
**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 4, 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 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 7.01. Regulation FD Disclosure.

On April 4, 2019, Entasis Therapeutics Holdings Inc. (the “Company”) issued a press release announcing that the Company initiated a Phase 3 pivotal clinical trial to evaluate its product candidate, ETX2514SUL, for the treatment of patients with pneumonia and bloodstream infections caused by carbapenem-resistant *Acinetobacter baumannii*. 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 April 4, 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
Michael Gutch
Chief Financial Officer and Chief Business Officer

Dated: April 4, 2019



Entasis Therapeutics Initiates Global Phase 3 Pivotal Trial of ETX2514SUL for Patients with Carbapenem-Resistant *Acinetobacter* Infections

WALTHAM, Mass. April 4, 2019 – Entasis Therapeutics Holdings Inc. (NASDAQ: ETTX), a clinical-stage biopharmaceutical company developing novel antibacterials to treat serious drug-resistant infections, today announced the initiation of the ATTACK (Acinetobacter Treatment Trial Against Colistin) Phase 3 pivotal clinical trial to evaluate ETX2514SUL, a fixed-dose combination of its broad-spectrum β -lactamase inhibitor ETX2514 with sulbactam, for the treatment of patients with pneumonia and bloodstream infections caused by carbapenem-resistant *Acinetobacter baumannii*.

A. baumannii is a Gram-negative bacterium that causes severe infections and is associated with high mortality, increasing rates of antibiotic resistance and growing significance as a hospital-acquired infection due to limited treatment options. Outbreaks of *A. baumannii* typically occur in intensive care units and healthcare settings with seriously ill patients, and can either cause or contribute to death. Resistance to carbapenems, a class of antibiotics commonly used for the treatment of severe bacterial infections, has grown substantially amongst *Acinetobacter* in the last decade, resulting in a significant unmet medical need.

“There are currently very limited antibiotic choices for the treatment of multidrug-resistant *A. baumannii* infections, and mortality rates approach 50%,” said Robin Isaacs, MD, Chief Medical Officer. “More than 60% of *A. baumannii* strains tested in the United States in 2016 were resistant to carbapenems, and in some European and Asian countries carbapenem resistance surpasses 80%. ETX2514SUL offers a precision, pathogen-targeted, approach to the treatment of *A. baumannii*. We look forward to enrolling patients in our ATTACK trial which will evaluate ETX2514SUL’s efficacy and safety in the treatment of drug-resistant *A. baumannii* infections.”

ATTACK is a global, two-part Phase 3 clinical trial that will enroll a total of 300 patients from 18 countries. The Company believes this single Phase 3 trial could be sufficient to support the filing of a new drug application with regulatory authorities in both the U.S. and Europe. Subject to necessary regulatory approvals, the clinical trial will also leverage the Company’s partnership with Zai Lab for patient enrollment in China, and potentially provide early access for patients in Asia-Pacific countries. The trial will also incorporate the BioFire® FilmArray® Pneumonia Panel to optimize and accelerate patient enrollment. For more information about the ATTACK trial, please visit www.clinicaltrials.gov (NCT03894046).

“We are excited to initiate our global ATTACK clinical trial with the ultimate goal of obtaining regulatory approval in the U.S. and other countries,” said Manos Perros, Chief Executive Officer, Entasis Therapeutics. “It is the culmination of extensive preclinical development and multiple Phase 1 and 2 clinical trials, which have shown that ETX2514SUL has great potential for the treatment of patients with carbapenem-resistant *A. baumannii* infections. We are fully funded through this study and look forward to reporting top-line data in the second half of 2020.”

The initiation of ATTACK follows the End-of-Phase-2 meeting with the U.S. Food and Drug Administration (FDA). ETX2514SUL has been designated a Qualified Infectious Disease Product (QIDP) by the U.S. FDA and granted Fast Track designation.

About ETX2514

ETX2514 is a novel, broad-spectrum inhibitor of class A, C, and D β -lactamases. ETX2514 restores the *in vitro* activity of multiple β -lactams against Gram-negative, multidrug-resistant (MDR) pathogens. Entasis Therapeutics is initially developing ETX2514SUL, the combination of ETX2514 and sulbactam, for the treatment of severe *A. baumannii* infections. Sulbactam is a generic β -lactam which has intrinsic antibacterial activity against *A. baumannii* but suffers from widespread β -lactamase-mediated resistance. In preclinical studies, ETX2514 restored sulbactam antibacterial activity against *A. baumannii*. ETX2514 has completed single- and multi-ascending dose Phase 1 trials and a Phase 2 trial, in combination with sulbactam, in complicated urinary tract infections.

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 about (i) the timing of the initiation, progress and scope of the Phase 3 clinical trial of ETX2514SUL; (ii) the timing of the availability of data; (iii) design of the Phase 3 clinical trial of ETX2514SUL, including plans to incorporate BIOFIRE Instruments and Pneumonia Panels into this trial and their ability to optimize and accelerate patient enrollment; (iv) the success of the Phase 3 clinical trial of ETX2514SUL; (v) the sufficiency of the single trial to support the filing of an NDA with the FDA; and (vi) potential clinical benefits of ETX2514SUL. 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. 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.

Entasis Company Contact

Kyle Dow
Entasis Therapeutics
(781) 810-0114
kyle.dow@entasistx.com

Investor Relations Contact

Lee Roth
The Ruth Group
646-536-7012
lroth@theruthgroup.com

Media Contact

Kirsten Thomas
The Ruth Group
(508) 280-6592
kthomas@theruthgroup.com
