
**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, 2018

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.

Item 2.02. Results of Operations and Financial Condition.

On November 14, 2018, Entasis Therapeutics Holdings Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2018. 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, 2018

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: November 14, 2018

Entasis Therapeutics Reports Third Quarter 2018 Financial Results and Provides Business Update

Completed \$75.0 million initial public offering in September

Reported positive Phase 2 topline results of lead program ETX2514SUL

On-track to initiate two Phase 3 clinical trials in 2019

WALTHAM, Mass., November 14, 2018 — Entasis Therapeutics (NASDAQ: ETTX), a clinical-stage biopharmaceutical company focused on the discovery and development of novel antibacterial products, announced financial results for the third quarter 2018 and provided a business update.

“2018 has been a very productive year thus far for Entasis,” commented Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. “The completion of our IPO in September positions us well to advance our robust pipeline of novel, pathogen-targeted product candidates that are addressing some of the most critical antibiotic resistance issues and unmet medical needs. In August we were pleased to report positive topline data for our lead program, ETX2514SUL, our novel β -lactam/ β -lactamase inhibitor combination product to treat MDR *Acinetobacter* infections. We look forward to the continued development of our pipeline of novel antibacterials and anticipate having two of our programs enter Phase 3 clinical trials in 2019.”

Third Quarter and Recent Business Highlights

- **Successfully completed IPO.** In September 2018, Entasis completed its initial public offering (IPO) of its common stock that resulted in net proceeds of approximately \$65.6 million. The Company expects to use the proceeds from this offering to fund its operations and pipeline of novel, precision antibacterial product candidates including the Phase 3 clinical trial of ETX2514SUL, the Phase 1 clinical trial of ETX0282CPDP and the advancement of other clinical candidates.
 - **Announced positive topline results from Phase 2 clinical trial of ETX2514SUL in patients with complicated urinary tract (cUTI) infections including acute pyelonephritis.** The Phase 2 double-blind, randomized, placebo-controlled clinical trial of intravenous (IV) ETX2514SUL, administered with imipenem/cilastatin (IMI), showed similar microbiological success in the microbiologically evaluable population as placebo plus IMI (80% vs. 81%) and both treatment groups achieved 100% clinical success in the clinically evaluable population. In an exploratory analysis, the trial evaluated the efficacy of ETX2514SUL plus IMI against cUTIs caused by imipenem-non-susceptible pathogens. Eight patients had a cUTI caused by imipenem-non-susceptible pathogens (three in the ETX2514SUL arm and five in the placebo arm). ETX2514SUL plus IMI eradicated isolates in all patients, 100% (3/3), compared to 60% (3/5) in patients receiving placebo plus IMI. ETX2514SUL was generally well tolerated with
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no serious adverse events (SAEs) reported in either arm.

- **Results from investigator-sponsored Phase 2 clinical trial evaluating zoliflodacin in patients with uncomplicated gonorrhea published in the *New England Journal of Medicine* (NEJM).** The Phase 2 clinical trial described in the NEJM was a multi-center randomized, open-label study that enrolled 179 participants between the ages of 18 to 55 with either symptoms of uncomplicated urogenital gonorrhea, untreated urogenital gonorrhea or sexual contact with someone with gonorrhea within 14 days of enrollment and was conducted by The National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). Zoliflodacin was well-tolerated and successfully treated a majority of the uncomplicated gonorrhea cases. Zoliflodacin received Fast Track designation and qualified infectious disease product (QIDP) designation by the U.S. Food and Drug Administration for development solely as an oral treatment for gonococcal infections and is expected to enter a Phase 3 clinical trial in 2019.
 - **Continued progress advancing novel antibacterial pipeline addressing antibiotic resistance.**
 - ETX2514SUL on track to initiate Phase 3 clinical trial in 1Q 2019. ETX2514 is a potent and 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 is developing ETX2514SUL, the combination of ETX2514 and sulbactam, for the treatment of severe *Acinetobacter baumannii* infections. ETX2514SUL received Fast Track designation and QIDP designation by the U.S. Food and Drug Administration. Entasis retains global commercial rights to ETX2514SUL excluding the Asia-Pacific region which was out-licensed to Zai Lab in April 2018.
 - Zoliflodacin remains on track to initiate the Phase 3 clinical trial in first half of 2019. Zoliflodacin is a potential first-line, single dose oral antibiotic for the treatment of uncomplicated gonorrhea. The Phase 3 program is fully funded in partnership with the Drugs for Neglected Disease initiative (DNDi) and with the Global Antibiotic Research and Development Partnership (GARDP) in exchange for commercial rights for zoliflodacin in low-income and specific middle-income countries. Entasis retains all commercial rights in major markets including North America, Europe, and Asia-Pacific.
 - ETX0282CPDP results from Phase 1 clinical trial expected in first half of 2019. ETX0282CPDP is an oral fixed-dose combination of ETX0282 with cefpodoxime for the treatment of complicated UTIs, including those caused by ESBL-producing bacterial strains or by carbapenem-resistant *Enterobacteriaceae* (CRE). ETX0282 is engineered to inhibit Class A and Class C β -lactamases, which are the primary mechanisms of resistance associated with multi-drug resistant *Enterobacteriaceae* infections. ETX0282CPDP has the potential to be used in the hospital setting as an
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oral step-down from a short course of IV therapy or to avoid hospital admission in the first place. The ETX0282CPDP program is supported in-part by a grant from CARB-X.

- Entasis continues to advance its pre-clinical program on a novel class of non β -lactam penicillin-binding protein (PBP) inhibitors or NBPs, with an initial focus on multi-drug resistant *Pseudomonas* infections. Lead optimization work is ongoing with the goal of selecting a clinical candidate in 2019. The NBP program is supported in-part by a grant from CARB-X.

Third Quarter Financial Results

Entasis reported a net loss of \$8.5 million for the third quarter 2018 as compared to \$8.3 million for the prior year period. The increase in net loss for the quarter was primarily related to increases in research and development expenses, as well as increases in general and administrative expenses primarily related to professional fees associated with the company's preparation for its IPO. These increases are offset by an increase in grant income.

Research and development expenses were \$8.1 million for the third quarter 2018 as compared to \$7.2 million for the prior year period. The increase in research and development expenses was primarily driven by an increase in spending for preclinical and clinical development activities associated with the advancement of the Company's pipeline.

General and administrative expenses were \$2.1 million for the third quarter 2018 as compared to \$1.3 million for the prior year period. The increase in general and administrative expenses was primarily due to an increase in consulting and professional fees related to the preparation of the Company's financial statements as well as support for ongoing business operations, and the impact of stock-based compensation in 2018.

Grant income was \$1.7 million for the third quarter 2018 as compared to \$0.2 million for the prior year period. The increase in other income was primarily due to an increase in grant income associated with our grant agreement with the CARB-X program.

Entasis ended the quarter with \$94.0 million in cash and cash equivalents compared to \$55.1 million as of December 31, 2017. The increase was primarily the result of the completion of the Company's IPO on September 28, 2018, from which the Company received aggregate net proceeds of approximately \$67.0 million during the nine months ended September 30, 2018.

About Entasis

Entasis Therapeutics is developing a portfolio of innovative product candidates to treat serious Gram-negative multi-drug resistant bacterial infections. Entasis' anti-infective discovery platform has produced a pipeline of meaningfully differentiated programs which target serious bacterial infections, including ETX2514SUL (targeting *Acinetobacter baumannii* infections), zoliflodacin (targeting *Neisseria gonorrhoeae*), ETX0282CPDP (targeting *Enterobacteriaceae* infections), and non- β -lactam

Forward-Looking Statements

This press release includes certain disclosures which contain “forward-looking statements,” including, without limitation, statements regarding the progress, timing and results of the Company’s clinical trials, the association of data with treatment outcomes and the timing estimates of cash remaining to fund operations. Forward-looking statements are based on Entasis’ current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, unexpected safety or efficacy data observed during preclinical or clinical trials, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of the Company’s 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 section titled “Risk Factors” in the final prospectus related to Entasis’ initial public offering filed with the Securities and Exchange Commission. 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.

Entasis Therapeutics Holdings Inc.
Consolidated Statements of Operations
(In Thousands, Except Share and Per Share Amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ —	\$ —	\$ 5,000	\$ —
Operating expenses:				
Research and development	8,086	7,167	26,115	17,995
General and administrative	2,075	1,346	7,840	3,448
Total operating expenses	10,161	8,513	33,955	21,443
Loss from operations	(10,161)	(8,513)	(28,955)	(21,443)
Other income:				
Grant income	1,669	183	4,507	674
Interest income	19	6	47	18
Total other income	1,688	189	4,554	692
Loss before income taxes	(8,473)	(8,324)	(24,401)	(20,751)
Provision for income taxes	—	—	472	—
Net loss	(8,473)	(8,324)	(24,873)	(20,751)
Dividends declared	(9,142)	—	(9,142)	—
Net loss attributable to common shareholders				
Basic and diluted	\$ (17,615)	\$ (8,324)	\$ (34,015)	\$ (20,751)
Net loss per share attributable to common shareholders				
Basic and diluted	\$ (20)	\$ (5,107)	\$ (113)	\$ (25,183)
Weighted average common shares outstanding				
Basic and diluted	866,641	1,630	300,435	824

Entasis Therapeutics Holdings Inc.
Condensed Consolidated Balance Sheet Data
(In Thousands)
(Unaudited)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash and cash equivalents	\$ 94,021	\$ 55,101
Other assets	6,039	3,693
Total assets	<u>\$ 100,060</u>	<u>\$ 58,794</u>
Total liabilities	9,577	9,871
Preferred stock	—	104,713
Total stockholders' equity (deficit)	90,483	(55,790)
Total liabilities and stockholders' equity (deficit)	<u>\$ 100,060</u>	<u>\$ 58,794</u>

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