Entasis Therapeutics Reports Full Year 2020 Financial Results and Provides Business Update

March 23, 2021

– Phase 3 ATTACK registration trial more than three-quarters complete –
– ATTACK topline data readout expected second half of 2021 –
– Zoliflodacin Phase 3 trial adds clinical trial sites, continues enrollment –

WALTHAM, Mass., March 23, 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 full year 2020 financial results and provided a business update.

"Thanks to the tremendous work of our teams, partners and investigators, and the support of our patients and their families, we are entering 2021 with improved momentum for our Phase 3 registration clinical trials addressing multidrug-resistant *Acinetobacter* infections and uncomplicated gonorrhea, despite the continued headwinds of the COVID-19 pandemic," stated Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. "Based on the encouraging progress achieved during the fourth quarter of 2020 and early 2021 in the ATTACK trial and with a better understanding of the impact of the pandemic, we are now able to provide guidance and anticipate completing enrollment in the ATTACK trial in the coming months with a top-line data readout during the second half of 2021. Also during 2020, we continued to advance our early-stage pipeline and strengthen our balance sheet through two private placement transactions. We look forward to an exciting 2021, which we believe will be a transformative year for Entasis as we conclude the ATTACK trial and prepare for a potential NDA filing and commercialization of sulbactam-durlobactam (SUL-DUR)."

Fourth Quarter 2020 and Recent Highlights

Business Highlights

- The Company saw steady enrollment in the ATTACK trial, despite recruitment headwinds caused by the COVID-19 pandemic. The Company estimates that the ATTACK trial is currently more than 75% enrolled and based on the trailing 12-month enrollment rate, anticipates completion of enrollment in the clinical trial in the coming months with a top-line data readout in the second half of 2021.

- In January, the Company issued a press release regarding its expanded access program (EAP), also referred to as compassionate use, for SUL-DUR, an investigational drug for U.S. patients with *Acinetobacter baumannii* infections, including potential carbapenem and multidrug-resistant strains. Patients co-infected with COVID-19 are eligible if the treating physician feels the risk benefit supports making SUL-DUR available. In cooperation with the FDA, expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. In this circumstance, Entasis can provide a requesting physician with pre-approval access to SUL-DUR for the treatment of the physician's patient if specific conditions are met and there is adequate availability of drug supply.

SUL-DUR

- The Company continued enrollment of the ATTACK trial across approximately 95 clinical trial sites in 17 countries, including China. As of March 23, 2021, the ATTACK trial has randomized 160 patients and has had three pre-planned Data and Safety Monitoring Board reviews, including one most recently in February 2021. While the Company remains blinded to the clinical data, all three reviews recommended continuation of the trial without protocol modification. Entasis currently estimates completion of the ATTACK trial will require enrollment of approximately 170 patients to achieve the target of 120 evaluable patients. Based on the observed trailing 12-month enrollment rate, the Company anticipates completion of enrollment in the ATTACK trial in the coming months with top-line data readout in the second half of 2021.

- In February 2021, the Company published "*In vitro* activity and *in vivo* efficacy of sulbactam-durlobactam against pathogenic *Burkholderia* species" in *Antimicrobial Agents and Chemotherapy*. In addition, the Company presented four posters highlighting SUL-DUR's potential during the virtual IDWeek 2020 held on October 21-25, 2020. The Company's presentations highlighted findings which demonstrated activity of SUL-DUR against multidrug-resistant *Acinetobacter* clinical isolates from the Middle East as well as global *Acinetobacter baumannii-calcoaceticus* complex clinical isolates, a retrospective review of serious infections caused by carbapenem-susceptible and carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex, and *in vitro* intrinsic microbiological activity of durlobactam and combinations against multidrug resistant *Mycobacterium abscessus*.

Zoliflodacin

- The Company continues to support its partner, the Global Antibiotic Research and Development Partnership (GARDP), and its Phase 3 registration 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 is actively enrolling patients with uncomplicated gonorrhea, including infections potentially caused by multidrug-resistant strains of *N. gonorrhoeae*. GARDP plans to activate up to 16 clinical trial sites across the United States, the Netherlands, South Africa and Thailand, with some additional site activations occurring in the first half of 2021. Due to the unique challenges posed by the COVID-19 pandemic to this global clinical trial, the Company remains unable to provide guidance around the timeline for completion or top-line data readout and will continue to actively assess the impact of the pandemic, in consultation with GARDP, and provide updates on guidance when appropriate.

- In March 2021, the Company published "Susceptibility trends of zoliflodacin against multidrug-resistant *Neisseria gonorrhoeae* clinical isolates in Nanjing, China (2014-2018)" in *Antimicrobial Agents and Chemotherapy*. The article presents data on susceptibility to zoliflodacin of 986 Neisseria gonorrhoeae isolates collected from men in Nanjing, China between 2014 and 2018. Zoliflodacin demonstrated compelling *in vitro* activity against these clinical isolates, including those with resistance to ciprofloxacin, azithromycin, and extended spectrum cephalosporins.

Full Year 2020 Financial Results

The Company reported a net loss of $50.5 million for the year ended December 31, 2020, compared to a net loss of $43.9 million for the year ended December 31, 2019. The increase in net loss was primarily related to a decrease in revenue in 2020 versus the prior year.

Research and development expenses were $41.0 million for the year ended December 31, 2020, compared to $40.2 million for the year ended December 31, 2019. The increase of $0.9 million was primarily due to an increase in 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, 2020 and offset in part by a decrease in preclinical and clinical development expenses related to the advancement of our ETX0282CPDP product candidate and a decrease in clinical development expenses related to the advancement of our SUL-DUR product candidate.

General and administrative expenses were $13.2 million for the year ended December 31, 2020, compared to $13.8 million for the year ended December 31, 2019. The decrease of $0.6 million was driven by a decrease in consulting expenses, VAT and other taxes, and legal expenses and were partially offset by an increase in insurance premiums and personnel expenses associated with higher headcount and higher salaries.

As of December 31, 2020, cash, cash equivalents and short-term investments were $53.2 million, compared to $41.0 million as of December 31, 2019.

Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements through the end of the first 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.
Condensed Consolidated Statements of Operations
Unaudited
(in thousands, except share and per share data)

	Year Ended December 31,	
	2020	**2019**
Revenue	$ -	$ 7,000
Operating expenses:		
Research and development	41,022	40,166
General and administrative	13,209	13,770
Total operating expenses	54,231	53,936
Loss from operations	(54,231)	(46,936)
Other income:		
Grant income	3,562	2,300
Interest income	173	1,463
Total other income	3,735	3,763
Loss before income taxes	(50,496)	(43,173)
Provision for income taxes	-	677
Net loss	$ (50,496)	$ (43,850)
Net loss per share—basic and diluted	$ (2.10)	$ (3.33)
Weighted average common stock outstanding—basic and diluted	24,060,615	13,160,357

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

	December 31,	
	2020	**2019**
Cash, cash equivalents and investments	$ 53,247	$ 40,996
Other assets	8,311	10,038
Total assets	$ 61,558	$ 51,034
Total liabilities	$ 9,269	$ 8,877
Total stockholders' equity	52,289	42,157
Total liabilities and stockholders’ equity	$ 61,558	$ 51,034

Source: Entasis Therapeutics Holdings Inc.