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 15, 2023**

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 15, 2023, Jaguar Health, Inc. (the "Company") issued a press release announcing first quarter 2023 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 15, 2023.
104	Cover Page Interactive Data File (embedded within 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: May 15, 2023

Exhibit 99.1

Jaguar Health Reports First Quarter 2023 Financial Results

Net revenue decreased in Q1 2023 versus Q1 2022

Net loss improved over the same period

Jaguar has agreed, as described below, not to issue additional equity securities before October 22, 2023 – by which point the Company expects to have released top line data for the Phase 3 OnTarget trial

Completed and core near-term milestones:

- *Enrollment completed for Phase 3 OnTarget trial*
- *Submission of Investigational New Drug (IND) application planned for Q2 2023 to FDA for crofelemer for microvillus inclusion disease*

REMINDER: *Jaguar to host investor webcast Monday, May 15th at 8:30 a.m. Eastern regarding first-quarter 2023 financials and company updates; Click **here** to register for webcast*

SAN FRANCISCO, CA / May 15, 2023 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today reported consolidated first-quarter 2023 financial results and provided Company updates.

The combined net revenue for Mytesi® and the Company's other prescription product, Canalevia®-CA1, which became commercially available in April 2022, was approximately $2.00 million in the first quarter of 2023, representing a decrease of 40% compared to prescription product net revenue in the fourth quarter of 2022, which totaled approximately $3.3 million, and a decrease of approximately 25% over prescription product net revenue in the first quarter of 2022, which totaled approximately $2.6 million. The loss from operations decreased by $2.0 million, from $11.8 million in the quarter ended March 31, 2022 to $9.8 million during the same period in 2023.

"After five consecutive quarters of prescription product net sales growth, we had a decline in our Q1 2023 net sales. We may have lost sight of the depth, reach and importance of patient voice in the HIV community to facilitate the expansion of care that Mytesi can provide HIV patients. We are prioritizing learning from and listening to patient voice and this will be foundational to our preparations for the introduction of crofelemer to the much larger market for the prophylaxis of cancer therapy-related diarrhea (CTD)," said Lisa Conte, Jaguar's president and CEO. "In support of this goal, we're very pleased that Dr. Kelly Shanahan has joined our Scientific Advisory Board. As an independent patient advocate, Dr. Shanahan shares our deep commitment to patient comfort and dignity, especially to the importance of preventing and ameliorating noninfectious CTD."

"What is really powerful about crofelemer is that it is a pipeline within a product. Our key near-term clinical activity is our Phase 3 pivotal **OnTarget** trial of crofelemer for the follow-on indication of prophylaxis of CTD. We have completed patient enrollment for OnTarget, which is a key step on our journey to making crofelemer available to treat the neglected comorbidity of CTD. The top line results from this pivotal study are expected in October 2023," said Conte.

The Company's current cash position includes gross proceeds from a PIPE (private investment in public equity) transaction of approximately $1.86 million that closed last week. The PIPE purchase agreement stipulates that during the period commencing on the signing of the agreement and ending on October 22, 2023 (a time period that extends to the expected release date of the primary endpoint for the OnTarget trial), the Company will not effect or enter into any agreement to (i) issue securities in exchange for any securities of the Company issued and outstanding on the date of the agreement pursuant to Section 3(a)(9) of the Securities Act of 1933, as amended, including ATM utilization or (ii) effect issuance by the Company of common stock or common stock equivalents, subject to certain customary carve outs set forth in the agreement or with the consent of holders of a majority of shares issued in the PIPE.

A new near-term Company development goal focuses on microvillus inclusion disease—MVID—an ultra-rare pediatric CDD. MVID and SBS with intestinal failure are Jaguar's two prioritized rare disease investigative indications for a novel formulation of crofelemer. MVID is a catastrophic medical situation for pediatric patients, and there are currently no approved drug treatments. The Company is planning to submit an Investigational New Drug application to the FDA for MVID in Q2 2023.

For the European market, MVID and other CDD patients could potentially participate in revenue generating early access programs targeted for 2024. In accordance with the guidelines of specific European Union countries, publications of data from proof-of-concept trials could support participation in early patient access programs for crofelemer for CDD or SBS. Participation in early access programs, which do not exist in the United States, provides an opportunity for reimbursement while impacting the morbidity and high cost of care for these chronic unmet needs.

2023 FIRST QUARTER COMPANY FINANCIAL RESULTS:

Prescription product net revenue was approximately $2.0 million in the first quarter of 2023, representing a decrease of 40% compared to prescription product net revenue in the fourth quarter of 2022, which totaled approximately $3.3 million, and a decrease of approximately 25% over prescription product net revenue in the first quarter of 2022, which totaled approximately $2.6 million.

- **Mytesi Prescription Volume:** Mytesi prescription volume decreased approximately 9% in the first quarter of 2023 compared to the fourth quarter of 2022, and decreased approximately 1% in the first quarter of 2023 compared to the first quarter of 2022. Prescription volume differs from invoiced sales volume, which reflects, among other factors, varying buying patterns among specialty pharmacies in the closed network as they manage their inventory levels.

- **Net Mytesi Revenue:** Net revenue for Mytesi was approximately $2.0 million in the first quarter of 2023, representing a decrease of 40% compared to Mytesi net revenue in the fourth quarter of 2022, which totaled approximately $3.2 million, and a decrease of approximately 25% over Mytesi net revenue in the first quarter of 2022, which totaled approximately $2.6 million.

- **Net Canalevia-CA1 Revenue:** Net revenue for the Company's other crofelemer prescription product, Canalevia-CA1, which became commercially available in April 2022, was approximately $28,000 in the first quarter of 2023, representing an increase of 17% over Canalevia-CA1 net revenue in the fourth quarter of 2022, which totaled approximately $24,000.

- **Neonorm™:** Revenues for the non-prescription Neonorm products and Jaguar's Animal Health business unit were minimal for the first quarters of 2023 and 2022, in accordance with the Company's primary focus on human health and prescription products.

Financial Highlights (in thousands, except per share amounts)	Three Months Ended March 31, 2023	2022	$ change	% change
Net product revenue	$ 1,972	$ 2,625	(653)	-25%
Loss from operations	$ (9,845)	$ (11,754)	1,909	-16%
Net loss attributable to common stockholders	$ (12,202)	$ (17,986)	5,784	-32%
Net loss per share, basic and diluted	$ (2.39)	$ (23.10)	21	-90%

- **Cost of Product Revenue:** Total cost of product revenue decreased by $0.2 million, from $0.5 million for the quarter ended March 31, 2022 to $0.3 million for the quarter ended March 31, 2023. This is due to lower sales in Q1 2023 compared with Q4 2022.

- **Research and Development:** The R&D expense decreased by $0.2 million, from $5.0 million for the quarter ended March 31, 2022 to $4.8 million during the same quarter in 2023 primarily due to a decrease in aggregate amount of $0.8 from personnel and related benefits, stock-based compensation and other expenses, offset by an increase in the expense of the Phase 3 clinical trial and regulatory initiatives of $0.6 million largely for CTD.

- **Sales and Marketing:** The Sales and Marketing expense decreased by approximately $1.0 million, from $2.8 million for the quarter ended March 31, 2022 to $1.9 million during the same quarter in 2023. Direct marketing fees and expenses decreased due to decreased patient access programs and other Mytesi marketing initiatives, as well as stock-based compensation, personnel and related benefits due to less bonus and commission expenses.

- **General and Administrative:** The G&A expense decreased by $1.3 million, from $6.1 million for the quarter ended March 31, 2022, to $4.8 million during the same quarter in 2023. The decrease of $1.3 million was largely due to an aggregate decrease in personnel and related benefits, public company and stock-based compensation expenses.

- **Loss from Operations:** Loss from operations decreased by $2.0 million, from $11.8 million in the quarter ended March 31, 2022 to $9.8 million during the same period in 2023.

- **Net Loss:** Net loss attributable to common shareholders decreased by approximately $6.0 million, from $18.0 million in the quarter ended March 31, 2022 to $12 million in the same period in 2023. In addition to the loss from operations:

    - Interest expense decreased by $2.0 million from $4.2 million in the quarter ended March 31, 2022 to $2.2 million for the same period in 2023 primarily due to interest from the royalty and note agreements.

    - There was no loss recorded on extinguishment of debt in the first quarter of 2023. However, the Company recorded $2.8 million for the first quarter of 2022 related to the extinguishment loss from the exchange of the outstanding balance of a royalty agreement for shares of the Company’s common stock.

    - Change in fair value of financial instrument and hybrid instrument designated at Fair Value Option (“FVO") increased $126,000 from a loss of approximately $0.2 million for the three months ended March 31, 2022 to a loss of about $0.3 million for the same period in 2023 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.

- Other expenses decreased by about $0.8 million from the quarter ended March 31, 2022 to the same period in 2023 largely due to foreign currency transactions.

- **Non-GAAP Recurring EBITDA:** Non-GAAP recurring EBITDA for the first quarter of 2023 and the first quarter of 2022 were a net loss of $9.0 million and $9.4 million, respectively.

(in thousands)	Three Months Ending March 31, 2023	2022
	(unaudited)	
Net loss attributable to common stockholders	$ (12,202)	$ (17,986)
Adjustments:		
Interest expense	2,181	4,194
Property and equipment depreciation	20	131
Amortization of intangible assets	484	422
Share-based compensation expense	480	1,063
Income taxes	-	-
Non-GAAP EBITDA	(9,037)	(12,177)
Loss on extinguishment of debt	-	2,815
Non-GAAP Recurring EBITDA	$ (9,037)	$ (9,362)

Note Regarding Use of Non-GAAP Measures

The Company supplements its condensed consolidated financial statements presented on a GAAP basis by providing 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.

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 15, 2023, 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 Crofelemer

Crofelemer is the only oral FDA approved drug under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals, Jaguar Health's wholly owned U.S. subsidiary, has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for Indigenous communities.

About Jaguar Health, Napo Pharmaceuticals, Napo Therapeutics & Jaguar Animal Health

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. Our crofelemer drug product candidate 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. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe. Jaguar Animal Health is a tradename of Jaguar Health.

For more information about Jaguar Health, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.com. For more information about Napo Therapeutics, visit napotherapeutics.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.

Important Safety Information About Canalevia®-CA1

For oral use in dogs only. Not for use in humans. Keep Canalevia-CA1 (crofelemer delayed-release tablets) in a secure location out of reach of children and other animals. Consult a physician in case of accidental ingestion by humans. Do not use in dogs that have a known hypersensitivity to crofelemer. Prior to using Canalevia-CA1, rule out infectious etiologies of diarrhea. Canalevia-CA1 is a conditionally approved drug indicated for the treatment of chemotherapy-induced diarrhea in dogs. The most common adverse reactions included decreased appetite, decreased activity, dehydration, abdominal pain, and vomiting.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. **It is a violation of Federal law to use this product other than as directed in the labeling. Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-552.**

See full Prescribing Information at Canalevia.com.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the Company’s expectation that the top line results from the OnTarget study will be available in October 2023, the Company’s expectation that it will submit an Investigational New Drug application to the FDA for MVID in Q2 2023, the Company’s expectation that MVID and other CDD patients could potentially participate in revenue generating early access programs targeted for 2024 in Europe, the Company’s expectation that publications of data from proof-of-concept trials could support participation in early patient access programs for crofelemer for CDD or SBS, and the Company’s expectation that participation in early access programs provides an opportunity for reimbursement while impacting the morbidity and high cost of care for these chronic unmet needs. 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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