

**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 14, 2019**

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

001-36714

(Commission File Number)

46-2956775

(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):

- 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

Common Stock, Par Value \$0.0001 Per Share

Trading Symbol(s)

JAGX

Name of each exchange on which registered

The NASDAQ Capital Market

Item 2.02 Results of Operations and Financial Conditions

On November 14, 2019, Jaguar Health, Inc. (the “Company”) issued a press release announcing third quarter 2019 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 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: November 15, 2019



Jaguar Health, Inc. Reports 2019 Third Quarter Financial Results

Reminder: Company to Host Investor Call Today at 9 a.m. Eastern Regarding Interim Analysis of HALT-D Study of Mytesi (Crofelemer) for Prevention of Diarrhea in Breast Cancer Patients, Q3 Financials & Business Updates

SAN FRANCISCO, CA / November 14, 2019 / Jaguar Health, Inc. (NASDAQ: JAGX) (“Jaguar” or the “Company”) today reported third quarter 2019 results and issued the following highlights.

- Net product sales of approximately \$1.0 million resulting from product shipments less rebates and discounts decreased by a non-recurring and immaterial correcting adjustment in prior period of approximately \$0.34 million related to product donation. GAAP net sales in the third quarter of 2019 are 14% lower as compared to the third quarter of 2018, which totaled \$1.1 million. Adjusted Mytesi® gross and net sales of \$1.9 million and \$1.3 million, respectively, excluding the non-recurring adjustments in the third quarter of 2019 resulted in an increase of 18% in gross sales (non-GAAP) in the third quarter of 2019 as compared to the third quarter of 2018, which totaled approximately \$1.6 million, and an increase of 16% in net sales (non-GAAP) in third quarter of 2019 as compared to the third quarter of 2018, which totaled approximately \$1.1 million.
- Total Mytesi prescription volume, which is the combination of new prescriptions and refills, increased 20% in the third quarter of 2019 over the third quarter of 2018.
- Net product sales for the period of January through September 2019 totaled approximately \$4.3 million, which is an increase of approximately 61% over net product sales for the period of January through September 2018, which totaled approximately \$2.6 million. Gross product sales for the period of January through September 2019 totaled approximately \$6.1 million, which is an increase of approximately 68% over gross product sales for the period of January through September 2018, which totaled approximately \$3.6 million.

“As we pursue development of pipeline indications for Mytesi, our goal is to optimize efficiency in the commercialization of Mytesi for the current HIV indication. We are pleased with the continued prescribing growth in Q3, in light of the recent approximately 50% decrease in the size of our Mytesi sales force and the recent realignment to focus on what we call ‘super targets’ - family practitioners, general practitioners, internal medicine doctors, nurse practitioners, and physician assistants who were already prescribing anti-motility and anti-retroviral drugs and therefore were already engaging in conversations about diarrhea with their patients living with HIV/AIDS,” Lisa Conte, Jaguar’s president and CEO commented.”

Financial Highlights (in thousands, except per share amounts)	Three Months Ended September 30,		\$ change	% change
	2019	2018		
Net product revenue	\$ 973	\$ 1,132	(159)	-14%
Loss from operations	\$ (6,727)	\$ (6,506)	(221)	3%
Net loss and comprehensive loss	\$ (7,555)	\$ (6,138)	(1,417)	23%
Net loss attributable to common shareholders	\$ (11,683)	\$ (6,138)	(5,545)	90%
Net loss per share, basic and diluted	\$ (2.00)	\$ (37.77)		

	Three Months Ended		\$ change	% change
	September 30,			
	2019	2018		
Net product sales	\$ 973	\$ 1,132	(159)	-14%
Adjustment to net product sales due to donations	337	—		
Net product sales (non-GAAP)	\$ 1,310	\$ 1,132	178	16%
Gross product sales (non-GAAP)	\$ 1,913	\$ 1,617	296	18%

- In July 2019, the Company closed an underwritten public offering of units for gross proceeds of \$16.5 million, or net proceeds of \$14.6 million after deducting fees and expenses.
- Between May and September 2019, the Company reduced debt incurred to effect the 2017 merger of Jaguar Animal Health, Inc. and Napo Pharmaceuticals, Inc. (“Napo”) from approximately \$10.5 million to approximately \$6.7 million through issuance of common stock under exchange agreements.
- In September 2019, the Company reduced the exercise price of the Series 1 Warrants issued in July 2019 from \$2.00 per share to \$1.40 per share.
- When the stock closed at \$1.04 and \$0.79 on October 3, 2019 and October 9, 2019, respectively, a Series 1 warrant holder exercised its 1,250,000 Series 1 Warrants for common stock, with the Company receiving gross proceeds of approximately \$1.8 million. In consideration of this exercise of Series 1 Warrants, the Company issued 63 shares of Series B-1 Convertible Preferred Stock (convertible into 630,063 shares of the Company’s common stock) to the exercising Series 1 warrant holder.

2019 Third Quarter Company Financial Results:

- **Operating Expenses:** The total operating expense for the third quarter of 2019 was \$7.1 million as compared to \$7.6 million for the same period in 2018, an 8% decrease or a \$0.5 million decrease quarter over quarter. The 8% decrease in total operating expenses quarter over quarter is a combination of the \$0.2 million decrease in Research and Development, \$1.0 million decrease in sales and marketing, offset by a \$0.2 million increase in cost of product revenue and a \$0.4 million increase in General and Administrative expenses, primarily associated with the financing activities in the third quarter of 2019 and an increase in non-cash share-based compensation expense.
 - **Cost of Product Revenue:** The total cost of product revenue for the quarters ended September 30, 2019 and September 30, 2018 was \$0.9 million compared to \$0.7 million, respectively. The increase of Mytesi sales contributed to the increase in the costs of goods sold. However, there were non-recurring items recorded in the third quarter of 2019, such as a campaign batch cancellation fee of \$0.2 million, \$0.2 million of fees from the Company’s former distributor which is under discussion, and offset by the reversal of \$0.2 million of accrued royalty related to the termination of a royalty agreement.
 - **Research and Development:** The Research and Development expense was \$1.3 million for the quarter ended September 30, 2019 compared to \$1.5 million for the quarter ended September 30, 2018. The decrease of \$0.2 million in Research and Development for the third quarter of 2019 was due to a decrease of \$0.2 million in personnel and related benefits, a \$0.2 million decrease in consulting, formulation and regulatory fees, offset by an increase in non-cash share-based compensation expense of \$0.2 million related to the stock options granted in the third quarter of 2019 and a slight increase from the Company’s clinical trials.
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- **Sales and Marketing:** The Sales and Marketing expense was \$1.7 million for the three months ended September 30, 2019 as compared to \$2.7 million for the quarter ended September 30, 2018. The decrease of \$1.0 million was attributed to the \$0.4 million decrease in direct marketing and advertising costs for Mytesi, a decrease in the number of sales personnel of approximately 50%, and a decrease in related benefits by \$0.3 million as the Company focuses on consolidation of territories, refined targeting of health care providers, and simultaneously focuses on pipeline development, and a \$0.3 million decrease in consulting. From a sales strategy perspective, as previously announced, the core focus at Napo is now on what the Company calls “super targets”. Approximately 72% of the top Mytesi prescribers are primary care providers - family practitioners, general practitioners, internal medicine doctors, nurse practitioners and physician assistants - who are already prescribing anti-motility and anti-retroviral drugs and are therefore already engaging in conversations about diarrhea with their patients living with HIV/AIDS - and this segment has contributed to growth.
 - **General and Administrative:** The General and Administrative (G&A) expense for the quarter ended September 30, 2019 totaled \$3.1 million compared to \$2.7 million for the quarter ended September 30, 2018. The G&A 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 of \$0.4 million or 15% quarter over quarter was primarily due to the \$0.3 million increase in the non-cash share-based compensation expense related to the stock options granted during the third quarter of 2019, \$0.1 million related to the public company regulatory reporting and financing activities, and accounting fees of \$0.1 million.
 - **Loss from Operations:** For the third quarter of 2019, the net loss from operations was \$6.7 million, compared to a net loss of \$6.5 million in the third quarter of 2018. This was a \$0.2 million or 3% decrease in operating loss quarter over quarter due to the net decrease in total net revenue of \$0.2 million offset by a \$0.6 million decrease in operating expenses. A loss of \$0.6 million was recorded in the third quarter of 2019 due to the termination of a royalty agreement and none was recorded in the same quarter of 2018.
 - **Net Loss and Comprehensive Loss:** For the third quarter of 2019, the net loss was \$7.6 million compared to \$6.1 million for the third quarter of 2018. The third quarter of 2019 includes a \$0.3 million loss on extinguishment of debt, increased interest expense of \$0.5 million, \$0.6 million loss due to the royalty settlement, offset by a decrease in loss from operations of \$0.6 million and a gain of \$0.8 million on change in fair value of warrants, derivative liability and conversion of option liability.
 - **Net Loss Attributable to Common Shareholders:** For the third quarter of 2019, the net loss attributable to common shareholders was \$11.7 million compared to \$6.1 million for the third quarter of 2018. There were two deemed dividends recorded in the third quarter of 2019, whereas there were none recorded during the third quarter of 2018.
 - **Income Tax Rate:** The effective tax rate for the third 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. There was a \$10,000 tax expense recorded in the third quarter of 2019 related to the tax filing for our subsidiary.
 - **Non-GAAP EBITDA** for the third quarters of 2019 and 2018 was a net loss of \$4.7 million and \$4.1 million, respectively. Excluding the out-of-period correcting and immaterial adjustment in product sales related to a product donation recorded in the third quarter of 2019, non-recurring fees from a canceled campaign batch and fees from our former distributor which is under discussion, and the reversal of accrued royalty, non-GAAP Recurring EBITDA was \$4.1 million for the third quarters of 2019 and 2018.
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	Three Months Ended September 30,	
	2019	2018
Net loss and comprehensive loss	\$ (7,555)	\$ (6,138)
Adjustments:		
Interest expense and other expense, net	1,353	872
Property and equipment	10	15
Amortization of intangible assets	422	422
Share-based compensation expense	1,100	680
Income Taxes	10	—
Non-GAAP EBITDA	\$ (4,660)	\$ (4,149)
Adjustment to gross product revenue due to donations	337	—
Campaign batch cancelation fee	161	—
Distribution fees from former distributor (under discussions)	227	—
Reversal of accrued royalty due to termination of royalty agreement	(189)	—
Non-GAAP recurring EBITDA	\$ (4,124)	\$ (4,149)

Other Key Updates, as Announced This Week:

- The interim analysis requirement has been met for the Phase 2 HALT-D study: Georgetown University's Data Safety Monitoring Committee ("DSMC") has reviewed the interim analysis for futility for the third-party, investigator-initiated Phase 2 HALT-D study evaluating the effectiveness of Mytesi (crofelemer) for symptomatic relief in HER2 positive breast cancer patients receiving chemotherapy with trastuzumab, pertuzumab, and docetaxel or paclitaxel (THP) or trastuzumab, pertuzumab, carboplatin, and docetaxel (TCHP). The DSMC has notified the Principal Investigator that the study is allowed to enroll to completion. Enrollment in the study now exceeds 85%, and the treatment period for each patient is 3 months. With this important study milestone, 'Positive Interim Results', as defined in the July 2019 Company prospectus, has been achieved
- The Company has named Ian Wendt, an executive who has held commercial leadership roles across sales, marketing and operations at some of the largest brands in the pharmaceutical industry during his 25 years in the sector, to the role of vice president, commercial strategy for both Jaguar and Napo.

Company announcements regarding other third-quarter 2019 pipeline development, commercial, and business development news can be found on the investor relations section of Jaguar's website.

Note Regarding Use of Non-GAAP Measures

The Company supplements its condensed consolidated financial statements presented on a GAAP basis by providing gross sales, non-GAAP EBITDA and non-GAAP recurring EBITDA, which are considered non-GAAP under applicable SEC rules. Jaguar believes that the disclosure items of these non-GAAP measures provide investors with additional information that reflects the basis upon which Company management assesses and operates the business. These non-GAAP financial measures are not in accordance with GAAP and should not be viewed in isolation or as substitutes for GAAP net sales and GAAP net loss and are not substitutes for, or superior to, measures of financial performance in conformity with GAAP.

Gross sales percentages 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.

The Company defines non-GAAP EBITDA as net loss before interest expense and other expense, property and equipment, amortization of intangible assets, share-based compensation expense and provision for or benefit from income taxes. The Company defines non-GAAP Recurring EBITDA as non-GAAP EBITDA adjusted for certain non-recurring revenues and expenses, such as a non-recurring adjustment related to a donation. Company management believes that non-GAAP EBITDA and non-GAAP Recurring EBITDA are meaningful indicators of Jaguar's performance and provide useful information to investors regarding the Company's results of operations and financial condition.

Dial-In Instructions for Conference Call

When: November 14, 2019 at 9 a.m. Eastern Time

Dial-in (US Toll Free): 800-289-0438

Dial-in (International): 323-794-2423

Conference ID number: 3702255

Live webcast on the investor relations section of Jaguar's website ([click here](#))

Replay Instructions

Dial-in (US Toll Free): 844-512-2921

Dial-in (International): 412-317-6671

Replay Pin Number: 3702255

Replay of the webcast on the investor relations section of Jaguar's website ([click here](#))

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 the Company will host an investor call November 14, 2019. 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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