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 9, 2019**

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.)

201 Mission Street, Suite 2375 **San Francisco, California** (Address of principal executive offices)	**94105** (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 x

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. x

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 14, 2019, Jaguar Health, Inc. (the "Company") issued a press release announcing second quarter 2019 results and current and planned commercial, educational and product development activities related to Mytesi (crofelemer), the Company's first-in-class, FDA-approved anti-secretory human prescription drug. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information in this 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) Departure of Chief Financial Officer

On August 9, 2019, Ms. Karen S. Wright notified the Company of her decision to resign as Chief Financial Officer and Treasurer of the Company, effective immediately.

(c) Appointment of Chief Accounting Officer.

On August 13, 2019, the Company's Board of Directors (the "Board") appointed Carol R. Lizak, age 55, as the Company's Chief Accounting Officer, effective immediately. Ms. Lizak, who currently serves as Vice President of Finance and Corporate Controller of the Company, will assume the duties of the Company's principal financial officer and principal accounting officer. Ms. Lizak joined the Company in May 2019 as Vice President of Finance and Corporate Controller. Prior to joining the Company, Ms. Lizak served as Senior Director and Corporate Controller of Zosano Pharma Corporation from November 2017 to January 2019, as Controller of Quantum Secure, Inc. from July 2016 to August 2017, and as Executive Director, Corporate Controller of Alexza Pharmaceuticals, Inc. from September 2014 to July 2016. Prior thereto, she spent nine years as Corporate Controller of a subsidiary of HID Global Corporation. There are no reportable family relationships or related party transactions (as defined in Item 404(a) of Regulation S-K) involving the Company and Ms. Lizak.

There have been no new compensatory or other material arrangements entered into, or modifications to existing compensatory arrangements entered into, nor were there any grants or awards made to, Ms. Lizak in connection with her appointment as the Company's Chief Accounting Officer. Ms. Lizak will continue to be compensated pursuant to her existing compensatory arrangements until such time as the Compensation Committee of the Board determines the appropriate compensation for her new role at its next regular meeting. Ms. Lizak's current compensatory arrangements include her continued eligibility for annual or other grants under the Company's 2014 Stock Incentive Plan. Under the terms of an employment offer letter from the Company to Ms. Lizak, Ms. Lizak **is** entitled to an initial base salary of $225,000 and eligible to receive an annual target bonus of 30% of her base salary and participate in the employee benefit plans that the Company offers to its other employees.

In connection with her appointment, the Company expects that Ms. Lizak will enter into the Company's standard indemnification agreement which requires the Company, under the circumstances and to the extent provided for therein, to indemnify Ms. Lizak to the fullest extent permitted by applicable law against certain expenses and other amounts incurred by Ms. Lizak as a result of Ms. Lizak being made a party to certain actions, suits, proceedings and other actions by reason of the fact that Ms. Lizak is or was a director, officer, employee, consultant, agent or fiduciary of the Company.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 14, 2019.

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: Chief Executive Officer & President

Date: August 14, 2019

Jaguar Health, Inc. Reports 2019 Second Quarter Financial Results

Mytesi® Net Sales and Gross Mytesi® Sales Grew 102% and 93%, Respectively, in Q2 2019 Compared to Q2 2018

SAN FRANCISCO, CA / August 14, 2019 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis, today reported second quarter 2019 results and issued the following highlights.

Financial Highlights

(In thousands)	Q2 2019	Q2 2018	% Change
Product revenue	1,706	884	93%
Gross product sales (non-GAAP measure)	2,371	1,193	99%
Collaboration income	—	—	—
Loss from operations	(10,622)	(7,079)	50%
Net loss	(16,721)	(7,657)	118%
Net loss attributable to common shareholders	(16,721)	(8,652)	93%

2019 Second Quarter Company Financial Results

- **Mytesi Product Revenue:** Mytesi net sales in the second quarter of 2019 were approximately $1.7 million, and Mytesi gross sales (non-GAAP measure) were approximately $2.4 million, an increase of 102% and 93% of net sales and gross sales, respectively, over the second quarter of 2018. Total Mytesi prescription volume, which is the combination of new prescriptions and refills, as reported by IQVIA, a provider of analytics, technology solutions and contract research services to the life sciences industry, increased 78% in the second quarter of 2019 over the second quarter of 2018, and grew 11% in the second quarter of 2019 versus the first quarter of 2019. Jaguar's animal-related sales for the second quarter of 2019 and 2018 were $21K and $30K, respectively, due to minimal marketing and sales efforts.

- **Operating Expenses:** The total operating expense for the quarter ended June 30, 2019 was $12.3 million as compared to $8.0 million for the quarter ended June 30, 2018, a 54% increase or a $4.3 million increase quarter over quarter. The 54% increase in total operating expense quarter over quarter is a combination of the $0.7 million increase in cost of product revenue, less than $0.1 million increase in Research and Development, $0.1 million increase in General and Administrative expense, and $4.0 million impairment loss on indefinite-lived intangible assets, offset by a $0.5 million decrease in Marketing and Sales.

- **Cost of Product Revenue:** The total Cost of Product Revenue for the quarters ended June 30, 2019 and June 30, 2018 was $1.3 million compared to $0.6 million, respectively. The increase of $0.7 million was a direct result of an increase of Mytesi sales, equipment maintenance costs, and non-conforming inventory that was written off.

- **Research and Development**: The Research and Development expense was $1.7 million for the quarter ended June 30, 2019 compared to $1.6 million for the quarter ended June 30, 2018. The increase of $0.1 million in R&D for the second quarter of 2019 was primarily due to a $0.1 million investment in commercial manufacturing, increase of $0.1 million in clinical trial consulting, offset by a decrease of $0.1 million in personnel and related benefits.

- **Sales and Marketing**: The Sales and Marketing expense was $2.2 million for the three months ended June 30, 2019 as compared to $2.7 million for the quarter ended June 30, 2018. The major difference between the two periods is a decrease in marketing programs and advertising costs for Mytesi. Direct marketing and sales expense decreased $0.6 million, other expenses decreased $0.3 million largely due to decrease in advertising costs, offset by a $0.4 million increase in personnel and related benefits due to the expansion of our sales and marketing headcount in support of Mytesi.

- **General and Administrative**: The General and Administrative expense for the quarter ended June 30, 2019 totaled $3.2 million compared to $3.1 million for the quarter ended June 30, 2018, a 3% increase quarter over quarter. The G&A spend of $3.2 million for the quarter ended June 30, 2019 consisted of the continued G&A support functions such as audit, legal, compliance, accounting, human resources, IT, public company expense, financing and facilities. The increase in G&A quarter over quarter was primarily due to third-party consulting fees for the support of public company regulatory reporting and financing activities, and an increase in non-cash stock-based compensation expense.

- **Loss from Operations:** For the second quarter of 2019, the net loss from operations was $10.6 million, compared to a net loss of $7.1 million in the second quarter of 2018. This was a 50% increase in operating loss quarter over quarter due to a net increase in total net revenue of $0.8 million offset by a $4.3 million increase in operating expense. The $4.3 million increase in operating expenses includes a $4.0 million impairment loss on indefinite-lived intangible assets and $0.3 million increase in other operating expenses.

- **Net Loss:** For the second quarter of 2019, the net loss was $16.7 million compared to $7.7 million for the second quarter of 2018. The second quarter of 2019 includes a $2.7 million loss on extinguishment of debt, increased interest expense of $2.9 million, and $4.0 million impairment loss on indefinite-lived intangible assets, offset by a decrease in loss from operations of $0.5 million and a gain on change in fair value of warrants, derivative liability and conversion of option liability of $0.1 million.

- **Net Loss Attributable to Common Shareholders:** For the second quarter of 2019, the net loss attributable to common shareholders was $16.7 million compared to $8.7 million for the second quarter of 2018. The second quarter of 2018 includes a deemed dividend attributable to preferred stockholders in the amount of $1.0 million, which represents the accretion of the discount on the Series A preferred shares in the second quarter of 2018 due to a beneficial conversion in the transaction. The deemed dividend charge is reflected below net loss to arrive at net loss attributable to common stockholders on the Company's condensed consolidated statement of operations, resulting in a net increase in loss attributable to common stockholders of $8.0 million.

Income Tax Rate: The effective tax rate for the second quarter of 2019 and 2018 was zero percent, primarily as a result of the estimated tax loss for the year and a full valuation allowance.

Mytesi Commercial and Promotional Activities Updates

- As announced earlier this month, Indena S.p.A., one of the two contract manufacturers of the active pharmaceutical ingredient (API) in crofelemer, has successfully developed and implemented an improved crofelemer manufacturing process, effectively increasing yield and realizing reduced cost through increased manufacturing efficiencies while retaining the same phytochemical profile without compromising product quality, safety, purity and efficacy. The modified process allows Napo Pharmaceuticals, Inc. ("Napo"), the Company's wholly-owned, human-health focused subsidiary, to support the increased crofelemer manufacturing demand expected if crofelemer receives FDA approval for new indications, including approval for the symptomatic relief of cancer therapy-related diarrhea (CTD).

- As announced on August 7, 2019, Napo has launched a refreshed version of the Mytesi.com website. The site has been optimized to provide a more patient-centric user experience and help people living with HIV locate resources that can help them learn about and obtain access to Mytesi. These resources include a patient discussion guide, the Mytesi Copay Savings Card, and a new consumer-friendly infographic that illustrates how Mytesi works. Content has also been added to the site covering the history of Mytesi's plant-based source and Napo's ongoing sustainability program. Traffic to the updated website is being driven by Napo's ongoing digital and social media marketing efforts.

- On July 26, 2019, as previously announced, Napo hosted a Facebook Live conversation between Josh Robbins and Murray Penner, who serves as Executive Director, North America for the Prevention Access Campaign. The discussion can be viewed on Napo's Facebook page, facebook.com/napopharma. Prevention Access Campaign is a health equity initiative to end the dual epidemics of HIV and HIV-related stigma by empowering people with and vulnerable to HIV with accurate and meaningful information about their social, sexual, and reproductive health. This live discussion was the second event in the monthly "HIV Community Conversations presented by Napo Pharmaceuticals" series, which brings key advocates and activists in the HIV community together to talk about the issues that matter most to people living with and affected by HIV/AIDS. The series premiered this past June with a Facebook Live conversation about HIV Long-Term Survivor's Day between Josh Robbins and Tez Anderson, the founder of Let's Kick ASS-AIDS Survivor Syndrome, a grassroots movement empowering HIV Long-Term Survivors to thrive. Josh Robbins is an HIV/AIDS activist, blogger, writer, social media marketer, and a consultant to Napo. His work has been featured on The Advocate, Human Rights Campaign, Healthline, POZ and a myriad of additional publications.

Human Pipeline Updates

- As announced last month, Napo has agreed in principle to support a U.S.-based university's request to begin an institution-initiated clinical research study. The university will perform an open-label pilot study to evaluate the safety and effectiveness of crofelemer for treatment of chronic idiopathic diarrhea in non-HIV patients (the "Study"). Chronic idiopathic diarrhea is a common complaint of patients presenting to family practitioners and internists, and is one of the most common reasons for referral to gastroenterologists. It is estimated that the prevalence of chronic idiopathic diarrhea in developed countries (including the U.S.) is approximately 3-5%. It has a significant negative effect on health-related quality of life and causes a high economic burden on patients and society. The 2012 American Gastroenterological Association Burden of Illness study showed that the estimated annual direct and indirect costs associated with chronic idiopathic diarrhea is up to $524 million per year and $136 million per year, respectively. The planned Study, which has an expected duration of one year, will assess the efficacy of crofelemer during a 28-day treatment period in adult, non-HIV patients with chronic idiopathic diarrhea.

- In support of the Company's focus on the potential CTD indication, an ongoing investigator initiated trial (IIT) of crofelemer is underway:

    - Enrollment is ongoing for the HALT-D study in breast cancer patients receiving regimens containing Herceptin and Perjeta. Interim results from the study, which is sponsored by Georgetown University and funded by Genentech, a member of the Roche Group, are expected to be read out in the third quarter of 2019. The study's primary endpoint has an 81% power to detect a 40% difference in the percent and/or number of patients experiencing any grade of diarrhea for two consecutive days at a p value of 0.1. (The statistical power of a study, sometimes referred to as a study's sensitivity, is a measure of how likely the study is to distinguish an actual effect from one of chance). For the sake of clarity, the estimates of the percent of patients experiencing such diarrhea is postulated to be 60% in the placebo patients and 20% in the study's crofelemer-treated arms. The interim analysis, which is being conducted to ensure that the study has a chance to ultimately achieve the primary endpoint, will determine whether or not the study has a power of at least 20% to detect such a difference when 23 patients have been randomized. The interim analysis will be deemed positive and the trial will continue if the power is 20% or greater. The final study report is expected to be available in the first quarter of 2020.

    - Additionally, as announced June 18, 2019, a nonclinical pilot study to evaluate the severity of diarrhea caused by a specified dose of a specific tyrosine kinase inhibitor (TKI) in healthy dogs has been completed. A primary nonclinical study, which began last month, is underway to evaluate the effects of crofelemer on diarrhea induced in healthy dogs by the same TKI. Both studies, which are being funded by a third-party cancer agent manufacturer, are intended to provide additional scientific rationale and support for the use of crofelemer in providing symptomatic relief of noninfectious diarrhea in human patients receiving TKI-and/or-other targeted cancer therapy containing regimens in future human clinical investigations.

- The Company is planning to initiate formulation and regulatory activities to support an investigational new drug application for lechlemer, Napo's second-generation anti-secretory drug product candidate, for the indication of cholera along with efforts to pursue a tropical disease priority review voucher from FDA for this potential indication. Lechlemer, which is a drug candidate under the botanical guidance of the FDA, is approximately one-tenth the price to manufacture as crofelemer and therefore more economically feasible than Mytesi for marketing in resource-constrained countries. Priority review vouchers are granted by the FDA to drug developers as an incentive to develop treatments for neglected diseases and rare pediatric diseases. These vouchers are transferable and, in recent transactions by other companies, have sold for $67 million to $350 million, because they provide third-party purchasers a six-month priority review with the FDA for any product candidate in development.

  As announced on June 11, 2019, Napo will receive preclinical services from the National Institute of Allergy and Infectious Diseases ("NIAID") to support the development of lechlemer.

  According to the Centers for Disease Control and Prevention of the U.S. Department of Health & Human Services, cholera is an acute diarrheal illness caused by infection of the intestine with the bacterium *Vibrio cholerae*. An estimated 3-5 million cholera cases and more than 100,000 cholera-related deaths occur each year around the world. The infection is often mild or without symptoms, but can sometimes be severe. Approximately one in 10 (5-10%) of infected persons will have severe disease characterized by profuse watery diarrhea, vomiting, and leg cramps. In these people, rapid loss of body fluids leads to dehydration and shock. Without treatment, death can occur within hours. At this time, the largest cholera outbreak in recorded history is occurring in Yemen.

- As previously announced, Napo has approved a request for an investigator-initiated trial of crofelemer for idiopathic/functional diarrhea, and the Company's pipeline of potential follow-on indications also includes supportive care for diarrhea related to inflammatory bowel disease. Diarrhea stemming from irritable bowel syndrome is another target indication for crofelemer, for which Jaguar has completed two phase 2 studies. The chronic safety of crofelemer is an important distinguishing attribute for these possible indications.

- As previously announced, Napo has accepted a request for support submitted by Dr. Mohamad Miqdady, Chief of Pediatric Gastroenterology, Hepatology and Nutrition at Sheikh Khalifa Medical City (SKMC) in Abu Dhabi, for an investigator-initiated trial of crofelemer for congenital diarrheal disorders (CDDs) in children. Enrollment for this trial is planned in the second half of 2019 as the Company completes stability studies for a pediatric liquid formulation. CDDs are a group of rare, chronic intestinal channel diseases, occurring in early infancy, that are characterized by severe, lifelong diarrhea and a lifelong need for nutritional intake either parenterally or with a feeding tube. CDDs are related to specific genetic defects inherited as autosomal recessive traits, and the incidence of CDDs is much more prevalent in regions where consanguineous marriage is part of the culture. CDDs are directly associated with serious secondary conditions including dehydration, metabolic acidosis, and failure to thrive, prompting the need for immediate therapy to prevent death and limit lifelong disability.

Canalevia™ Updates

- As announced on June 19, 2019, the Target Animal Safety technical section of the Company's application for conditional approval of Canalevia™ (crofelemer delayed-release tablets) for chemotherapy-induced diarrhea (CID) in dogs is expected to be submitted to the U.S. Food & Drug Administration's Center for Veterinary Medicine in the third quarter of 2019. This technical section, which is the last of the four technical sections Jaguar is required to file for Canalevia for the proposed CID indication, will contain data from a 2017 target animal safety study indicating that the NOAEL (no-observed-adverse-effect level) of Canalevia in dogs is approximately six times greater than previously demonstrated, and that Canalevia is also safe for use in puppies. With receipt of conditional approval for this indication, the Company expects to conduct the commercial launch of Canalevia for CID in dogs in the first half of 2020.

Note Regarding Use of Non-GAAP Measures

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 is 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.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in 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.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit 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 increased crofelemer manufacturing demand will result if crofelemer receives FDA approval for new indications, including approval for the symptomatic relief of CTD, the expectation that a U.S.-based university will perform an open-label pilot study to evaluate the safety and effectiveness of crofelemer for treatment of chronic idiopathic diarrhea in non-HIV patients, the expectation that the interim results of the HALT-D trial will be read out in the third quarter of 2019 and that the final study report will be available in the first quarter of 2020, the Company’s plan to initiate formulation and regulatory activities to support an investigational new drug application for lechlemer for the indication of cholera along with efforts to pursue a tropical disease priority review voucher from FDA for this potential indication, the belief that enrollment will begin in the second half of 2019 for an investigator-initiated trial of crofelemer for CDDs in children, the expectation that the Target Animal Safety technical section of the Company’s application for conditional approval of Canalevia for CID in dogs will be submitted to the U.S. FDA’s Center for Veterinary Medicine in the third quarter of 2019, and the expectation that, with receipt of conditional approval for this indication, the Company will conduct the commercial launch of Canalevia for CID in dogs in the first half of 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 a number of 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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