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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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, 2018**

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**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**

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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  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

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**Item 2.02 Results of Operations and Financial Conditions.**

On November 14, 2018, Jaguar Health, Inc. (“Jaguar” or the “Company”) issued a press release announcing third quarter 2018 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.

As previously announced, the Company will host a conference call on November 15, 2018 at 8:00 am ET, during which members of its senior management team will discuss these same topics. The call will be open to all interested investors through a live audio web broadcast via the Internet at: <http://pr.report/9lHaF3gL> and the Company’s website under “Events and Presentations”. The call also will be available to investors and analysts by dialing toll-free: 800-289-0438 or international: 323-794-2423. The conference ID number is 3492327. A replay of the webcast can also be accessed through the Company’s website.

The information in this Form 8-K and the exhibit attached 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	<a href="#">Press Release, dated November 14, 2018.</a>

**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/ Karen S. Wright

Name: Karen S. Wright

Title: Chief Financial Officer

Date: November 14, 2018



## Jaguar Health, Inc. Reports Third-Quarter 2018 Results

**Mytesi® Gross Sales and Net Sales Grew 36% and 28%, Respectively, in the Third Quarter of 2018 Compared to the Second Quarter of 2018**

**Company to Host Conference Call Thursday, November 15, 2018 at 8:00 a.m. Eastern Time to Review Third-Quarter Results and Provide Updates Regarding Mytesi® Commercial, Educational & Product Development Activities**

**SAN FRANCISCO, CA / November 14, 2018** / 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 third quarter 2018 results and issued the following highlights.

### Financial Highlights

(In thousands except for percentages)	Q3 18	Q3 17	% Change
Gross product sales	\$ 1,617	\$ 473	242%
Net product revenue	\$ 1,132	\$ 446	154%
Collaboration income	\$ —	\$ 655	-100%
Net income (loss) from operations	\$ (6,506)	\$ (7,340)	11%

### Third-Quarter 2018 Company Financial Results

- Mytesi Net Product Revenue:** Mytesi gross sales in the third quarter of 2018 were approximately \$1.6 million, and Mytesi net sales were approximately \$1.1 million, an increase of 242% and 154% of gross and net sales, respectively, over the third quarter of 2017. In 2018, the Company’s animal product research and development efforts have been intentionally minimal, and Jaguar’s animal-related sales have also been minimal.
- Operating Expenses:** The total operating expense for the quarter ended September 30, 2018 was \$7.6 million. The human health segment operating expense was \$5.3 million, and the parent company segment operating expense was \$2.3 million. The operating expense for the quarter ended September 30, 2017 was \$8.4 million, which was \$5.4 million for the human health segment and \$3.0 million for the parent company segment operating expense. The 9.8% decrease in total operating expense quarter over quarter is a combination of a \$2.8 million increase in operational expense in the third quarter of 2018 offset by a \$3.6 million goodwill impairment charge in the third quarter of 2017 as a result of the Napo-Jaguar merger.
- The R&D expense was \$1.5 million for the quarter ended September 30, 2018 compared to \$0.9 million for the quarter ended September 30, 2017. The human health segment incurred expenses of \$0.9 million for the quarter ended September 30, 2018 and the animal segment incurred expenses of \$0.6 million in the same quarter. The total R&D expense for the quarter ended September 30, 2017 consisted of animal health clinical trials and regulatory expenses for the development of Canalevia™ for the possible indication of chemotherapy-induced diarrhea (CID) in dogs. The 67% increase of R&D expenses quarter over quarter represents the Company’s investment in commercial manufacturing serialization requirements and enhanced manufacturing process improvements the Company is developing to reduce the cost of revenue and prepare for future pipeline projects.

- The sales and marketing expense for the quarter ended September 30, 2018 was \$2.7 million as compared to \$0.7 million for the quarter ended September 30, 2017. The \$2.0 million increase represents an approximately \$0.8 million increase in Mytesi promotional spend and a \$1.2 million increase in spend on the formation of a salesforce and commercial resources for the commercial operations of Mytesi.
- The general and administrative expense for the quarter ended September 30, 2018 totaled \$2.7 million compared to \$3.1 million for the quarter ended September 30, 2017, a 13% decrease quarter over quarter. The G&A spend of \$2.7 million for the quarter ended September 30, 2018 consisted of the continued G&A support functions for the human commercial entity such as audit, legal, accounting, human resources, IT, public company expense, and facilities. The decrease in G&A quarter over quarter was primarily due to a decrease in legal fees of \$0.6 million offset by an increase of third party consulting fees of \$0.3 million for the support of public company regulatory reporting and financing activities.
- **Operating Income (Loss) from Operations:** For the third quarter of 2018, net loss from operations was \$6.5 million, compared to \$7.3 million in the third quarter of 2017. This was a 11% decrease in operating loss from operations quarter over quarter due to a 154% increase in net product revenue offset by a 13% decrease in operating expense.
- **Other Income (expense), net:** A \$1.2 million settlement from the Napo-Valeant purchase agreement executed in March 2016 was received in the third quarter of 2018 and recorded as a gain on settlement.
- **Income Tax Rate:** The forecasted effective tax rate for the three months ended September 30, 2018 and 2017, respectively was zero percent, primarily as a result of the estimated tax loss for the year and the change in valuation allowance.

#### Mytesi Sales Updates

- Mytesi total prescription volume, which is the combination of new prescriptions and refills, grew 36% in the third quarter of this year versus the second quarter, and increased 122% in the third quarter versus the same period last year.
  - Using IQVIA data to compare the third quarter of this year to the second quarter, there was a 36% increase in healthcare practitioners writing two-plus Mytesi prescriptions and a 49% increase in breadth, as defined by healthcare practitioners writing at least one prescription. Looking at the highest Mytesi prescribers—those who write six or more prescriptions, the Company realized a 51% increase in the third quarter of 2018 versus the prior quarter. Based on IQVIA data through September of this year, 75% of healthcare practitioners have now written more than two prescriptions. At present, 14% of Mytesi prescribers have written more than 25 prescriptions.
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- For the third quarter of 2018, the ratio of new-to-brand Mytesi prescriptions to total prescriptions is 21.3%, which is more than twice the rate IQVIA traditionally sees for chronic brands.

### **Mytesi Commercial and Promotional Activities Updates**

- As announced September 24, 2018, Jaguar executed a Distribution, License and Supply Agreement that grants Knight Therapeutics Inc. the exclusive right to commercialize Mytesi and related products in Canada and Israel and a right of first negotiation to commercialize Mytesi and related products in specified Latin American countries.
- In the third quarter of 2018, Mytesi was added to the AIDS Drug Assistance Program (ADAP) formularies in New York, Tennessee, Mississippi and DC. With the anticipated addition of Mytesi to the ADAP formularies of one to two key states that had a delay due to the various natural disasters in the third quarter, the Company expects Mytesi access will soon be available to greater than 85% of ADAP lives nationally, based on data from healthcare research firm Decision Resource Group.
- On August 26, 2018, the Company launched its first integrated digital campaign. The campaign represents a strategic shift in messaging, employing content intended to convey a more upbeat and motivational message to both patients and healthcare practitioners. Although the campaign has only been in the market less than three months, results have exceeded expectations. After eight weeks, the campaign has delivered an almost 1,000% increase in visitors to Mytesi.com, and, perhaps more importantly, an ~1,100% increase in returning visitors—an early indicator that the target audience is finding the site of value.

### **Human Pipeline Updates**

- The Company's lead pipeline target indication is cancer therapy-related diarrhea (CTD). Diarrhea continues to be a significant comorbidity for patients undergoing cancer treatment. Diarrhea has been reported as the most common side effect of novel targeted agents used in adjuvant therapy, such as tyrosine kinase inhibitors—TKIs, which include epidermal growth factor receptor antibodies such as Herceptin, and which increase natural chloride and fluid secretion in the gastrointestinal mucosa, thereby leading to secretory diarrhea. The Company's near-term pipeline-related achievement includes, most significantly, the filing with FDA for a discussion by the end of 2018 or in the beginning of 2019 on the anticipated pivotal protocol for the planned CTD indication, which will use the same formulation and dosing of Mytesi used in the approved HIV-related indication.
  - In the first half of 2019, the Company expects interim results of a Genentech-Roche-funded investigator-initiated trial of crofelemer in breast cancer patients suffering from CTD to be available.
  - Napo recently 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 Mytesi, for which Jaguar has completed two phase 2 studies. The chronic safety of Mytesi is an important distinguishing attribute for these possible indications.
  - The Company is planning 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. Cholera is an acute diarrheal illness that kills thousands of people worldwide each year due to rapid dehydration in the first 2-18 hours after infection. Lechlemer, Jaguar's second-generation anti-secretory botanical drug product candidate formerly referred to as SB-300, is approximately one-tenth the price to manufacture as
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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 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.

**Dial-In Instructions for Conference Call**

**When:** November 15, 2018 at 8:00 a.m. Eastern Time

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

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

**Conference ID number:** 3492327

**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

**Conference ID number:** 3492327

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

**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 cashflow 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 has 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 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.

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## 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](http://jaguar.health). For more information about Napo, visit [napopharma.com](http://napopharma.com).

## Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the expectation that, with the anticipated addition of Mytesi to the ADAP formularies of one to two key states that had a delay due to the various natural disasters in the third quarter, access will soon be available to greater than 85% of ADAP lives nationally, the expectation that interim results of a Genentech-Roche-funded investigator-initiated trial of crofelemer in breast cancer patients suffering from CTD will be available in the first half of 2019, and the Company’s plans 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. 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.

### Contact:

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