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 5, 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 Global Market

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 November 5, 2020, Entasis Therapeutics Holdings Inc., or the Company, issued a press release announcing its financial results for the quarter ended September 30, 2020. 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, or 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 November 5, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: November 5, 2020

Entasis Therapeutics Reports Third Quarter 2020 Financial Results and Provides a Business Update

WALTHAM, Mass., November 5, 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 today its third quarter 2020 financial results and provided a business update.

"We made considerable progress during the quarter despite the sustained headwinds of the COVID-19 pandemic, as we continued to advance our Phase 3 registration clinical trials addressing *Acinetobacter* infections and gonorrhea, further delivered on our pipeline, and strengthened our balance sheet from the closing of a $25 million private placement" commented Manos Perros, President and Chief Executive Officer of Entasis Therapeutics.

"In addition to our operational progress in the third quarter, we also presented at multiple investor conferences and were pleased to present four posters on SUL-DUR at the virtual IDWeek 2020 Conference, which included demonstration of its robust activity against global multidrug resistant *Acinetobacter baumannii* clinical isolates. We continue to be encouraged by our progress against our objectives and believe we are optimally positioned and well-funded as we conclude 2020 and look toward 2021."

Third Quarter 2020 and Recent Highlights

Business Highlights

- In August, the Company announced that it had entered into a $25 million private placement agreement with two healthcare investors. The Company intends to use the net proceeds for the continued support of the ongoing ATTACK Phase 3 registration clinical trial as well as for working capital and other general corporate purposes. ATTACK is a global Phase 3 registration trial evaluating SUL-DUR for the treatment of patients with pneumonia and bloodstream infections caused by *Acinetobacter baumannii*, including carbapenem-resistant strains.

- In September, the Company presented virtually at the H.C. Wainwright & Co. 22nd Annual Global Investment Conference, the Cantor 2020 Virtual Global Healthcare Conference, and the Oppenheimer Fall Healthcare Life Sciences & MedTech Summit. In August, the Company presented at the 2020 Wedbush PacGrow Healthcare Virtual Conference and at the Canaccord Genuity 40th Annual Growth Conference.

SUL-DUR

- The Company continues with enrollment of the ATTACK Phase 3 registration clinical trial in 17 countries, and to-date has had two pre-planned Data and Safety Monitoring Board reviews, including one most recently in July 2020. Although the Company remains blinded to the data, both reviews recommended continuation of the trial without protocol modification. While not providing specific guidance on the timing of top-line data from ATTACK due to the unpredictability of the COVID-19 pandemic, the Company remains in close contact with its contract research organization to optimize the allocation of its resources and funded activities in an effort to mitigate the impact on its trial sites and anticipated timeline.

- During the virtual IDWeek 2020 held on October 21-25, the company presented four posters highlighting SUL-DUR's potential. Two posters detailed findings demonstrating activity of SUL-DUR against multidrug-resistant *Acinetobacter* clinical isolates from the Middle East as well as global *Acinetobacter baumannii-calcoaceticus* complex clinical isolates. In addition, a retrospective review of serious infections caused by carbapenem-susceptible and carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex was presented, which concluded that such infections are associated with high mortality rates and that carbapenem resistance appears to be a contributing factor. Lastly, the Company highlighted the in vitro

intrinsic microbiological activity of durlobactam and combinations against multidrug resistant *Mycobacterium abscessus*.

Zoliflodacin

- With patient enrollment and other trial activities resuming in July 2020, the Company is continuing to support the Phase 3 registration clinical trial of zoliflodacin for the treatment of uncomplicated gonorrhea with the Global Antibiotic Research and Development Partnership (GARDP). The trial plans to enroll patients with uncomplicated gonorrhea, including infections caused by multidrug resistant strains of *N. gonorrhoeae*, at 14 clinical trial sites across the United States, Netherlands, South Africa and Thailand, and will assess the safety and efficacy of oral zoliflodacin versus the combination of intramuscular ceftriaxone plus oral azithromycin, the current standard of care. While not providing specific guidance on the timing of top-line data from this trial due to the unpredictability of the COVID-19 pandemic, the Company and GARDP are working to optimize the allocation of their resources and funded activities in an effort to mitigate the impact on their trial sites and anticipated timeline.

- In August, the Company co-authored a review of recent progress in adapting non-clinical models to facilitate research and development of new agents for treating gonorrhea, based on the November 2019 expert workshop organized by the Global Antibiotic Research and Development Partnership (GARDP). The review was featured in the peer-reviewed journal, Clinical Microbiology and Infection.

Discovery Research

- In October, the Company presented at the Boston Area Antimicrobial Resistance Network (BAARN) Meeting 2020 an oral presentation titled, “Antibacterial Drug Discovery: Competing Methyl Efforts on Biochemical Potency and Cell Accumulation.”

Third Quarter 2020 Financial Results

The Company reported a net loss of $11.1 million for the quarter ended September 30, 2020, compared to a net loss of $3.5 million for the quarter ended September 30, 2019. The increase in net loss was primarily related to a decrease in revenue recorded during the third quarter 2020 versus the same period last year.

Research and development expenses were $9.4 million for the quarter ended September 30, 2020, compared to $7.6 million for the quarter ended September 30, 2019. The increase of $1.8 million was driven primarily by increased spending related to our SUL-DUR product candidate, increased personnel expenses associated with higher headcount, salaries and stock-based compensation expense, and increased spending related to our ETX0462 product candidate. These increases were offset by decreased spending related to our ETX0282 product candidate.

General and administrative expenses were $3.2 million for the quarter ended September 30, 2020, compared to $3.5 million for the quarter ended September 30, 2019. The decrease of $0.3 million was driven primarily by decreases in VAT tax associated with payments received from our collaboration with Zai Lab.

As of September 30, 2020, cash, cash equivalents and short-term investments were $61.2 million, compared to $50.8 million as of June 30, 2020. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2021.

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	$ —	$ 7,000	$ —	$ 7,000
Operating expenses:				
Research and development	9,387	7,606	31,249	29,286
General and administrative	3,213	3,521	10,235	10,130
Total operating expenses	12,600	11,127	41,484	39,416
Loss from operations	(12,600)	(4,127)	(41,484)	(32,416)
Other income:				
Grant income	1,458	634	1,519	1,835
Interest income	9	332	170	1,240
Total other income	1,467	966	1,689	3,075
Loss before income taxes	(11,133)	(3,161)	(39,795)	(29,341)
Provision for income taxes	—	324	—	467
Net loss	$ (11,133)	$ (3,485)	$ (39,795)	$ (29,808)
Net loss per share —basic and diluted	$ (0.37)	$ (0.27)	$ (1.97)	$ (2.27)
Weighted average common stock outstanding—basic and diluted	29,960,219	13,134,538	20,151,570	13,130,837

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents and investments	$ 61,190	$ 40,996
Other assets	8,772	10,038
Total assets	$ 69,962	$ 51,034
Total liabilities	$ 7,726	$ 8,877
Total stockholders' equity	62,236	42,157
Total liabilities and stockholders' equity	$ 69,962	$ 51,034