** Mytesi gross revenue during the third quarter of 2021 was approximately $3.2 million, and approximately $4.9 million in the second quarter of 2021, a decrease of $1.7 million quarter over quarter. Mytesi gross revenue decreased by $3.1 million in the third quarter of 2021 versus the third quarter of 2020. As described above, the third quarter of 2021 was significantly impacted by the one-time inventory draw-down of approximately 1,300 bottles of Mytesi across the Company's third-party logistics warehouse, wholesalers, distributors, and retail stores. The Company expects essentially a full transition to Mytesi prescriptions being dispensed through specialty pharmacies by the end 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 38% of total sales volume in the third quarter of 2021 compared to approximately 17% in the second 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, and prepares the Company's U.S. distribution network for the anticipated future indication expansion of crofelemer to other populations of patients with complex medical needs.

- **Neonorm™:** Neonorm non-prescription product revenues were minimal for the third quarters of 2021 and 2020, in accordance with the Company's primary focus on human health and prescription products.

Financial Highlights	**Three months Ended September 30,**			
(in thousands)	**2021**	**2020**	$ change	% change
Gross product sales				
Mytesi	$ 3,184	$ 6,303	$ (3,119)	-49%
Neonorm	15	13	2	15%
Total gross product	3,199	6,316	(3,117)	-49%
Medicare rebates	(449)	(588)	139	-24%
Sales discounts	(1,599)	(2,218)	619	-28%
Sales returns	(36)	(107)	71	-66%
Wholesaler fee	(485)	(630)	145	-23%
Net product sales	$ 630	$ 2,773	$ (2,143)	-77%

Financial Highlights	**Three Months Ended September 30,**			
(in thousands, except per share amounts)	**2021**	**2020**	$ change	% change
Net product revenue	$ 630	$ 2,773	(2,143)	-77%
Loss from operations	$ (9,529)	$ (5,375)	(4,154)	77%
Net loss attributable to common shareholders	$ (12,192)	$ (8,271)	(3,921)	47%
Net loss per share, basic and diluted	$ (0.27)	(0.62)	0.35	-56%

- **Cost of Product Revenue:** Total cost of product revenue for the quarter ended September 30, 2021 was $0.6 million compared to $0.8 million for the quarter ended September 30, 2020, representing a $0.2 million decrease over the third 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 $3.3 million for the third quarter of 2021 compared to $1.5 million for the third quarter of 2020, an increase of $1.8 million quarter over quarter. Clinical and contract manufacturing increased $0.9 million in the third 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 $0.5 million in the third quarter of 2021 compared to the same period in 2020 due to compensation and additional headcount. Stock-based compensation expense increased $0.2 million in the third quarter of 2021 compared to the third quarter of 2020 due to continued vesting of option grants and restricted stock units granted in the last twelve months. Other expenses consisting of consulting, formulation, and regulatory fees increased $0.1 million in the third 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 $2.3 million for the third quarter of 2021 compared to $1.5 million for the third quarter of 2020, an increase of $ 0.8 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 $4.0 million for the third quarter of 2021 compared to $4.3 million for the third quarter of 2020, a decrease of $0.3 million quarter over quarter. The decrease in G&A expenses was largely due to a decrease in other expenses of $1.0 million, a decrease in rent and lease of $0.1 million offset by an increase of $0.3 million in personnel and related benefits due to the addition of three employees and salary increase, an increase in stock-based compensation of $0.3 million due to continued vesting of option grants, and an increase in public company expense of $0.2 million due to investor relations and consulting related to annual shareholder meeting.

- **Loss from Operations:** For the third quarter of 2021, the loss from operations was $9.5 million compared to a loss of $5.4 million in the third quarter of 2020, an increase of $4.1 million quarter over quarter.

- **Net Loss:** For the third quarter of 2021, the net loss was $12.2 million, compared to a net loss of $7.9 million in the third quarter of 2020, an increase of $4.3 million quarter over quarter. In addition to the loss from operations:

    - Interest expense increased by $1.5 million from $0.6 million in the three months ended September 30, 2020 to $2.1 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 decreased $1.5 million from a loss of $2.1 million in the three months ended September 30, 2020 to $0.6 million in 2021 designated at FVO.

- **Non-GAAP EBITDA:** Non-GAAP EBITDA for the third quarter of 2021 and the third quarter of 2020 was a net loss of $8.5 million and $6.2 million, respectively.

(in thousands)	Three Months Ended September 30, 2021	2020
	(unaudited)	
Net loss	$ (12,192)	$ (7,866)
Adjustments:		
Interest expense	2,078	581
Property and equipment depreciation	8	11
Amortization of intangible assets	422	422
Share-based compensation expense	1,165	675
Income taxes	-	-
Non-GAAP EBITDA	(8,519)	(6,177)
Series 3 warrants inducement expense	-	-
Non-GAAP Recurring EBITDA	$ (8,519)	$ (6,177)

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 reflets 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 Today's Webcast

When: Wednesday, November 17, 2021, 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 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 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. Crofelemer is the subject of the OnTarget study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Napo EU S.p.A., the majority owned Italian subsidiary of Napo Pharmaceuticals, focuses on expanding crofelemer access in Europe.

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 Company’s expectation that essentially a full transition to Mytesi prescriptions being dispensed through specialty pharmacies will be complete by the end of 2021, the expectation that results of the Phase 2 HALT-D study will be presented at the San Antonio Breast Cancer Symposium in December 2021, the Company’s expectation that the conditional approval and launch of Canalevia™-CA1 for CID in dogs will take place in late-December 2021, the expectation that a final decision about ODD for crofelemer for SBS in the EU may occur within the next 30 days, the expectation that Jaguar will host an investor webcast on November 17, 2021, the Company’s expectation that the transition to a closed network of specialty pharmacies will result in a meaningful reduction in Mytesi distribution costs, and the Company’s plans to grow the Napo EU team in Italy. 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

# # #