



Eidos Therapeutics Reports First Quarter 2020 Financial Results and Business Update

May 8, 2020

SAN FRANCISCO, May 08, 2020 (GLOBE NEWSWIRE) -- Eidos Therapeutics, Inc. (Eidos) (Nasdaq:EIDX), today reported its financial results for the first quarter ended March 31, 2020 and provided an update on the company's operations.

"We are living in unprecedented times as the impact of the COVID-19 pandemic spreads globally. We know ATTR patients are at great risk from COVID-19, and we are working with our investigators, clinical trial site administrators and patient advocacy leaders to put the health and welfare of our patients first," said Neil Kumar, PhD, chief executive officer of Eidos. "We have made several operational changes to ensure their safety, critically ensuring that our investigational medicine is supplied without interruption, which in many cases has required direct delivery to study participants at their homes. We continue to believe that AG10 could be a best-in-class, convenient oral therapy for ATTR patients and remain committed to developing the drug as quickly and safely as possible."

Update on Company Operations

Due to the impact of COVID-19, the Company has made several operational changes to ensure patient safety, comply with global health authorities' guidance, and maintain the integrity of its planned and ongoing clinical trials to evaluate the safety and efficacy of AG10 as a therapy for ATTR patients. These changes include:

- Arranging alternatives to clinic visits for trial participants and study staff to minimize in-person interactions
- Facilitating home delivery of investigational medicine to enrolled participants where possible
- Identifying and implementing solutions to track and reduce missing data and protocol deviations

As COVID-19's long-term impact on study enrollment remains uncertain – the pandemic has unavoidably led to a slowdown in site activation and participant enrollment – the Company cannot predict with certainty the timing of the completion of enrollment in ATTRibute-CM. We currently expect enrollment of ATTRibute-CM to be completed in the first half of 2021 and plan to initiate our Phase 3 study of AG10 in ATTR-PN (ATTRibute-PN) in the second half of 2020.

The company has raised a total of \$48.1 million since December 2019, including \$24.1 million during the three months ended March 31, 2020, through "at-the-market" offerings under the 2019 Registration Statement on Form S-3. We believe the company is well positioned with sufficient capital to fund through the receipt of Part A data from the Phase 3 ATTR-CM trial.

First Quarter 2020 Financial and Operating Results

Cash and cash equivalents totaled \$196.5 million at March 31, 2020 compared with \$191.2 million at December 31, 2019.

Eidos reported a net loss attributable to common stockholders of approximately \$22.8 million or \$0.60 per common share, for the first quarter of 2020, as compared to a net loss attributable to common stockholders of \$11.7 million or \$0.32 per common share, for the first quarter of 2019. The increase in net loss attributable to common stockholders was driven primarily by research and development expenses related to AG10 clinical trials and other pre-clinical studies, and general and administrative expenses for operations.

Research and development expenses for the first quarter of 2020 were \$17.6 million, as compared to \$8.5 million for the same period in the prior year. Research and development expenses for the first quarter included costs related to contract manufacturing and the preparation for and conduct of clinical trials of AG10.

General and administrative expenses for the first quarter of 2020 were \$5.3 million, as compared to \$4.0 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 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.

About AG10

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, AG10 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 AG10 Phase 2 OLE.

AG10 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 AG10 in patients with ATTR-PN (ATTRibute-PN) in the second half of 2020.

AG10 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, AG10 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 AG10, 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 AG10, the impact of the COVID-19 pandemic on our research and development activities and other business operations, our ability to enroll patients in and conduct the ATTRibute-CM trial and to initiate and conduct our planned Phase 3 clinical trial of AG10 in ATTR-PN in accordance with our plans, future clinical and regulatory milestones of AG10, 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 AG10 through current and future milestones, our ability to raise additional funding to complete the development of AG10, our dependence on the success of AG10, 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 AG10 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 March 31, 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	
	March 31,	
	2020	2019
Research and development	\$ 17,575	\$ 8,549
General and administrative	5,311	4,035
Total operating expenses	22,886	12,584
Loss from operations	(22,886)	(12,584)
Interest expense	(518)	-
Other income (expense), net	580	851
Net and comprehensive loss	\$ (22,824)	\$ (11,733)
Net loss attributable to common stockholders	\$ (22,824)	\$ (11,733)
Net loss per share attributable to common stockholders	\$ (0.60)	\$ (0.32)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,009,621	36,175,523

* Includes stock-based compensation as follows

Research and development	\$ 915	\$ 452
General and administrative	1,012	512
Total stock-based compensation expense	\$ 1,927	\$ 964

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

	March 31,	December 31,
	2020	2019
Assets		
Current assets:		
Cash	\$ 196,515	\$ 191,157
Related party receivable	125	85
Prepaid expenses and other current assets	3,952	4,678
Total current assets	200,592	195,920
Property and equipment, net	1,283	1,259
Operating lease, right of use asset	3,897	4,010
Other assets	2,825	2,631
Total assets	\$ 208,597	\$ 203,820
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,972	\$ 3,151
Related party payable	323	316
Lease liabilities	569	554
Accrued expenses and other current liabilities	6,956	6,409
Total current liabilities	11,820	10,430
Debt, non-current	16,316	16,112
Lease liabilities, non-current	4,443	4,591
Embedded Derivative	1,103	1,165
Other liabilities	63	95
Total liabilities	33,745	32,393
Stockholders' equity (deficit):		
Common stock	39	38
Additional paid-in capital	300,742	274,494
Accumulated deficit	(125,929)	(103,105)
Total stockholders' equity	174,852	171,427
Total liabilities and stockholders' equity	\$ 208,597	\$ 203,820

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Source: Eidos Therapeutics, Inc.