
**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

ENTASIS THERAPEUTICS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction of incorporation)

001-38670
(Commission File Number)

82-4592913
(I.R.S. Employer Identification No.)

35 Gatehouse Drive
Waltham, Massachusetts
(Address of principal executive offices)

02451
(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:
Common Stock, \$0.001 par value

Trading Symbol(s)
ETTX

Name of each exchange on which registered
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 November 14, 2019, Entasis Therapeutics Holdings Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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 November 14, 2019

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 14, 2019

Exhibit 99.1

Entasis Therapeutics Reports Third Quarter 2019 Financial Results and Provides Business Update

WALTHAM, Mass., November 14, 2019 (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 third quarter financial results for the period ended September 30, 2019 and provided a business update.

“We are extremely pleased by the continued progress we have made advancing our pipeline during the third quarter of 2019,” stated Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. “We reached another pivotal milestone in September with the advancement of our second program, zoliflodacin, a novel antibiotic for the treatment of uncomplicated gonorrhea, into a Phase 3 clinical trial. In addition to zoliflodacin, sulbactam-durlobactam (SUL-DUR) is being studied in carbapenem-resistant *Acinetobacter* infections in the ongoing ATTACK Phase 3 clinical trial.”

Dr. Perros added, “We also strengthened our company with the additions of Dr. Howard Mayer to our board of directors, effective August 5, 2019 and David Altarac, M.D., MPA as Chief Medical Officer, effective November 4, 2019. Dr. Mayer brings significant clinical expertise in the infectious and rare disease space as well as operational leadership to both our board and company. Dr. Altarac brings over 20 years of biopharmaceutical R&D leadership and has led multiple new drug approvals and product extensions in major markets. Overall, we remain committed to executing our strategic initiatives and believe our skilled leadership team, strong pipeline, and focused business plan position us well in anticipation of our first Phase 3 data readout from the ATTACK clinical trial during the second half of 2020.”

Third Quarter and Recent Highlights

- In September, the Global Antibiotic Research and Development Partnership (GARDP) initiated the global Phase 3 pivotal 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. Our partner GARDP is fully funding and sponsoring the trial, and in return we have provided them with exclusive commercial rights in low to select middle income countries. A data readout from the Phase 3 pivotal trial is expected in 2021.
- Entasis strengthened its board of directors through the addition of industry veteran Howard Mayer, M.D. Dr. Mayer has held positions in executive management at both mid-sized and large pharmaceutical companies including Pfizer, Bristol-Myers Squibb, Merck KGaA and Shire Plc, and brings a wealth of experience leading and executing clinical programs, including programs in the infectious disease space.
- In November, David Altarac, M.D., MPA joined the Company as Chief Medical Officer, concurrent with the retirement of Dr. Robin Isaacs who has served as the Company’s Chief Medical Officer since July 2015. Dr. Altarac is a recognized industry R&D leader and brings broad experience from previous roles, most recently as senior vice president and head of global regulatory affairs, global drug safety and R&D quality and compliance at Shire Plc.
- At IDWeek 2019, the Company highlighted the latest advancements in the antibacterial activity of our lead candidate SUL-DUR through two poster presentations. For the first time, the Company described the robust *in vitro* and *in vivo* antibacterial activity of SUL-DUR against *Burkholderia* species, a challenging group of pathogens that have the potential to cause serious respiratory infections, especially in patients with cystic fibrosis. Dr. Perros, President and CEO, also participated in an industry panel discussion on how to reinvigorate antibiotic development

in the current market environment. The Company hosted an advisory panel on SUL-DUR and discussed aspects of the pivotal ATTACK clinical trial and SUL-DUR's potential for the treatment of multidrug-resistant *Acinetobacter* infections.

- The Company bolstered its liquidity by entering into a Common Stock Purchase Agreement with Aspire Capital Fund, LLC. Under the agreement, the Company may issue and sell shares of its common stock having an aggregate gross sales price of up to \$20.0 million. The Company has the sole discretion to present Aspire with a purchase notice directing Aspire to purchase up to 50,000 shares of common stock per business day.

Third Quarter Financial Results

The Company reported a net loss of \$3.5 million for the quarter ended September 30, 2019, compared to a net loss of \$8.5 million for the quarter ended September 30, 2018. The decrease in net loss was primarily due to milestone revenue of \$7.0 million from our collaboration with Zai Lab Limited (NASDAQ: ZLAB) in 2019 related to the achievement of key milestones in our ATTACK clinical trial.

Research and development expenses were \$7.6 million for the quarter ended September 30, 2019, compared to \$8.1 million for the quarter ended September 30, 2018. The decrease in research and development expenses was primarily attributable to decreases in drug manufacturing costs, partially offset by increases in clinical development expenses related to the advancement of our SUL-DUR product candidate.

General and administrative expenses were \$3.5 million for the quarter ended September 30, 2019, compared to \$2.1 million for the quarter ended September 30, 2018, an increase driven by costs associated with additional headcount and VAT taxes associated with the milestone revenue from our collaboration with Zai Lab Limited.

As of September 30, 2019, cash, cash equivalents and short-term investments were \$48.8 million, compared to \$59.5 million as of June 30, 2019. The Company believes its current cash position, together with earned milestones from our collaboration with Zai Lab Limited, provides a cash runway into the fourth quarter of 2020. Additionally, the Company signed a \$20 million common stock purchase agreement with Aspire Capital Fund, LLC on October 21, 2019.

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*), and ETX0282CPDP (targeting *Enterobacteriaceae* infections). Entasis is also using its platform to develop a novel class of antibiotics, non- β -lactam inhibitors of the penicillin-binding proteins (NBPs) (targeting Gram-negative 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,	
	2019	2018	2019	2018
Revenue	\$ 7,000	\$ —	\$ 7,000	\$ 5,000
Operating expenses:				
Research and development	7,606	8,086	29,286	26,115
General and administrative	3,521	2,075	10,130	7,840
Total operating expenses	11,127	10,161	39,416	33,955
Loss from operations	(4,127)	(10,161)	(32,416)	(28,955)
Other income:				
Grant income	634	1,669	1,835	4,507
Interest income	332	19	1,240	47
Total other income	966	1,688	3,075	4,554
Loss before income taxes	(3,161)	(8,473)	(29,341)	(24,401)
Provision for income taxes	324	—	467	472
Net loss	(3,485)	(8,473)	(29,808)	(24,873)
Dividends declared	—	(9,142)	—	(9,142)
Net loss attributable to common shareholders—basic and diluted	\$ (3,485)	\$ (17,615)	\$ (29,808)	\$ (34,015)
Net loss per share —basic and diluted	\$ (0.27)	\$ (20.33)	\$ (2.27)	\$ (113.22)
Weighted average common stock outstanding—basic and diluted	13,134,538	866,641	13,130,837	300,435

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

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Cash, cash equivalents and short-term investments	\$ 48,810	\$ 85,092
Other assets	14,477	4,182
Total assets	<u>\$ 63,287</u>	<u>\$ 89,274</u>
Total liabilities	\$ 8,393	\$ 6,391
Total stockholders' equity	54,894	82,883
Total liabilities and stockholders' equity	<u>\$ 63,287</u>	<u>\$ 89,274</u>
