Entasis Therapeutics Reports Second Quarter 2020 Financial Results and Business Update

August 6, 2020

WALTHAM, Mass., Aug. 06, 2020 (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 second quarter 2020 financial results and provided a business update.

"I'm pleased to report substantial progress across a number of areas of the Company in the second quarter of 2020 despite significant adjustments to adapt our clinical trial operations to the COVID-19 pandemic restrictions," commented Manos Perros, President and Chief Executive Officer of Entasis Therapeutics. "First, our two ongoing Phase 3 registration trials addressing carbapenem-resistant *Acinetobacter* infections and uncomplicated gonorrhea due to *Neisseria gonorrhea*, two "CDC urgent threats," continue to make progress in enrolling patients. Each trial, however, has been impacted by the COVID-19 pandemic as it disrupts healthcare facilities and practitioners around the world. As a result of the unpredictability of these disruptions, at this time we cannot provide specific guidance when each trial will be completed."

"Second, we have strengthened our balance sheet by completing the closing of the $35 million common stock and warrant investment from Innoviva, Inc., which strategically positions us to fund the ATTACK Phase 3 registration trial and advance our pipeline. Third, we secured two non-dilutive funding awards to support our pipeline of novel antibacterial programs. We are pleased to continue our relationship with CARB-X, which, in June, exercised a new option award under our existing arrangement that will support development of ETX0462 to Phase 1-ready status. ETX0462 is being developed to potentially address multidrug-resistant *Pseudomonas* infections. Additionally, we have been awarded a contract from the National Institute of Allergy and Infectious Diseases (NIAID) that included an initial amount of approximately $3 million and the potential to receive up to $15.5 million. We believe this contract further validates the potential of our NBP platform to yield novel molecules with expanded Gram-negative spectrum against antibiotic-resistant bacterial pathogens. Finally, seven articles were published across our clinical programs SUL-DUR, zoliflodacin, and ETX0282CPDP, including a zoliflodacin article that was chosen as the Editors' Choice in the May 12, 2020 edition of ACS Infectious Disease. Taken together, these accomplishments provide us with momentum to continue executing on our business objectives in the second half of 2020."

Second Quarter 2020 and Recent Highlights

Business Highlights

- In June, the Company closed its securities purchase agreement with Innoviva for gross proceeds of $35 million. The stock purchase occurred in two tranches. The first tranche was closed in April for an aggregate purchase price of approximately $3.3 million. In the second tranche, which was completed in June, Innoviva purchased 12,677,490 shares of common stock and warrants for gross proceeds of approximately $31.7 million.

- In June the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a global non-profit partnership dedicated to accelerating antibacterial research to tackle the global rising threat of drug-resistant bacteria, exercised a new option under our existing arrangement. The option provides non-dilutive support for additional pre-clinical work to further develop ETX0462, our first product candidate from our non-β-lactam inhibitor (NBP) platform, to Phase 1-ready status.

- In June, the Company also received a contract from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The contract initiated on July 1, 2020 and included an initial award of approximately $3 million, with the potential to increase up to $15.5 million. Proceeds from the contract will be used to develop novel molecules from Entasis' non-β-lactam inhibitor (NBP) platform with expanded antimicrobial spectrum.

- In June, the Company presented at the BMO virtual 2020 Prescriptions for Success Healthcare Conference.

SUL-DUR

- The Company continues to advance ATTACK, a global two-part Phase 3 registration trial evaluating SUL-DUR for the treatment of patients with pneumonia and bloodstream infections caused by carbapenem-resistant *Acinetobacter baumannii*. The trial has now opened approximately 89 clinical sites across 16 countries, and a July 2020 Drug and Safety Monitoring Board review recommended continuation of the trial without protocol modification. Despite the continued progress, the COVID-19 pandemic continues to intermittently disrupt the operations of the ATTACK global clinical trial sites. The timing, scope and duration of these interruptions are unpredictable and, as a consequence, we cannot accurately assess their impact on the expected timeline for completion of the trial. Therefore, the Company is suspending guidance on top-line data from this study. We will continue to monitor the situation and provide updates as available.

- A publication from the Company (Seifert H., et al. Antimicrob Chemother. 2020 Jun 9) and a separate publication from our

partner Zai Lab (Yang Q., et al. Antimicrob Chemother. 2020 Jul 1;75(7)) highlighted the in vitro potency of SUL-DUR against global isolates of carbapenem-resistant *Acinetobacter baumannii* and clinical isolates of *Acinetobacter baumannii* from China, respectively. In addition, the Company also published Phase 1 results demonstrating that durlobactam was generally safe and well tolerated when administered either alone or in combination with sulbactam and/or imipenem-cilastatin (Lickliter JD, Lawrence K, O'Donnell J, Isaacs R. Antimicrob Agents Chemother. 2020 Jun 23;64(7)).

Zoliflodacin

- The Company is continuing to support the Phase 3 registration trial of zoliflodacin for the treatment of uncomplicated gonorrhea in partnership with the Global Antibiotic Research and Development Partnership (GARDP). The trial is set to enroll approximately 1,000 patients with urogenital gonorrhea at clinical trial sites in the United States and around the world and will assess the safety and efficacy of zoliflodacin versus the combination of azithromycin and ceftriaxone, the current standard of care. In late-March, GARDP, with the Company's agreement, made the decision to temporarily suspend patient enrollment into the Phase 3 registration trial at U.S. sites and activation of new clinical trial sites in ex-U.S. regions due to the COVID-19 pandemic. Although patient enrollment and other trial activities resumed in July 2020, the Company is suspending guidance on the timing of the Phase 3 data readout while it continues to assess the potential impact of the COVID-19 pandemic on the global clinical trial sites and patient enrollment.

- The Company published a review of zoliflodacin's full range of in vitro antibacterial activity against *Neisseria gonorrhea*, as well as *Chlamydia trachomatis, Mycoplasma genitalium, Staphylococcus aureus* (both methicillin-susceptible and methicillin-resistant), and *Streptococcus spp.* and reviewed the current state of clinical development. The publication was selected as ACS Infectious Disease Editors' Choice (Bradford PA, Miller AA, O'Donnell J, Mueller JP. ACS Infect Dis. 2020 Jun 12;6(6)).

ETX0282CPDP

- Following completion of initial Phase 1 studies, the Company proceeded with development of an extended release formulation aiming to optimize the safety and projected efficacy of the combination product. Having achieved preclinical proof-of-concept, the Company is now progressing with development of an appropriate clinical formulation to be initially evaluated in a Phase 1 clinical trial before progressing to clinical studies in patients.

- The Company had three articles published on its novel oral product candidate ETX0282CPDP. The initial discovery of ETX0282, a novel orally available β-lactamase inhibitor with broad spectrum activity was described (Durand-Reville TF, et al. .J Med Chem. 2020 Jul 13). Additionally, the Company had two ETX0282 publications highlighted in the ACS Infectious Diseases "Special issue on Antibiotics." From in vitro, in vivo, and PK/PD analyses, the orally available combination of ETX0282 and cefpodoxime-proxetil exhibited favorable attributes for the potential treatment of ESBL- and carbapenemase-producing uropathogens or Enterabacterales (O'Donnell J, et al. ACS Infect Dis. 2020 Jun 12;6(6):1378-1388 and Miller AA, et al. ACS Infect Dis. 2020 Jun 12;6(6):1389-1397).

Second Quarter 2020 Financial Results

The Company reported a net loss of $13.4 million for the quarter ended June 30, 2020, which is consistent with a net loss of $13.4 million for the quarter ended June 30, 2019.

Research and development expenses were $10.2 million for the quarter ended June 30, 2020, compared to $10.7 million for the quarter ended June 30, 2019. The decrease of $0.5 million was primarily due to decreases in spending related to our SUL-DUR product candidate and were partially offset by an increase in personnel expenses associated with higher headcount, salaries and stock-based compensation expense.

General and administrative expenses were $3.2 million for the quarter ended June 30, 2020, compared to $3.4 million for the quarter ended June 30, 2019. The decrease of $0.2 million was driven primarily by a decrease in legal and consulting expenses and were partially offset by an increase in personnel expenses associated with higher headcount.

As of June 30, 2020, cash, cash equivalents and short-term investments were $50.8 million, compared to $27.5 million as of March 31, 2020 . In April, the Company also entered into an agreement with Innoviva Inc. for the private placement of $35 million. 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 into the second quarter of 2021.

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 the impact of the COVID-19 pandemic, 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 10,239	$ 10,677	$ 21,862	$ 21,679
General and administrative	3,241	3,421	7,021	6,609
Total operating expenses	13,480	14,098	28,883	28,288
Loss from operations	(13,480)	(14,098)	(28,883)	- (28,288)
Other income:				
Grant income	48	372	62	1,201
Interest income	36	417	159	908
Total other income	84	789	221	2,109
Loss before income taxes	(13,396)	(13,309)	(28,662)	(26,179)
Provision for income taxes	-	73	-	144
Net loss	$ (13,396)	$ (13,382)	$ (28,662)	$ (26,323)
Net loss per share—basic and diluted	$ (0.78)	$ (1.02)	$ (1.89)	$ (2.00)
Weighted average common stock outstanding—basic and diluted	17,095,140	13,131,291	15,193,351	13,128,956

Entasis Therapeutics Holdings Inc.
Condensed Consolidated Balance Sheets
Unaudited

(in thousands)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and investments	$ 50,771	$ 40,996
Other assets	5,693	10,038
Total assets	$ 56,464	$ 51,034
Total liabilities	$ 7,177	$ 8,877
Total stockholders' equity	49,287	42,157
Total liabilities and stockholders’ equity	$ 56,464	$ 51,034

Source: Entasis Therapeutics Holdings Inc.