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): **August 13, 2024**

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 August 13, 2024, Jaguar Health, Inc. (the "Company") issued a press release announcing second quarter 2024 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 August 13, 2024.
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: August 13, 2024

Jaguar Health Reports Second Quarter 2024 Financial Results

The combined net Q2 2024 revenue of approximately $2.72 million for prescription and non-prescription products increased approximately 16% versus net Q1 2024 revenue of $2.35 million and 2.0% versus net Q2 2023 revenue of $2.67 million

Company to complete analysis of full data for first and second 12-week periods of pivotal phase 3 OnTarget trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD) in support of FDA discussion; Jaguar to explore possible approval pathway for crofelemer in breast and lung cancer based on phase 3 results

Jaguar planning to begin commercial launch in October 2024 for Gelclair®, the company's third prescription product

Import permit for crofelemer granted for independent, investigator-initiated proof-of-concept trial in Abu Dhabi in pediatric patients for the rare and orphan disease indications of microvillus inclusion disease (MVID) and short bowel syndrome (SBS) with intestinal failure

***REMINDER:** Jaguar to host investor webcast Tuesday, August 13th at 8:30 a.m. Eastern regarding Q2 2024 financials and company updates; Click **here** to register for webcast*

SAN FRANCISCO, CA / August 13, 2024 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today reported its consolidated second-quarter 2024 financial results and provided Company updates.

The combined net revenue for the Company's crofelemer prescription products, Mytesi® and Canalevia®-CA1, and the Company's non-prescription products, was approximately $2.72 million in the second quarter of 2024, representing an increase of approximately 16% over the combined net revenue in the first quarter of 2024, which totaled approximately $2.35 million, and 2.0% over the combined net revenue in the second quarter of 2023, which totaled approximately $2.67 million.

Jaguar, with strong leadership and participation from Jaguar family companies Napo Pharmaceuticals and Napo Therapeutics, is supporting investigator-initiated proof-of-concept (POC) studies of crofelemer for the rare disease indications of microvillus inclusion disease (MVID) and short bowel syndrome (SBS) with intestinal failure in the US, EU, and Middle East/North Africa (MENA) regions, with results expected by the end of 2024 and throughout 2025. The import permit for crofelemer for Abu Dhabi for the POC study in pediatric patients with MVID or SBS with intestinal failure has been granted. In accordance with the guidelines of specific EU countries, published data from clinical investigations in such rare diseases could support early patient access to crofelemer for these debilitating conditions in those countries.

Lisa Conte, Jaguar's president and CEO, said, "Our paramount near-term activities are our planned October 2024 commercial launch of the FDA-approved oral mucositis prescription product Gelclair® in the U.S., progressing our rare disease development business, and our ongoing analysis of full data for the first and second 12-week stages of our pivotal phase 3 OnTarget trial of crofelemer for prophylaxis of cancer therapy-related diarrhea (CTD). As announced, we are collaborating with our clinical and scientific advisers to evaluate the significance of the clinically meaningful results identified in patients with breast and lung cancer in the initial data from OnTarget, as we plan to engage in discussions with the FDA to explore the possible pathway of approval to make crofelemer available to breast and lung cancer patients for CTD."

According to the World Health Organization, in 2022 breast cancer was the most common cancer in women in 157 countries out of 185, with 2.3 million women diagnosed with breast cancer globally.[1] Lung cancer is the most common cancer worldwide, with 2,480,675 new cases of lung cancer in 2022. It is the most common cancer in men and the second most common in women.[2]

2024 SECOND QUARTER COMPANY FINANCIAL RESULTS:

- **Net Mytesi Revenue:** The combined net revenue for Mytesi was approximately $2.64 million in the second quarter of 2024, representing an increase of approximately 15% over the combined net revenue in the first quarter of 2024, which totaled approximately $2.35 million, and an increase of 1% over the combined net revenue for the second quarter of 2023, which totaled approximately $2.62 million.

- **Mytesi Prescription Volume:** Mytesi prescription volume increased in the second quarter of 2024 compared to the first quarter of 2024 by 5.2%. Prescriptions decreased by 0.4% in the second quarter of 2024 compared to the second quarter of 2023. 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.

- **Neonorm™**: Revenues for the non-prescription Neonorm products were minimal for the second quarters of 2024 and 2023.

Financial Highlights (in thousands, except per share amounts)	Three Months Ended June 30, 2024	2023	$ change	% change
Net product revenue	$ 2,720	$ 2,676	44	2%
Loss from operations	$ (7,198)	$ (8,102)	904	-13%
Net loss attributable to common shareholders	$ (9,492)	$ (12,150)	2,658	-28%
Net loss per share, basic and diluted	$ (4.04)	$ (41.35)	37	-924%

- **Cost of Product Revenue:** Total cost of product revenue decreased by approximately $70,000 from $0.50 million for the quarter ended June 30, 2023 compared to $0.43 million for the quarter ended June 30, 2024

- **Research and Development:** The R&D expense decreased by $0.6 million, from $4.3 million for the quarter ended June 30, 2023 to $3.7 million during the same quarter in 2024, primarily due to the winding down of activities related to the phase 3 OnTarget clinical trial, regulatory activities for the trial, and the Company's initiatives for rare disease product development.

- **Sales and Marketing:** The Sales and Marketing expense decreased by approximately $0.1 million, from $1.6 million for the quarter ended June 30, 2023 to $1.5 million during the same quarter in 2024. Direct marketing fees and expenses decreased due to continued savings associated with the utilization of a more cost-effective patient support services vendor, other Mytesi marketing initiatives, as well as decreased stock-based compensation, and commission expenses.

- **General and Administrative:** The G&A expense decreased by $0.1 million, from $4.4 million for the quarter ended June 30, 2023, to $4.3 million during the same quarter in 2024, due to decreases in personnel and benefits, rent and lease, stock-based compensation, travel and other expenses. However, this decrease is offset by an increase in consulting, audit, tax and accounting services, and public company expenses.

- **Loss from Operations:** Loss from operations decreased by $0.9 million, from $8.1 million in the quarter ended June 30, 2023 to $7.2 million during the same period in 2024.

- **Net Loss:** Net loss attributable to common shareholders decreased by approximately $2.6 million, from $12.1 million in the quarter ended June 30, 2023 to $9.5 million in the same period in 2024. In addition to the loss from operations:

    - Interest expense decreased by $3.3 million from ($0.11) million in the quarter ended June 30, 2024 versus $3.5 million for the same period in 2023, primarily due to certain debt instruments being accounted for using the fair value option. The lower interest expense was offset with a higher loss on change in fair value of debt instruments.

    - Change in fair value of financial instrument and hybrid instrument designated at FVO increased by $1.0 million from a loss of $1.8 million in the three months ended June 30, 2024 compared to a loss of $0.8 million for the same period in 2023 primarily due to fair value adjustments in liability classified warrants and notes payable designated at FVO.

- **Non-GAAP Recurring EBITDA:** Non-GAAP recurring EBITDA for the second quarter of 2024 and the second quarter of 2023 were a net loss of $8.8 million and $7.7 million, respectively.

	Three Months Ending June 30,	
(in thousands)	2024	2023
	(unaudited)	
Net loss attributable to common shareholders:	$ (9,492)	$ (12,150)
Adjustments:		
Interest expense	(108)	3,453
Property and equipment depreciation	17	20
Amortization of intangible assets	430	484
Share-based compensation expense	387	529
Non-GAAP EBITDA	(8,766)	(7,665)
Non-GAAP Recurring EBITDA	$ (8,766)	(7,665)

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: Tuesday, August 13, 2024, 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 prescription 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, a Jaguar family company, 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 the Jaguar Health Family of Companies

Jaguar Health, Inc. (Jaguar) is a commercial stage pharmaceuticals company focused on developing novel proprietary prescription medicines sustainably derived from plants from rainforest areas for people and animals with gastrointestinal distress, specifically associated with overactive bowel, which includes symptoms such as chronic debilitating diarrhea, urgency, bowel incontinence, and cramping pain. Jaguar family company Napo Pharmaceuticals (Napo) focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo's crofelemer is FDA-approved under the brand name Mytesi® for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Jaguar family company Napo Therapeutics is an Italian corporation Jaguar established in Milan, Italy in 2021 focused on expanding crofelemer access in Europe and specifically for orphan and/or rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp. that emerged from Jaguar's Entheogen Therapeutics Initiative (ETI), is focused on developing novel prescription medicines derived from plants for mental health indications.

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

Visit the *Make Cancer Less Shitty* patient advocacy program at makecancerlessshitty.com and on X, Facebook & Instagram

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.

About Gelclair®

INDICATIONS

GELCLAIR® has a mechanical action indicated for the management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiation therapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. Also, indicated for diffuse aphthous ulcers.

IMPORTANT SAFETY INFORMATION

- Do not use GELCLAIR if there is a known or suspected hypersensitivity to any of its ingredients.
- No adverse effects have been reported in clinical trials, although postmarketing reports have included infrequent complaints of burning sensation in the mouth.
- If GELCLAIR is swallowed accidentally, no adverse effects are anticipated.
- If no improvement is seen within 7 days, a physician should be consulted.

You are encouraged to report negative side effects of prescription medical products to the FDA.
Visit www.fda.gov/safety/medwatch, call 1-855-273-0468 or fill-in the form at this link.

Please see full Prescribing Information at:
https://gelclair.com/assets/Gelclair_PI_Decemeber_2021.pdf

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 Jaguar's expectation that it will host an investor webcast on August 13, 2024, the Company's expectation that it will begin the commercial launch in October 2024 for Gelclair, Jaguar's expectation that the Company may engage in discussions with the FDA after evaluating the significance of the clinical outcome signals from the OnTarget trial, Jaguar's expectation that an approval pathway may exist to make crofelemer available to breast and lung cancer patients for CTD, the Company's expectation that results from investigator-initiated and IND proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure will be available by the end of 2024 and throughout 2025, and the Company's expectation, that in accordance with the guidelines of specific EU countries, published data from clinical investigations of crofelemer in MVID and SBS could support early patient access to crofelemer for these conditions in those countries. 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.

[1] https://www.who.int/news-room/fact-sheets/detail/breast-cancer
[2] https://www.wcrf.org/cancer-trends/lung-cancer-statistics/

Source: Jaguar Health, Inc.

Contact:
hello@jaguar.health

Jaguar-JAGX