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):
March 11, 2020

ENTASIS THERAPEUTICS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38670**	**82-4592913**
(state or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

35 Gatehouse Drive **Waltham, Massachusetts**	**02451**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(781) 810-0120**

(Former name or former address, if changed since last report.)

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))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	ETTX	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in 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. ☒

Item 2.02. Results of Operations and Financial Condition.

On March 11, 2020, Entasis Therapeutics Holdings Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Form 8-K, including 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, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of the Company, dated March 11, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ENTASIS THERAPEUTICS HOLDINGS INC.

By: /s/ Michael Gutch, Ph.D.
Michael Gutch, Ph.D.
Chief Financial Officer and Chief Business Officer

Dated: March 11, 2020

Entasis Therapeutics Reports Full Year 2019 Financial Results and Business Update

WALTHAM, Mass., March 11, 2020 (GLOBE NEWSWIRE) – Entasis Therapeutics Holdings Inc. (NASDAQ: ETTX), a clinical-stage biopharmaceutical company focused on the discovery and development of novel antibacterial products, announced its full year 2019 financial results and business highlights.

"2019 marked a pivotal year for the Company as we made great strides both advancing our clinical programs and strengthening our leadership team," stated Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. "We continued to make significant progress across all of our clinical candidates as we initiated two Phase 3 registration trials in 2019 and reported encouraging topline data from our Phase 1 study of ETX0282 for Gram-negative infections caused by multidrug-resistant (MDR) *Enterobacteriaceae*. In April, we launched the global ATTACK (***A**cinetobacter* **T**reatment **T**rial **A**gainst **C**olistin) Phase 3 registration trial, evaluating a fixed-dose combination of sulbactam plus durlobactam (SUL-DUR) as a potential treatment for carbapenem-resistant *Acinetobacter baumannii* infections. We then achieved a second key milestone in September with the advancement of zoliflodacin, a novel antibiotic for the treatment of uncomplicated gonorrhea, into a Phase 3 registration trial."

Dr. Perros added, "To further drive our strategic initiatives, we bolstered our leadership team through the additions of several key members of management. We appointed two biopharmaceutical veterans, Dr. David Altarac as Chief Medical Officer and Eric Kimble as Chief Commercial Officer, who combined have nearly 50 years of industry experience. Additionally, we strengthened our Board of Directors through the additions of David Meek as the Chairman of the Board and Dr. Howard Meyer. We are extremely excited to build upon our strong 2019 performance and look forward to ATTACK and zoliflodacin Phase 3 registration trial data readouts."

Full Year 2019 and Recent Highlights

- In April, we initiated the ATTACK Phase 3 registration trial to evaluate SUL-DUR for the treatment of patients with pneumonia and bloodstream infections caused by carbapenem-resistant *Acinetobacter baumannii*. ATTACK is a global, two-part Phase 3 registration trial set to enroll a total of approximately 300 patients. As pre-planned, after randomization of approximately 40 patients into the primary efficacy arm (Part A, which will include a total of 136 evaluable patients), the Data Safety Monitoring Board, or DSMB, conducted a pre-specified pharmacokinetics assessment to confirm our projected SUL-DUR exposures. Although we remain blinded to treatment assignment, the DSMB has advised us to continue enrollment without modification of the trial protocol and in addition has allowed us to open the Part B arm of the trial, which is an open-label treatment of approximately 80 patients with *Acinetobacter* infections who are not otherwise eligible for the randomized comparison. Due to the coronavirus outbreak in countries where we are conducting the ATTACK registration trial, we now anticipate topline results from the study to be available in early 2021. This is a change from our previous guidance of the second half of 2020 as we anticipate some effect on the ATTACK trial timeline from this epidemic, the extent of which we continue to monitor and are working to mitigate.

- In September, the Global Antibiotic Research and Development Partnership (GARDP) initiated the global Phase 3 registration trial of zoliflodacin for the treatment of uncomplicated gonorrhea. The randomized, open label trial will enroll approximately 1,000 adults with urogenital gonorrhea at clinical trial sites in the United States and internationally and will assess the safety and efficacy of zoliflodacin versus the combination of azithromycin and ceftriaxone, the current standard of care. GARDP is fully funding and sponsoring the Phase 3 trial. In return, the Company has provided them with exclusive commercial rights in low-income and select middle-income countries. A data readout from the Phase 3 registration trial is expected in 2021.

- In June, the Company reported preliminary results from its randomized, double-blind, placebo-controlled Phase 1 clinical study of ETX0282, an oral beta-lactamase inhibitor, being developed to combat multidrug-resistant *Enterobacteriaceae*. The trial was designed to evaluate the safety, tolerability and pharmacokinetics of ETX0282 either alone or in combination with cefpodoxime proxetil (ETX0282CPDP) in healthy volunteers. Results from the

Phase 1 clinical study demonstrated that plasma concentrations of the beta-lactamase inhibitor were in the projected therapeutic range. Additionally, ETX0282 was generally well tolerated either alone or in combination with cefpodoxime proxetil, and no serious adverse events were reported. Modified-release formulation efforts are now ongoing.

- In December the Company selected ETX0462 as a clinical candidate from its non-b-lactam penicillin binding protein inhibitor (NBP) program. ETX0462 potentially represents a new Gram-negative class of antibiotics and is initially being developed for the treatment of multidrug-resistant *Pseudomonas* infections. Data from the program will be presented at an upcoming medical conference.

- The Company strengthened its management team with the appointment of key industry leaders including Eric Kimble as Chief Commercial Officer to build and oversee the Company's global commercialization strategy and product launch initiatives. Mr. Kimble, who was appointed in April, has over 25 years of commercial leadership experience in sales, marketing and commercial strategy, and product launches from Cubist Pharmaceuticals, Biogen Inc. and Merck & Co. In November, the Company also appointed David Altarac, M.D., MPA as Chief Medical Officer. Dr. Altarac is a recognized industry R&D leader and brings broad experience, most recently as senior vice president and head of global regulatory affairs, global drug safety and R&D quality and compliance at Shire Plc.

Full Year 2019 Financial Results

Entasis reported revenue of $7.0 million and grant income of $2.3 million for the year ended December 31, 2019, compared to revenue of $5.0 million and $5.3 million of grant income for the year ended December 31, 2018. The revenue in 2019 was attributable to milestones achieved pursuant to the Company's collaboration agreement with Zai Lab (Shanghai) Co., Ltd.

The Company reported a net loss of $43.9 million for the year ended December 31, 2019, compared to a net loss of $33.0 million for the year ended December 31, 2018. The increase in net loss was primarily due to increases in development expense and general and administrative expense and a decrease in other income, partially offset by the aforementioned increase in revenue year over year.

Research and development expenses were $40.2 million for the year ended December 31, 2019, compared to $33.0 million for the year ended December 31, 2018. The increase in research and development expenses was primarily attributable to increases in clinical and manufacturing development expenses related to the advancement of our SUL-DUR product candidate and increased headcount, partially offset by decreases in preclinical and clinical development expenses related to the advancement of our ETX0282CPDP product candidate.

General and administrative expenses were $13.8 million for the year ended December 31, 2019, compared to $10.2 million for the year ended December 31, 2018. The increase was driven by costs associated with additional headcount, director and officer insurance costs, and VAT and other taxes associated with the milestone revenue from our collaboration with Zai Lab Limited.

As of December 31, 2019, cash, cash equivalents and short-term investments were $41.0 million, compared to $85.1 million as of December 31, 2018. The Company believes its current cash position provides a runway into the fourth quarter of 2020.

About Entasis
Entasis is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel antibacterial products to treat serious infections caused by multidrug-resistant Gram-negative bacteria. Entasis' pathogen-targeted design platform has produced a pipeline of product candidates, including sulbactam-durlobactam (targeting *Acinetobacter baumannii* infections), zoliflodacin (targeting *Neisseria gonorrhoeae* infections), ETX0282CPDP (targeting *Enterobacteriaceae* infections) and ETX0462 (targeting *Pseudomonas* infections). For more information, visit www.entasistx.com.

Entasis Forward-looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar

expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Entasis' expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected and changes in expected or existing competition, changes in the regulatory environment, failure of Entasis' collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Many of these factors are beyond Entasis' control. These and other risks and uncertainties are described more fully in the Entasis' filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Forward-looking statements contained in this announcement are made as of this date, and except as required by law, Entasis assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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(Financial Tables Follow)

Entasis Therapeutics Holdings Inc.
Consolidated Statements of Operations
Unaudited
(in thousands, except share and per share data)

	Year Ended December 31,	
	2019	2018
Revenue	$ 7,000	$ 5,000
Operating expenses:		
Research and development	$ 40,166	$ 33,046
General and administrative	13,770	10,161
Total operating expenses	53,936	43,207
Loss from operations	(46,936)	(38,207)
Other income:		
Grant income	2,300	5,337
Interest income	1,463	390
Total other income	3,763	5,727
Loss before income taxes	(43,173)	(32,480)
Provision for income taxes	677	472
Net loss	(43,850)	(32,952)
Dividends declared	—	(9,142)
Net loss attributable to common shareholders—basic and diluted	$ (43,850)	$ (42,094)
Net loss per share—basic and diluted	$ (3.33)	$ (12.31)
Weighted average common stock outstanding—basic and diluted	13,160,357	3,419,720

Entasis Therapeutics Holdings Inc.
Condensed Consolidated Balance Sheets
Unaudited
(in thousands)

	December 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 40,996	$ 85,092
Other assets	10,038	4,182
Total assets	$ 51,034	$ 89,274
Total liabilities	$ 8,877	$ 6,391
Total stockholders' equity	42,157	82,883
Total liabilities and stockholders' equity	$ 51,034	$ 89,274