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 27, 2022

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 April 27, 2022, Entasis Therapeutics Holdings Inc., or the Company, issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 April 27, 2022
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/ Kristie Wagner
Kristie Wagner
Vice President Corporate Controller

Dated: April 27, 2022

Entasis Therapeutics Announces First Quarter 2022 Financial Results and Provides Business Update

- Highlights of landmark Phase 3 ATTACK trial for sulbactam-durlobactam (SUL-DUR) presented at ECCMID 2022 annual conference
- SUL-DUR NDA submission on track for mid-2022
- Zoliflodacin Phase 3 trial progressing; enrollment completion now anticipated in 2023

WALTHAM, Mass. — April 27, 2022 (Globe Newswire)— Entasis Therapeutics Holdings Inc. (Nasdaq: ETTX), an advanced late-stage clinical biopharmaceutical company focused on the discovery and development of novel antibacterial products, today announced its first quarter 2022 financial results and provided a business update.

"During our first quarter we continued to advance our pipeline and lay the foundations of our development into a fully-integrated entity with research, development and commercialization capabilities. Our focus remains on the preparation of our NDA for sulbactam-durlobactam (SUL-DUR) that we expect to file with the FDA in mid-2022. We were pleased to see data from our landmark Phase 3 ATTACK trial for SUL-DUR featured prominently at this year's ECCMID conference, and are confident that if approved, SUL-DUR has the potential to become the life-saving treatment of choice for patients with drug resistant *Acinetobacter* infections. We also continue to advance the rest of our pipeline, led by the zoliflodacin Phase 3 registrational trial, that we anticipate will complete enrollment in 2023. For the remainder of 2022, we will continue to focus our current resources on the SUL-DUR NDA, while preparing for commercialization in the US should the product be approved. We will also continue supporting our partner GARDP to complete the zoliflodacin Phase 3 trial, and invest responsibly in advancing our earlier pipeline, including ETX0462, the first in a new class of agents with activity against multiple Gram-negative pathogens including *Pseudomonas aeruginosa* and multiple high-priority biothreat pathogens."

Business Highlights

SUL-DUR

- Multiple presentations on SUL-DUR were delivered at the *European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)* annual conference, held April 23-26, 2022.
  - Two oral presentations presented by Drs. Alita Miller, Vice President, Microbiology and David Altarac, Chief Medical Officer, highlighted topline results and sub-analysis from the landmark ATTACK Phase 3 Trial

    - Five poster presentations also highlighted additional SUL-DUR and ATTACK details and results
- The Company is on track for submission of the NDA for SUL-DUR to the FDA 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 14 clinical trial sites across the United States, the Netherlands, South Africa and Thailand. Given the improved progress with enrollment over the past 3 quarters, we now anticipate completion of trial enrollment in 2023.

Innoviva Proposal

- On February 1, 2022, the Company's Board of Directors received a preliminary, non-binding proposal from its majority stockholder Innoviva Inc. ("Innoviva"), to acquire all the outstanding equity securities of the Company that are not currently owned by Innoviva for a per share consideration of $1.80, payable in cash. On March 15, 2022, Innoviva revised its non-binding offer to acquire the Company to increase the per share consideration to $2.00. All other terms of the offer remain unchanged. The offer letters delivered by Innoviva to the Board of Directors are publicly available in the Schedule 13D amendments dated February 1, 2022 and March 15, 2022, filed by Innoviva with the Securities and Exchange Commission. The Board of Directors of Entasis, which does not include any members appointed by or affiliated with Innoviva, has retained MTS Health Partners, L.P. and Covington & Burling LLP to explore alternatives and to assist the board of directors in its evaluation of the proposal consistent with its fiduciary duties.

Innoviva Private Placement

- On February 18, 2022, the Company issued and sold to Innoviva, in a private placement, a convertible promissory note. The gross proceeds to the Company from the transaction totaled $15 million. The company intends to use the proceeds primarily for the NDA filing preparation and other general corporate purposes.

2022 First Quarter Financial Results

The Company reported a net loss of $15.3 million for the period ended March 31, 2022, compared to a net loss of $10.7 million for the prior year quarter. The increase in net loss was primarily related to increases in research and development expenses related to SUL-DUR, an increase in general and administrative expenses primarily related to professional expenses and a decrease in grant income from our agreements with CARB-X and NIH.

Research and development expenses were $11.0 million for the quarter ended March 31, 2022, compared to $9.4 million for the prior year quarter. The increase of $1.6 million was primarily due to an increase of $1.6 million in expenses related to SUL-DUR primarily associated with manufacturing and NDA support partially offset by a decrease in clinical trial costs, an increase of $0.7 million of personnel expenses associated with higher salary and related costs and an increase of $0.4 million in other preclinical programs offset in part by a decrease of $1.1 million in preclinical and clinical development expenses related to the advancement of ETX0462.

General and administrative expenses were $4.9 million for the quarter ended March 31, 2022, compared to $3.3 million for the prior year quarter. The increase of $1.6 million was driven by an increase of professional expenses primarily due to increases of $1.1 million in consulting expense, $0.4 million in legal expenses and $0.1 million in investor and public relations expenses.

As of March 31, 2022, we had cash and cash equivalents of $33.5 million, compared to $32.3 million as of December 31, 2021. 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 through the third quarter of 2022.

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

About Entasis Therapeutics Holdings Inc.
Entasis is an advanced late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of targeted antibacterial products that address high unmet medical needs to treat serious infections caused by multidrug-resistant pathogens. 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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---tables to follow---

Entasis Therapeutics Holdings Inc.
Condensed Consolidated Statements of Operations
Unaudited
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 10,992	$ 9,370
General and administrative	4,936	3,307
Total operating expenses	15,928	12,677
Loss from operations	(15,928)	(12,677)
Other income, net:		
Grant income	672	1,972
Interest income	4	4
Interest expense	(10)	—
Total other income, net	666	1,976
Net loss	(15,262)	(10,701)
Net loss per share—basic and diluted	$ (0.32)	$ (0.29)
Weighted average common stock outstanding—basic and diluted	47,851,779	37,078,478

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 33,547	$ 32,307
Other assets	10,543	8,613
Total assets	$ 44,090	$ 40,920
Total liabilities	$ 27,443	$ 9,708
Total stockholders' equity	16,647	31,212
Total liabilities and stockholders' equity	$ 44,090	$ 40,920