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): **April 6, 2020**

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**	**94105**
(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 April 6, 2020, Jaguar Health, Inc. (the "Company") issued a press release announcing 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

Exhibit No.	Description
99.1	Press Release, dated April 6, 2020.

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: April 6, 2020

Exhibit 99.1

Jaguar Health Reports 2019 Financial Results and Business Updates

Mytesi® net sales and gross sales grew 38% and 44%, respectively, in 2019 compared to 2018

Reminder: Company to host investor call Monday, April 6 at 8:30 a.m. Eastern

SAN FRANCISCO, CA / April 6, 2020 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company") today reported consolidated financial results for the year ended December 31, 2019 and provided business updates.

"We are very pleased to see strong Mytesi® (crofelemer) sales growth in 2019 over 2018," Lisa Conte, Jaguar's president and CEO, commented. "Looking forward, we believe 2020 has the potential to be a transformative year for the Company. Our core goals for the year include forging a regional, ex-US business development deal to bring in non-dilutive dollars to support efforts to move key potential Mytesi pipeline indications into development, commercialization, and access outside the U.S., and completing the roll-out of our new, recently announced patient support program for Mytesi. Subject to additional financing, we are also planning to initiate three clinical trials in the second half of 2020 – a pivotal trial for the indication of prevention and treatment of cancer therapy-related diarrhea (CTD) in adult cancer patients, and two studies for the rare pediatric disease indications of congenital diarrheal disease and short bowel syndrome. For the adult CTD study, we've been in active discussions with the FDA, and in meetings with key opinion leaders, and have received their input on the clinical trial and statistical analysis plan. We are revising the clinical protocol to accommodate their input and preparing the requisite documents including the statistical analysis plan, the informed consent and other requirements to initiate this pivotal adult CTD trial under a new IND. The principal investigator is at a major cancer institution in the US. Finally, at a time when the world is grappling with a pandemic, we are pleased to announce that our wholly owned subsidiary, Napo Pharmaceuticals, will receive additional preclinical services from the National Institute of Allergy and Infectious Diseases ("NIAID") to support development of lechlemer, Napo's second generation, plant-based anti-secretory drug candidate for treatment of diarrhea associated with the enduring scourge of cholera. Under NIAID's suite of preclinical services, NIAID-funded contractors will conduct toxicology testing for a 28-day rat study. NIAID is part of the National Institutes of Health."

2019 Company Financial Results:

- **Mytesi Net Product Revenue:** 2019 Mytesi net sales were approximately $5.7 million, and Mytesi gross (non-GAAP) sales were approximately $8.2 million, an increase of 38% and 44%, respectively, year over year. In 2019, the Company's animal product research and development efforts were intentionally minimal, and Jaguar's animal-related sales were also minimal.

- **Total Mytesi Prescription Volume**: Total Mytesi prescription volume increased 62% in the year 2019 over the year 2018.

Financial Highlights (in thousands, except per share amounts)	Year-Ended December 31, 2019	2018	$ change	% change
Net product revenue	$ 5,775	$ 4,239	1,537	36%
Loss from operations	$ (28,948)	$ (30,824)	1,876	-6%
Net loss	$ (38,539)	$ (32,146)	(6,393)	20%
Net loss attributable to common shareholders	$ (44,726)	$ (32,146)	(12,580)	39%
Net loss per share, basic and diluted	$ (9.01)	$ (153.27)		

- **Operating Expenses:** The total operating expense for the year 2019 was $34.7 million as compared to $35.2 million for the year 2018, a 1%, or $0.5 million, decrease year over year. The decrease in total operating expenses was primarily due to the write-off of goodwill of $5.2 million in the year 2018, offset by an impairment of long-lived intangible assets of $4.0 million and $0.6 million in the settlement of the Tempesta royalty license agreement.

- **Cost of Product Revenue:** Total cost of product revenue for the year ended December 31, 2019 and December 31, 2018 was $3.8 million compared to $2.8 million, respectively, a 38%, or $1.0 million, increase year over year. The increase in cost of product revenue was due to increased sales of Mytesi, including non-recurring charges of material costs for a campaign batch cancellation fee of $0.1 million and the write-off of $0.4 million non-conforming inventory, and distribution fees of $0.2 million from the Company's former distributor, offset by the reversal of $0.2 million of accrued royalties related to the termination of a royalty agreement.

- **Research and Development**: The R&D expense was $5.8 million for the year 2019 compared to $5.2 million for the year 2018, a 13%, or $0.7 million, increase year over year. The increase in R&D expense was due to increased clinical and contract manufacturing expenses of $0.6 million primarily due to an increase in contract manufacturing costs for enhanced manufacturing process improvements the Company is developing to reduce the cost of revenue, an increase in non-cash stock-based compensation of $0.3 million primarily due to an increase in the number of option grants, and an increase in other expenses, consisting primarily of consulting, formulation and regulatory fees of $0.3 million, offset by a decrease in personnel and related benefits of $0.5 million due to changes in headcount and related salaries.

- **Sales and Marketing**: The Sales and Marketing expense was $6.9 million for the year 2019 compared to $9.8 million for the year 2018, a 29%, or $2.9 million, decrease year over year. The decrease in Sales and Marketing expense was also due to a decrease in direct marketing and sales expense of $2.5 million from decreased marketing programs for Mytesi, and a decrease in other expenses of $0.4 million largely due to a reduction in advertising costs.

- **General and Administrative**: The G&A expense was $13.5 million for the year 2019 compared to $12.3 million for the year 2018, a 10%, or $1.2 million, increase year over year. The increase in G&A expense was due to an increase in accounting fees of $0.2 million due to a change in the timing of services provided, an increase in non-cash stock-based compensation expense of $0.6 million related to the stock options granted during the year 2019, an increase in rent and lease expense of $0.3 million due to contractual increases of office facilities, and a net increase in other general and administrative expenses of $0.1 million in consulting and legal fees.

- **Loss from Operations:** For the year 2019, the loss from operations was $28.9 million compared to a loss of $30.8 million in 2018, a 6%, or $1.9 million, decrease year over year. This decrease in operating loss was due primarily to the write-off of goodwill of $5.2 million in 2018, offset by the impairment of indefinite-live intangible assets of $4.0 million in 2019.

- **Net Loss:** For the year 2019, the net loss was $38.5 million compared to a net loss of $32.1 million in 2018, a 20%, or $6.4 million, increase year over year. The increase in net loss was primarily due to an increase of interest expense of $3.1 million, loss on extinguishment of debt of $4.4 million, a gain from the Valeant settlement of $1.2 million in 2018 compared to zero in 2019, offset by a total decrease in operating expenses of $0.5 million, an increase in total revenue of $1.5 million, and a net decrease in other income of $0.4 million.

- **Net Loss Attributable to Common Shareholders:** For the year 2019, net loss attributable to common shareholders was $44.7 million compared to $32.1 million for the year 2018. There were four deemed dividends recorded in the year 2019, whereas there were none recorded during the year 2018.

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

- **Non-GAAP EBITDA**: Non-GAAP EBITDA for the years 2019 and 2018 was a net loss of $28.1 million and $25.7 million, respectively. Excluding the impairment of goodwill, loss on extinguishment of debt, and other non-recurring expenses, non-GAAP Recurring EBITDA was a loss of $19.0 million and $20.0 million for the years 2019 and 2018, respectively.

	Year-Ended December 31,	
	2019	2018
	(unaudited)	
Net loss	$ (38,539)	$ (32,146)
Adjustments:		
Interest expense	5,731	2,629
Property and equipment depreciation	50	61
Amortization of intangible assets	1,687	1,687
Share-based compensation expense	2,989	2,024
Income taxes	(10)	—
Non-GAAP EBITDA	(28,092)	(25,745)
Impairment of goodwill	—	5,211
Impairment of indefinite-lived intangible assets	4,000	—
Loss on extinguishment of debt	4,941	544
Campaign batch cancelation fee	78	—
Distribution fees from former distributor	227	—
Reversal of accrued royalty due to termination of royalty agreement	(189)	—
Non-GAAP Recurring EBITDA	$ (19,035)	$ (19,990)

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: April 6, 2020 at 8:30 a.m. Eastern Time
Dial-in (US Toll Free): 888-394-8218
Dial-in (International): 323-701-0225
Conference ID number: 7352525

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: 7352525

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 belief that 2020 has the potential to be a transformative year for the Company, the Company’s goal of forging an ex-US business development deal to bring in non-dilutive dollars to support efforts to move key potential Mytesi pipeline indications into development, commercialization, and access outside the U.S., the Company’s plans to complete the roll-out of its new patient support program for Mytesi, plans to initiate three clinical trials in the second half of 2020, subject to additional financing, the expectation that Napo will receive additional preclinical services from NIAID to support development of lechlemer, and the expectation that the Company will host an investor call on April 6, 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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