# Entasis Therapeutics Announces Year End 2021 Financial Results and Provides Business Update

March 3, 2022

- Phase 3 ATTACK registrational trial for sulbactam-durlobactam (SUL-DUR) achieved all primary and secondary endpoints, NDA submission planned for mid-2022
- Zoliflodacin Phase 3 trial progressing; enrollment completion now anticipated in 2023
- Entasis' pathogen-directed platform and latest candidate ETX0462 highlighted by seminal publication in the prestigious scientific journal *Nature*
- Receipt of acquisition proposal from existing majority shareholder Innoviva, Inc.

WALTHAM, Mass., March 03, 2022 (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 full year 2021 financial results and provided a business update.

"The incredible effort and commitment of our employees and partners in 2021 has resulted in a very productive year for Entasis," said Manos Perros, Chief Executive Officer at Entasis. "We successfully achieved our major objective for the year, announcing positive top-line data from our landmark Phase 3 ATTACK trial in patients with *Acinetobacter* infections, in which SUL-DUR achieved all primary and secondary endpoints. SUL-DUR is the first investigational drug to not only demonstrate efficacy in 28-day all-cause mortality in this patient population, but also showed 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. During the year we also continued to advance our pipeline, highlighted by the meaningful progress of the zoliflodacin Phase 3 registrational trial that we now anticipate completion of enrollment in 2023. In addition, the recent publication of our latest candidate ETX0462 in the prestigious journal *Nature* further validates our approaches to discovering and developing innovative therapies to address antimicrobial resistance. 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. Looking ahead to 2022, we intend to use our current resources to support our NDA submission for SUL-DUR in mid-2022, and we look forward to discussing our data with the regulatory agencies in the coming weeks."

**Business Highlights**

**SUL-DUR**

- The Company, and its partner Zai Lab (Nasdaq: ZLAB), announced positive 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 continues to plan for an 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. Given the improved progress with enrollment over the past 2 quarters, we now anticipate completion of trial enrollment in 2023.
- The Company was a co-author of the peer reviewed article "Thorough QT study to evaluate the effect of zoliflodacin, a novel therapeutic for gonorrhea, on cardiac repolarization in healthy adults" in *Antimicrobial Agents and Chemotherapy*, 2021. 65(12):e0129221.

**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

*Yersinia pestis* and *Burkholderia 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.*

**Innoviva Proposal**

- 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 Entasis that are not currently owned by Innoviva for a per share consideration of $1.80 payable in cash. The offer letter delivered by Innoviva to the Board of Directors is publicly available in the Schedule 13D amendment dated February 1, 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, L.L.P. 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.

**2021 Year End Financial Results**

The Company reported a net loss of $47.1 million for the year ended December 31, 2021, compared to a net loss of $50.5 million for the year ended December 31, 2020. The decrease in net loss was primarily related to a decrease in research and development expenses related SUL-DUR and an increase in grant income from our agreements with CARB-X and NIH, partially offset by additional general and administrative expenses related primarily to additional personnel expenses associated with higher headcount.

Research and development expenses were $37.1 million for the year ended December 31, 2021, compared to $41.0 million for the year ended December 31, 2020. The decrease of $3.9 million was primarily due to a decrease of $6.5 million in clinical development expenses related to the advancement of SUL-DUR; offset in part by an increase of $2.1 million of personnel expenses associated with higher headcount, higher salaries and higher stock-based compensation expense resulting from options and restricted stock units granted during the year ended December 31, 2021, an increase of $0.3 million in preclinical and clinical development expenses related to the advancement of ETX0462 and an increase of $0.3 million in other preclinical programs.

General and administrative expenses were $15.2 million for the year ended December 31, 2021, compared to $13.2 million for the year ended December 31, 2020. The increase of $2.0 million was driven by an increase of $1.0 million in personnel expenses associated with higher headcount and higher salaries, an increase of $0.6 million in professional expenses and an increase of $0.4 million in insurance expenses. The increase of $0.6 million in professional expenses was primarily due to an increase of $0.3 million in consulting expenses, an increase of $0.2 million in investor and public relations expenses and an increase of $0.1 million in legal expenses.

As of December 31, 2021, we had cash and cash equivalents of $32.3 million, compared to $53.2 million as of December 31, 2020. Based on our current operating plan, including the $15.0 million received from Innoviva from the convertible promissory note, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through the end of the third quarter of 2022.

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

**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.

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

| | Year Ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Operating expenses: | | |
| Research and development | $ 37,105 | $ 41,022 |
| General and administrative | 15,212 | 13,209 |
| Total operating expenses | 52,317 | 54,231 |
| Loss from operations | (52,317) | (54,231) |
| Other income: | | |
| Grant income | 5,163 | 3,562 |
| Interest income | 13 | 173 |
| Total other income | 5,176 | 3,735 |
| Net loss | $ (47,141) | $ (50,496) |
| Net loss per share—basic and diluted | $ (1.09) | $ (2.10) |
| Weighted average common stock outstanding—basic and diluted | 43,340,826 | 24,060,615 |

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

| | **December 31, 2021** | **December 31, 2020** |
|---|---|---|
| Cash, cash equivalents and investments | $ 32,307 | $ 53,247 |
| Other assets | 8,613 | 8,311 |
| Total assets | $ 40,920 | $ 61,558 |
| | | |
| Total liabilities | $ 9,708 | $ 9,269 |
| Total stockholders' equity | 31,212 | 52,289 |
| Total liabilities and stockholders’ equity | $ 40,920 | $ 61,558 |

Source: Entasis Therapeutics Holdings Inc.