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):
August 11, 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 August 11, 2021, Entasis Therapeutics Holdings Inc., or the Company, issued a press release announcing its financial results for the quarter ended June 30, 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 August 11, 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: August 11, 2021

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

– Management to Host Conference Call on August 12 at 8am ET –

- *Patient Enrollment in the ATTACK Phase 3 Registrational Trial Completed; Top-Line Data Readout Expected Early Fourth Quarter 2021*
- *SUL-DUR Launch Planning Progresses with Appointment of Anna Diaz Triola as Chief Commercial Officer*
- *Data On SUL-DUR and ETX0462 Presented at World Microbe Forum*
- *$20 Million Private Placement Transaction Completed with Innoviva*

WALTHAM, Mass., August 11, 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 financial results for the second quarter 2021 and issued a business update for the quarter and recent weeks.

"During our second quarter and in recent weeks we continued to build upon the momentum in our clinical programs that began earlier in the year. We completed enrollment in the ATTACK Phase 3 registrational trial which is evaluating sulbactam-durlobactam (SUL-DUR) for the treatment of carbapenem-resistant *Acinetobacter* infections, and continued enrollment in the Phase 3 registrational trial that is evaluating zoliflodacin for the treatment of uncomplicated gonorrhea," said Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. "As announced recently, we now expect top-line data readout from the ATTACK trial early in the fourth quarter. To further our commercialization planning, we are pleased to welcome Anna Diaz Triola as our new Chief Commercial Officer. Anna brings a track record of commercializing products across multiple therapeutic areas, including antibacterials, and we look forward to her advancing our commercialization capabilities. We are also excited by progress in the rest of our pipeline, specifically our new first-in-class candidate ETX0462, a novel diazabicyclooctane with antimicrobial activity against multiple Gram-negative pathogens including *Pseudomonas aeruginosa* as well as a number of high-priority biothreat pathogens. With the completion of the second tranche of our $20 million private placement transaction with Innoviva, we now anticipate that our cash runway will be sufficient to fund our operations through the second quarter of 2022. We are pleased with our progress this quarter and continue to work toward transforming Entasis into a commercial stage company."

Second Quarter 2021 and Recent Highlights

SUL-DUR

- The Company, along with its partner Zai Lab (NASDAQ: ZLAB), announced the completion of patient enrollment in ATTACK, a single Phase 3 registrational trial that is evaluating the safety and efficacy of SUL-DUR in patients with confirmed carbapenem-resistant *Acinetobacter* infections. Over 120 evaluable patients were enrolled into the primary efficacy arm, sufficient to complete the trial. The Company anticipates top-line data readout early in the fourth quarter.

- The Company will host an *Expert Perspectives on Acinetobacter Infections Webinar*, Tuesday August 24 at 10:00 AM ET. This program will feature presentations by Infectious Disease experts Dr. David van Duin of the University of North Carolina and Dr. Michael J. Rybak of Wayne State University, who will discuss the burden and current treatment landscape of *Acinetobacter* infections. The program is open to all interested parties, and registration is available on our website www.entasistx.com.

World Microbe Forum

- Entasis presented 7 posters and one oral presentation highlighting ETX0462, a novel, first-in-class, diazabicyclooctane with antimicrobial activity against multiple Gram-negative pathogens including *Pseudomonas aeruginosa* as well as a number of high-priority biothreat pathogens. This novel class of agents is designed to potentially target a broad spectrum of multidrug resistant bacterial pathogens that are included in both the Center for Disease Control and World Health Organization lists of high unmet medical need pathogens. Presentations also included updates on SUL-DUR and ETX0282CPDP, an oral β-lactam/β-lactamase inhibitor being developed to treat multidrug-resistant Gram-negative pathogens, including those caused by extended-spectrum β-lactamases (ESBLs) and carbapenem-resistant *Enterobacteriaceae* (CRE).

Corporate & Business Highlights

- The Company appointed Anna Diaz Triola as its Chief Commercial Officer, effective July 19, 2021. Ms. Triola brings over 20 years of experience in the launch and commercialization of products across multiple therapeutic areas and diverse settings of care, including the hospital and community. She previously served as the Vice President, Marketing at Summit Therapeutics where she was instrumental in developing the commercial strategy for the company's first product against *C. difficile* infections. Prior to joining Summit, Ms. Triola held commercial leadership roles at Flexion Therapeutics, Chiasma, Cubist, and Biogen. Ms. Triola holds an M.B.A from Harvard Business School and a B.A. from Wellesley College.

- The Company completed a private placement to sell Entasis common stock and warrants to a wholly-owned subsidiary of Innoviva Inc. (Nasdaq: INVA), Entasis' largest shareholder. The gross proceeds to the Company from the transaction totaled $20 million, before deducting offering expenses payable by the Company. The Company intends to use the net proceeds for completing the ATTACK trial, NDA filing preparation, SUL-DUR launch readiness as well as working capital and other general corporate purposes.

Second Quarter Financial Results

The Company reported a net loss of $12.0 million for the three months ended June 30, 2021, compared to a net loss of $13.4 million for the three months ended June 30, 2020. The decrease in net loss was primarily related to an increase in grant income during the second quarter of 2021 versus the prior year.

Research and development expenses were $10.0 million during the three months ended June 30, 2021, compared to $10.2 million during the three months ended June 30, 2020. The decrease of $0.2 million was primarily due to a decrease of $1.1 million in expenses related to our SUL-DUR product candidate, attributable to a decrease in clinical trial costs. This decrease was partially offset by an increase in expenses related to our ETX0462 product candidate and personnel expenses associated with higher headcount.

General and administrative expenses were $3.3 million for the three months ended June 30, 2021, compared to $3.2 million during the three months ended June 30, 2020. The increase of $0.1 million was driven primarily by an increase in insurance related costs.

As of June 30, 2021, cash and cash equivalents were $56.4 million, compared to $53.2 million as of December 31, 2020. Based our current operating plan, we believe that our existing cash and cash equivalents, including amounts received from the most recent private offering, will be sufficient to fund our operating expenses and capital expenditure requirements through the second quarter of 2022.

Conference Call

Investors and the general public are invited to listen to a live audio webcast of the conference call, which may be accessed five minutes prior to the start of the call by dialing 877-407-4018 (U.S.) or 201-689-8471 (international) Conference ID 13721936 or at the website http://public.viavid.com/index.php?id=145976. A replay of the call will be available from the Entasis website at www.entasistx.com following the call.

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), ETX0462 (targeting multiple Gram-negative pathogens including *Pseudomonas aeruginosa*) and ETX0282CPDP (targeting *Enterobacteriaceae* 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 9,986	$ 10,239	$ 19,356	$ 21,862
General and administrative	3,311	3,241	6,618	7,021
Total operating expenses	13,297	13,480	25,974	28,883
Loss from operations	(13,297)	(13,480)	(25,974)	(28,883)
Other income:				
Grant income	1,264	48	3,236	62
Interest income	3	36	7	159
Total other income	1,267	84	3,243	221
Net loss	(12,030)	(13,396)	(22,731)	(28,662)
Net loss per share —basic and diluted	$ (0.29)	$ (0.78)	$ (0.58)	$ (1.89)
Weighted average common stock outstanding—basic and diluted	41,107,067	17,095,140	39,103,901	15,193,351

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

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 56,406	$ 53,247
Other assets	7,159	8,311
Total assets	$ 63,565	$ 61,558
Total liabilities	$ 10,505	$ 9,269
Total stockholders' equity	53,060	52,289
Total liabilities and stockholders' equity	$ 63,565	$ 61,558