Eidos Therapeutics Reports Second Quarter 2020 Financial Results and Business Update

August 6, 2020

SAN FRANCISCO, Aug. 06, 2020 (GLOBE NEWSWIRE) -- Eidos Therapeutics, Inc. (Eidos) (Nasdaq:EIDX), today reported its financial results for the second quarter ended June 30, 2020 and provided an update on the company's operations.

"While the COVID-19 pandemic poses an unpredictable threat to our clinical development program, our team continues to work tirelessly with the ATTR patient community, our investigators and collaborators, and regulators to ensure the progression and integrity of our trials," said Neil Kumar, PhD, chief executive officer of Eidos. "Though the situation is far from resolved, we are incredibly grateful to these groups for their commitment to our program and are encouraged to have observed a re-opening of clinical research activities worldwide in recent months. The determination and resilience of this community inspires our efforts to develop acoramidis (formerly AG10) as a potentially best-in-class treatment option for ATTR patients."

Acoramidis selected as non-proprietary name for AG10

The International Nonproprietary Naming Committee of the World Health Organization (WHO) has selected acoramidis (pronounced "a kor am' i dis") as the proposed International Nonproprietary Name, or pINN, for the company's lead product candidate, AG10. The established suffix "-amidis" was utilized to convey the molecule's proposed mode of action to inhibit amyloid deposition.

WHO's INN Expert Group assigns simple, informative and unique nonproprietary names for drugs to allow for clear communication among health professionals and to identify chemical/pharmacological relationships. Eidos will use "acoramidis" in upcoming presentations, publications and public statements as the company continues progressing toward commercialization of the product.

Update on Company Operations

The Company expects enrollment of patients in its Phase 3 clinical trial of acoramidis in ATTR-CM patients (ATTRibute-CM) to be completed in the first half of 2021 and the Company plans to initiate a Phase 3 study of acoramidis in ATTR-PN (ATTRibute-PN) in the second half of 2020.

Second Quarter 2020 Financial and Operating Results

Cash and cash equivalents totaled $174.8 million at June 30, 2020 compared with $191.2 million at December 31, 2019.

Eidos reported a net loss attributable to common stockholders of approximately $28.8 million or $0.76 per common share, for the second quarter of 2020, as compared to a net loss attributable to common stockholders of $14.1 million or $0.39 per common share, for the second quarter of 2019. The increase in net loss attributable to common stockholders was driven primarily by research and development expenses related to acoramidis (formerly AG10) clinical trials and other pre-clinical studies, and general and administrative expenses for operations.

Research and development expenses for the second quarter of 2020 were $17.9 million, as compared to $12.5 million for the same period in the prior year. Research and development expenses for the second quarter included costs related to contract manufacturing and the preparation for and conduct of clinical trials of acoramidis.

General and administrative expenses for the second quarter of 2020 were $10.3 million, as compared to $2.3 million for the same period in the prior year. The increase in general and administrative expense in the second quarter of 2020 was due primarily to an increase in financial advisory consulting services, marketing costs, salaries and employee-related expense primarily due to an increase in headcount to support the growth of our operations, and other administrative expenses.

Six Months Ended June 30, 2020 Financial Results

Eidos reported a net loss attributable to common stockholders of $51.7 million or $1.35 per common share, for the six months ended June 30, 2020, as compared to a net loss attributable to common stockholders of $25.8 million or $0.71 per common share for the six months ended June 30, 2019. The increase in net loss attributable to common stockholders was driven primarily by research and development expenses related to acoramidis clinical trials and other pre-clinical studies, and general and administrative expenses for operations.

Research and development expenses for the six months ended June 30, 2020 were $35.5 million, as compared to $21.0 million for the same period in the prior year. Research and development expenses for the period included costs related to contract manufacturing, and the preparation for, and the increase in, activity related to our clinical trials.

General and administrative expenses for the six months ended June 30, 2020 were $15.6 million, as compared to $6.3 million for the same period in the prior year. The increase in general and administrative expense in these periods was due primarily to an increase in financial advisory consulting services, professional service fees, salaries and employee-related expense primarily due to an increase in headcount to support the growth of our operations, and other administrative expenses.

About acoramidis

Acoramidis (formerly AG10) is an investigational, orally-administered small molecule designed to potently stabilize tetrameric transthyretin, or TTR, thereby halting at its outset the series of molecular events that give rise to TTR amyloidosis, or ATTR. In a randomized, placebo-controlled Phase 2 clinical trial in patients with symptomatic ATTR-CM, acoramidis was generally well tolerated, demonstrated greater than 90% average TTR stabilization at day 28, and increased serum TTR concentrations, a prognostic indicator of survival in a retrospective study of ATTR-CM patients, in a dose-dependent manner. The open label extension of this Phase 2 clinical trial, or the Phase 2 OLE, identified no safety signals of potential clinical concern associated with administration of AG10 15 months after study initiation. In an exploratory analysis, lower rates of all-cause mortality (including death and cardiac transplantation) and cardiovascular hospitalizations were observed in study participants than in placebo-treated ATTR-CM patients in the ATTR-ACT study. Cardiac biomarkers and echocardiographic parameters were stable in the acoramidis Phase 2 OLE.

Acoramidis is currently being studied in a Phase 3 clinical trial in patients with ATTR-CM (ATTRibute-CM), and we expect to initiate a Phase 3 clinical trial of acoramidis in patients with ATTR-PN (ATTRibute-PN) in the second half of 2020.

Acoramidis was designed to mimic a naturally-occurring variant of the TTR gene (T119M) that is considered a rescue mutation because co-inheritance has been shown to prevent ATTR in individuals also inheriting a pathogenic, or disease-causing, mutation in the TTR gene. To our knowledge, acoramidis is the only TTR stabilizer in development that has been observed to mimic the stabilizing structure of this rescue mutation.

About transthyretin amyloidosis (ATTR)

There is significant medical need in ATTR given the large patient population and limited current standard of care. ATTR is caused by the destabilization of TTR due to inherited mutations or aging and is commonly divided into three distinct categories: wild-type ATTR cardiomyopathy (ATTRwt-CM), mutant ATTR cardiomyopathy (ATTRm-CM), and ATTR polyneuropathy (ATTR-PN). The worldwide prevalence of each disease is approximately 400,000 patients, 40,000 patients and 10,000 patients, respectively.

All three forms of ATTR are progressive and fatal. For patients with ATTRwt-CM and ATTRm-CM, symptoms usually manifest later in life (age 50+), with median survival of three to five years from diagnosis. ATTR-PN either presents in a patient's early 30s or later (age 50+), and results in a median life expectancy of five to ten years from diagnosis for untreated patients. Progression of all forms of ATTR causes significant morbidity, impacts productivity and quality of life, and creates a significant economic burden due to the costs associated with progressively greater patient needs for supportive care.

About Eidos Therapeutics

Eidos Therapeutics is a clinical stage biopharmaceutical company focused on addressing the large and growing unmet need in diseases caused by transthyretin (TTR) amyloidosis (ATTR). Eidos is developing acoramidis, a potentially disease-modifying therapy for the treatment of ATTR. For more information, please visit www.eidostx.com.

Forward-Looking Statements

This release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act. All statements other than statements of historical facts, including the statements about the potential therapeutic and clinical benefits of acoramidis, the impact of the COVID-19 pandemic on our research and development activities and other business operations, our ability to complete the enrollment of patients in and conduct the ATTRibute-CM trial and to initiate and conduct our planned Phase 3 clinical trial of acoramidis in ATTR-PN in accordance with our plans, future clinical and regulatory milestones of acoramidis, the timing of these events, the indications we intend to pursue and our possible clinical or other business strategies, and our capital requirements and ability to fund our clinical development plans, are forward-looking statements. Forward-looking statements can be identified by terms such as “believes,” “expects,” “plans,” “potential,” “would” or similar expressions and the negative of those terms. These forward-looking statements are based on our management’s current beliefs and assumptions about future events and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks include, but are not limited to, risks and uncertainties related to: our limited operating history and historical losses, our liquidity to fund the development of acoramidis through current and future milestones, our ability to raise additional funding to complete the development of acoramidis, our dependence on the success of acoramidis, our ability to enroll patients in our ongoing and planned clinical trials, results from our clinical trials and pre-clinical studies and those of third parties working in the same area as our product candidate, our ability to advance acoramidis in clinical development in accordance with our plans, and our dependence on third parties in connection with our manufacturing, clinical trials and pre-clinical studies. Additional risks and uncertainties that could affect our future results are included in the section titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, to be filed with the Securities and Exchange Commission concurrently herewith. Additional information on potential risks will be made available in other filings that we make from time to time with the SEC. In addition, any forward-looking statements contained in this press release are based on assumptions that we believe to be reasonable as of this date. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

EIDOS THERAPEUTICS, INC.
Condensed 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**
Research and development	$ 17,924	$ 12,497	$ 35,499	$ 21,046
General and administrative	10,317	2,297	15,628	6,332

Total operating expenses	28,241	14,794	51,127	27,378
Loss from operations	(28,241)	(14,794)	(51,127)	(27,378)
Interest expense	(604)	-	(1,122)	-
Other income (expense), net	(4)	741	576	1,592
Net and comprehensive loss	$ (28,849)	$ (14,053)	$ (51,673)	$ (25,786)
Net loss attributable to common stockholders	$ (28,849)	$ (14,053)	$ (51,673)	$ (25,786)
Net loss per share attributable to common stockholders	$ (0.75)	$ (0.39)	$ (1.35)	$ (0.71)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,291,414	36,309,740	38,150,520	36,242,814
*** Includes stock-based compensation as follows**				
Research and development	$ 1,448	$ 552	$ 2,363	$ 1,004
General and administrative	1,270	614	2,282	1,126
Total stock-based compensation expense	$ 2,718	$ 1,166	$ 4,645	$ 2,130

EIDOS THERAPEUTICS, INC.
Condensed Balance Sheets
(Unaudited)
(In thousands)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash	$ 174,821	$ 191,157
Related party receivable	154	85
Prepaid expenses and other current assets	3,818	4,678
Total current assets	178,793	195,920
Property and equipment, net	1,317	1,259
Operating lease, right of use asset	3,781	4,010
Other assets	2,779	2,631
Total assets	$ 186,670	$ 203,820
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,240	$ 3,151
Related party payable	359	316
Lease liabilities	584	554
Accrued expenses and other current liabilities	12,206	6,409
Total current liabilities	15,389	10,430
Debt, non-current	16,522	16,112
Lease liabilities, non-current	4,293	4,591
Embedded Derivative	1,124	1,165
Other liabilities	31	95
Total liabilities	37,359	32,393
Stockholders' equity (deficit):		
Common stock	39	38
Additional paid-in capital	304,050	274,494
Accumulated deficit	(154,778)	(103,105)
Total stockholders' equity	149,311	171,427
Total liabilities and stockholders' equity	$ 186,670	$ 203,820

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