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 5, 2021

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, par value $0.001 per share	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 May 5, 2021, Entasis Therapeutics Holdings Inc., or the Company, issued a press release announcing its financial results for the quarter ended March 31, 2021. 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 May 5, 2021
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: May 5, 2021

Exhibit 99.1

Entasis Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

– ATTACK Phase 3 topline data readout remains on track for second half of 2021 –
– Strengthened balance sheet with $20M financing –

WALTHAM, Mass., May 5, 2021 (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 first quarter 2021 financial results and provided a business update.

"Through the dedication of our employees and partners, we have maintained momentum in our Phase 3 registrational trials addressing multidrug-resistant *Acinetobacter* infections and uncomplicated gonorrhea," commented Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. "We are especially encouraged by the progress achieved in ATTACK, our Phase 3 trial for multidrug-resistant *Acinetobacter* infections where we now have a clear line of sight to enrolling 120 evaluable patients with carbapenem-resistant infections. Given this progress, we remain confident ATTACK is on-track to complete enrollment in the coming weeks and for topline data readout during the second half of 2021. While advancing SUL-DUR remains our top-priority, we are also excited by the progression of our pipeline, including the Phase 3 trial for zoliflodacin, which we believe has the potential to provide a solution for the millions of annual cases of gonorrhea around the world. We are also pleased to recently announce the closing of the first tranche of a $20 million private placement transaction. The second tranche of the financing will occur upon shareholder approval, which is anticipated in June 2021. As a result of the first tranche of the offering, we now anticipate that our cash runway will be sufficient to fund our operations into the second quarter of 2022. 2021 is poised to be a transformative year for Entasis as we conclude our Phase 3 ATTACK registration trial and initiate preparations to become a commercial stage company."

First Quarter 2021 and Recent Highlights

Business Highlights

- The Company, along with our partner Zai Lab (Nasdaq: ZLAB), has enrolled 108 patients with confirmed carbapenem-resistant *Acinetobacter* infections in the ATTACK Phase 3 registration trial. The Company estimates that the ATTACK trial is approximately 90% enrolled and expects to complete enrollment in the coming weeks and remains on-track for top-line data readout in the second half of 2021.

- The Company recently announced that it had entered into a private placement agreement to sell Entasis common stock and warrant securities to a subsidiary of Innoviva, Inc. (Nasdaq: INVA) ("Innoviva"), Entasis' largest shareholder. The gross proceeds to the Company from the transaction after both closings are expected to be approximately $20 million, before deducting estimated offering expenses payable by the Company. The closing of the first tranche of the financing, consisting of approximately $7.5 million, occurred on May 3, 2021. The closing of the second tranche, consisting of approximately $12.5 million, is expected to occur in early June, assuming approval of the financing at a special meeting of stockholders. The Company intends to use the net proceeds for the continued support of the ongoing ATTACK trial, NDA filing preparation as well as working capital and other general corporate purposes.

SUL-DUR

- As of May 1, 2021, 167 patients have been enrolled in the ATTACK trial across approximately 90 clinical trial sites in 17 countries, including China. ATTACK is our single Phase 3 registration trial that will evaluate SUL-DUR in patients with confirmed carbapenem-resistant *Acinetobacter* pneumonia and/or bloodstream infections. Entasis currently estimates the trial is approximately 90% enrolled, as microbiological analyses have confirmed 108 carbapenem-resistant evaluable patients out of the target of

120 evaluable patients necessary for completion of the trial, with another 16 enrolled patients pending confirmation. The Company expects to complete enrollment in the ATTACK trial in the coming weeks with a top-line data readout in the second half of 2021.

Zoliflodacin

- The Company continues to support the Global Antibiotic Research and Development Partnership (GARDP), and the Phase 3 registration trial of zoliflodacin for the treatment of uncomplicated gonorrhea. The trial, designed to assess the safety and efficacy of oral zoliflodacin versus the current standard of care combination of intramuscular ceftriaxone plus oral azithromycin, is actively enrolling patients with uncomplicated gonorrhea, including infections potentially caused by multidrug-resistant strains of *N. gonorrhoeae*. In Q1, GARDP activated additional clinical trial sites in the US, Thailand, and South Africa, and plans to activate up to 16 additional clinical trial sites across these countries and the Netherlands during the first half of 2021. Due to the unique challenges to site activation and enrollment precipitated by the COVID-19 pandemic, the Company remains unable to provide guidance for completion of the trial. The Company will continue to monitor and consult with GARDP and will provide updates on guidance when appropriate.

First Quarter 2021 Financial Results

The Company reported a net loss of $10.7 million for the three months ended March 31, 2021, compared to a net loss of $15.3 million for the three months ended March 31, 2020. The decrease in net loss was primarily related to a decrease in operating expenses during the first quarter of 2021 versus the prior year.

Research and development expenses were $9.4 million during the three months ended March 31, 2021, compared to $11.6 million during the three months ended March 31, 2020. The decrease of $2.3 million was primarily due to a decrease of $3.4 million in expenses related to our SUL-DUR product candidate attributable to decreases in clinical trial costs, manufacturing costs, spending related to commercial readiness and NDA support. These decreases were offset by increases in expenses related to our ETX0462 product candidate, other preclinical expenses and personnel expenses associated with higher headcount.

General and administrative expenses were $3.3 million for the three months ended March 31, 2021, compared to $3.8 million during the three months ended March 31, 2020. The decrease of $0.5 million was driven primarily by decreases in legal expenses and personnel related expenses, and was offset by an increase in insurance related costs.

As of March 31, 2021, cash and cash equivalents were $44.9 million, compared to $53.2 million as of December 31, 2020. Based on our current operating plan, we believe that our existing cash and cash equivalents, including amounts received from the first tranche of the most recent private offering, will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2022.

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 March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 9,370	$ 11,623
General and administrative	3,307	3,780
Total operating expenses	12,677	15,403
Loss from operations	(12,677)	(15,403)
Other income:		
Grant income	1,972	13
Interest income	4	124
Total other income	1,976	137
Net loss	(10,701)	(15,266)
Net loss per share—basic and diluted	$ (0.29)	$ (1.15)
Weighted average common stock outstanding—basic and diluted	37,078,478	13,291,563

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 44,937	$ 53,247
Other assets	7,888	8,311
Total assets	$ 52,825	$ 61,558
Total liabilities	$ 8,568	$ 9,269
Total stockholders' equity	44,257	52,289
Total liabilities and stockholders' equity	$ 52,825	$ 61,558