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 4, 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 November 4, 2021, Entasis Therapeutics Holdings Inc., or the Company, issued a press release announcing its financial results for the quarter ended September 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 November 4, 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: November 4, 2021

Exhibit 99.1

Entasis Therapeutics Announces Third Quarter 2021 Financial Results and Provides Business Update

– Management to host a conference call on November 4, 2021 at 8:00am ET –

- Sulbactam-durlobactam (SUL-DUR) achieved all primary and secondary endpoints from landmark Phase 3 ATTACK trial
- Robust dataset builds compelling case for SUL-DUR which if approved, could become the first, uniquely differentiated and life-saving treatment option for patients with *Acinetobacter* infections
- Preparing for commercialization ahead of NDA submission in mid-2022, under the leadership of newly appointed Chief Commercial Officer Anna Diaz Triola
- Entasis' pathogen-directed platform and latest candidate ETX0462 highlighted by seminal publication in the prestigious scientific journal *Nature*

WALTHAM, Mass. — November 4, 2021 (Globe Newswire)— Entasis Therapeutics Holdings Inc. (Nasdaq: ETTX), a late-stage clinical biopharmaceutical company focused on the discovery and development of novel antibacterial products, today announced financial results for the third quarter 2021 and issued a business update for the quarter and recent weeks.

"The past few weeks have been an exciting period for Entasis, with announcement of topline data from the landmark Phase 3 ATTACK trial in patients with *Acinetobacter* infections, where SUL-DUR achieved all primary and secondary endpoints," said Manos Perros, Chief Executive Officer at Entasis. "SUL-DUR is the first investigational drug to not only demonstrate efficacy in 28-day all-cause mortality in this patient population, but also show a meaningful advantage in clinical cure rates as well as safety. In a therapeutic area where incremental improvements have long been the norm, our data provides the prospect of SUL-DUR being a potential life-saving treatment for patients with *Acinetobacter* infections. We look forward to discussing our data with the regulatory agencies in preparation for NDA submission in mid-2022. During the past quarter we also accelerated our commercial readiness activities for SUL-DUR with the appointment of Anna Diaz Triola as our Chief Commercial Officer to spearhead this effort. Lastly, we continue to make progress with the rest of our pipeline, including publication of our latest candidate ETX0462 in the prestigious journal *Nature*. ETX0462 is the first in a new class of agents with activity against multiple Gram-negative pathogens including *Pseudomonas aeruginosa* as well as several high-priority biothreat pathogens."

Third Quarter and Recent Weeks Highlights

SUL-DUR

– The Company, and its partner Zai Lab (Nasdaq: ZLAB), announced topline data from ATTACK, a single Phase 3 registrational trial that evaluated the safety and efficacy of SUL-DUR in patients with confirmed carbapenem-resistant *Acinetobacter* infections. SUL-DUR achieved the primary endpoint of 28-day all-cause mortality in patients with carbapenem-resistant *Acinetobacter* infections (CRABC m-MITT* population in Part A of the study), demonstrating statistical non-inferiority versus colistin. Mortality analyses in all pre-specified populations included in the topline results unequivocally favored SUL-DUR versus colistin. At Test of Cure, there was a statistically significant difference in clinical

cure rate favoring SUL-DUR over colistin. SUL-DUR also met the primary safety objective of the study achieving statistically significant reduction in nephrotoxicity.

- The Company is currently planning for a NDA submission in mid-2022.

Zoliflodacin

- The Company continues to support its partner, the Global Antibiotic Research and Development Partnership (GARDP), and its Phase 3 registrational trial of zoliflodacin for the treatment of uncomplicated gonorrhea. The trial will assess the safety and efficacy of oral zoliflodacin versus the current standard of care combination of intramuscular ceftriaxone plus oral azithromycin. The trial continues to actively enroll patients with uncomplicated gonorrhea, including infections potentially caused by multidrug-resistant strains of *N. gonorrhoeae* at 12 clinical trial sites across the United States, the Netherlands, South Africa and Thailand, including 6 new sites activated since the start of the year.

ETX0462

- In pre-clinical data presented at the *World Microbe Forum*, ETX0462 exhibited robust antibacterial activity against multiple Gram-negative pathogens, and bactericidal activity reaching >3-log drop vs. initial inoculum in a neutropenic murine lung model against clinical isolates of *P. aeruginosa*. Similar *in vivo* efficacy was also demonstrated for the biothreat pathogens *Y. pestis* and *B. pseudomallei*. The scientific platform from which ETX0462 was developed and its preclinical profile were the subject of a recent publication in the prestigious journal *Nature.*

Corporate & Business Highlights

- In July, the Company announced the appointment of Anna Diaz Triola as its Chief Commercial Officer, with responsibilities for global commercial strategy including U.S. sales and marketing operations. Ms. Triola previously served as the Vice President, Marketing at Summit Therapeutics, and prior to that held leadership roles at Flexion Therapeutics, Chiasma, Cubist, and Biogen.

Third Quarter Financial Results

The Company reported a net loss of $12.4 million for the three months ended September 30, 2021, compared to a net loss of $11.1 million for the three months ended September 30, 2020. The increase in net loss was primarily related to an increase in general and administrative expenses as the Company initiated select pre-commercialization activities.

Research and development expenses were $9.3 million during the three months ended September 30, 2021, compared to $9.4 million during the three months ended September 30, 2020. The decrease of $0.1 million was primarily due to a decrease of $0.5 million in expenses related to our SUL-DUR product candidate and a decrease of $0.2 million in expenses related to our ETX0462 product candidate, partially offset by an increase of $0.6 million in personnel expenses.

General and administrative expenses were $4.3 million for the three months ended September 30, 2021, compared to $3.2 million during the three months ended September 30, 2020. The increase of $1.1 million was driven primarily by increases of $0.3 million in legal costs, $0.3 million in personnel costs, $0.2 million in consulting costs and $0.1 million in insurance related costs.

As of September 30, 2021, cash and cash equivalents were $44.1 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, will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2022.

*Carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* Complex Microbiologically Modified Intent-to-Treat Population

Conference Call & Webcast

The company will host a conference call and webcast at 8:00AM Eastern Time to discuss its results and provide a clinical and corporate update. A question-and-answer session will follow management's prepared remarks. 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 888-394-8218 (U.S.) or 323-701-0225 (international) or through the link Entasis Third Quarter Financial Results Call. A replay of the call will be available from the Entasis website at www.entasistx.com following the call.

About Entasis Therapeutics Holdings Inc.

Entasis is a late-stage clinical 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 SUL-DUR (targeting *Acinetobacter baumannii* infections), zoliflodacin (targeting *Neisseria gonorrhoeae* infections), ETX0282CPDP (targeting Enterobacterales infections) and ETX0462 (targeting Gram-negative infections including *Pseudomonas*). 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 "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would," or the negative or plural of those terms, and similar expressions are intended to identify forward-looking statements. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements 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, rejection of our regulatory submissions, 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.

Research on ETX0462 reported in this news release is partially supported by CARB-X. CARB-X's funding for this project is sponsored by the Cooperative Agreement Number IDSEP160030 from ASPR/BARDA and by an award from Wellcome Trust, as administrated by CARB-X. The content is solely the responsibility of the authors and does not necessarily represent the official views of CARB-X or any of its funders.

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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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 9,282	$ 9,387	$ 28,638	$ 31,249
General and administrative	4,320	3,213	10,938	10,235
Total operating expenses	13,602	12,600	39,576	41,484
Loss from operations	(13,602)	(12,600)	(39,576)	(41,484)
Other income:				
Grant income	1,208	1,458	4,444	1,519
Interest income	3	9	10	170
Total other income	1,211	1,467	4,454	1,689
Net loss	(12,391)	(11,133)	(35,122)	(39,795)
Net loss per share —basic and diluted	$ (0.26)	$ (0.37)	$ (0.84)	$ (1.97)
Weighted average common stock outstanding—basic and diluted	47,310,254	29,960,219	41,869,412	20,151,570

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

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 44,124	$ 53,247
Other assets	6,642	8,311
Total assets	$ 50,766	$ 61,558
Total liabilities	$ 9,531	$ 9,269
Total stockholders' equity	41,235	52,289
Total liabilities and stockholders' equity	$ 50,766	$ 61,558