
**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):
May 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))

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.

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

Item 2.02. Results of Operations and Financial Condition.

On May 14, 2019, Entasis Therapeutics Holdings Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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 May 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: May 14, 2019

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

Transformative start to the year with the first Phase 3 trial underway and key additions to the leadership team

WALTHAM, Mass., May 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 first quarter financial results ended March 31, 2019 and provided a business update.

“We believe 2019 will be a transformative year for Entasis as we advance our late-stage pipeline and expand our leadership team,” commented Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. “To kick off the year, we recently initiated our global Phase 3 trial for ETX2514SUL against carbapenem-resistant *Acinetobacter*, for which we expect to have top line data in 2020. The initiation of this trial represents a major step forward for the Company. We also anticipate both the initiation of our Phase 3 trial for zoliflodacin for uncomplicated gonorrhea in collaboration with our partner Global Antibiotic Research and Development Partnership (GARDP), and Phase 1 data read-out of ETX0282CPDP, in mid-2019. With our first Phase 3 clinical trial underway, we have started to prepare our global commercialization strategy by bolstering our organization with the appointment of Eric Kimble as Chief Commercial Officer and Elizabeth Keiley as General Counsel. We look forward to leveraging their expertise as we advance towards commercialization.”

First Quarter and Recent Business Highlights

- Recently, the Company launched its Phase 3 clinical trial of ETX2514SUL, ATTACK (Acinetobacter Treatment Trial Against Colistin), as a potential treatment for infections caused by carbapenem-resistant *A. baumannii*. ATTACK is a two-part global study that will enroll a total of 300 patients. The U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations to ETX2514SUL.
 - The Company strengthened its management team with the appointment of Eric Kimble as Chief Commercial Officer to build and oversee the Company’s global commercialization strategy and product launch initiatives. Mr. Kimble 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 April, Elizabeth Keiley was appointed General Counsel and is responsible for leading the Company’s legal, governance and compliance initiatives. Ms. Keiley will be instrumental in supporting our commercialization efforts while ensuring compliance with applicable laws and regulations and the protection of Entasis’ intellectual property, including patents and FDA designation.
 - Entasis presented promising findings from multiples studies related to its clinical assets, ETX2514SUL and ETX0282CPDP, as well as its preclinical non-beta-lactam PBP inhibitor (NBP) program at the 29th European Congress of Clinical Microbiology & Infectious Diseases
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(ECCMID) in Amsterdam, Netherlands. These data presentations highlighted the Company's pipeline of innovative antimicrobial assets and their potential value as therapeutic agents.

First Quarter Financial Results

The Company reported a net loss of \$12.9 million for the quarter ended March 31, 2019, compared to a net loss of \$10.7 million for the quarter ended March 31, 2018. The increase in net loss was primarily related to an increase in research and development expenses, partially offset by increases in other income.

Research and development expenses were \$11.0 million for the quarter ended March 31, 2019, compared to \$8.6 million for the quarter ended March 31, 2018. The increase in research and development expenses was primarily attributable to preclinical and clinical development expenses related to the advancement of our ETX2514SUL product candidate.

General and administrative expenses remained flat at \$3.2 million for the quarter ended March 31, 2019 compared to the quarter ended March 31, 2018, as increased costs associated with additional headcount were offset by lower legal costs.

As of March 31, 2019, cash, cash equivalents and short-term investments were \$74.6 million, compared to \$85.1 million as of December 31, 2018.

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' targeted-design platform has produced a pipeline of product candidates, including ETX2514SUL (targeting *A. 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. Forward-looking statements contained in this press release include statements regarding (i) the progress, timing and results of Entasis' clinical trials; (ii) design of the Phase 3 clinical trial of ETX2514SUL, including plans to incorporate BIOFIRE Instruments and Pneumonia Panels into this trial; (iii) GARDP's role in the Phase 3 clinical trial of zoliflodacin; and (iv) use of proceeds from the initial public offering. 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.
Condensed Consolidated Statements of Operations
Unaudited
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 11,002	\$ 8,550
General and administrative	3,189	3,128
Total operating expenses	14,191	11,768
Loss from operations	(14,191)	(11,768)
Other income:		
Grant income	829	1,089
Interest income	492	12
Total other income	1,321	1,101
Loss before income taxes	(12,870)	(10,667)
Provision for income taxes	71	—
Net loss	\$ (12,941)	\$ (10,667)
Net loss per share—basic and diluted	\$ (0.99)	\$ (844.01)
Weighted average common stock outstanding—basic and diluted	13,126,595	12,639

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

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Cash, cash equivalents and investments	\$ 74,555	\$ 85,092
Other assets	6,712	4,182
Total assets	<u>\$ 81,267</u>	<u>\$ 89,274</u>
Total liabilities	\$ 10,693	\$ 6,391
Total stockholders' equity	70,574	82,883
Total liabilities and stockholders' equity	<u>\$ 81,267</u>	<u>\$ 89,274</u>
