UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 11, 2018

AEGLEA BIOTHERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37722**	**46-4312787**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

901 S. MoPac Expressway
Barton Oaks Plaza One
Suite 250
Austin, TX **78746**
(Address of principal executive offices) **(Zip Code)**

(512) 942-2935
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On December 11, 2018, Aeglea BioTherapeutics, Inc. (the "Company") issued a press release announcing the design of its global pivotal Phase 3 PEACE (Pegzilarginase Effect on Arginase 1 Deficiency Clinical Endpoints) trial to evaluate the safety and efficacy of the Company's lead investigational therapy, in patients with Arginase 1 Deficiency. A copy of the press release is attached as Exhibit 99.1 to this report.

The information furnished with this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

Exhibit Number	Description
99.1	Press Release issued by Aeglea BioTherapeutics, Inc., on December 11, 2018

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AEGLEA BIOTHERAPEUTICS, INC.

Date: December 11, 2018

By: /s/ Charles N. York II
Charles N. York II
Chief Financial Officer

Exhibit 99.1

Aeglea BioTherapeutics Announces Design of Pivotal Phase 3 PEACE Trial Evaluating Pegzilarginase in Arginase 1 Deficiency

Single, Global Pivotal Trial to Support Registration; Primary Endpoint of Arginine Reduction

Expected to Initiate in Q2 2019; Topline Data Anticipated in Q1 2021

Company to Host Conference Call Today at 5:00 p.m. ET

Austin, Texas, December 11, 2018 - Aeglea BioTherapeutics, Inc. (NASDAQ: AGLE), a clinical-stage biotechnology company that designs and develops innovative human enzyme therapeutics for patients with rare genetic diseases and cancer, today announced the design of its global pivotal Phase 3 PEACE (Pegzilarginase Effect on Arginase 1 Deficiency Clinical Endpoints) trial to evaluate the safety and efficacy of pegzilarginase, the Company's lead investigational therapy, in patients with Arginase 1 Deficiency (ARG1-D). The Company has aligned the trial design and endpoints with input from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), and plans to conduct a single, global pivotal trial to support registration. Aeglea expects to dose the first patient in the PEACE trial in the second quarter of 2019 and expects topline data will be available in the first quarter of 2021.

PEACE is a global, randomized, double-blind trial designed to assess the effects of treatment with pegzilarginase versus placebo over 24 weeks with a primary endpoint of statistically significant plasma arginine reduction from baseline. The primary endpoint is intended to assess the effectiveness of pegzilarginase in lowering plasma arginine levels given the evidence that improved plasma arginine control has the potential to improve the clinical status and slow disease progression in patients with ARG1-D. Secondary endpoints assessing changes in clinically meaningful outcomes including mobility, adaptive behavior, safety and pharmacokinetics will be used to describe the broader impact of pegzilarginase relative to placebo on multiple aspects of ARG1-D.

"Arginine is the key driver of this devastating disease and pegzilarginase is the first ever approach that has demonstrated substantial lowering of plasma arginine levels," said Anthony G. Quinn, M.B Ch.B, Ph.D., president and chief executive officer of Aeglea. "Finalization of our pivotal trial protocol represents an important advance for ARG1-D patients who lack effective treatments options. Our expectation is that the data from the PEACE trial could be sufficient to support marketing applications for pegzilarginase in ARG1-D."

The company plans to enroll 30 (pediatric and adult) patients with ARG1-D. Patients enrolled in the trial will be randomized on a two-to-one basis to receive weekly infusions of pegzilarginase (0.1 mg/kg), or placebo for the double-blind treatment period of 24 weeks. Dose adjustments during this period can be made to optimize plasma arginine control for levels outside the range of 50 to 150 μM.
Patients will be considered eligible for the PEACE trial if they exhibit average plasma arginine of greater than 250 μM, are greater than two years of age and have a deficit in mobility or adaptive behavior. All assessments and dose adjustments will be conducted in a blinded fashion at pre-specified intervals. Patients will remain on current disease management for the duration of the Phase 3 PEACE trial.

In addition to the primary endpoint of plasma arginine reduction, secondary endpoints in the Phase 3 PEACE trial will evaluate pegzilarginase relative to placebo through a multi-dimensional assessment of clinical outcome. Measures of clinical outcome are defined as a patient exhibiting improvement from baseline in mobility (2 Minute Walk Test or Functional Mobility Assessment) or adaptive behavior (Vineland Adaptive Behavior Scale). Additional secondary endpoints include a response rate for each individual assessment, the total number of mobility and adaptive behavior responses per patient, the proportion of patients with plasma arginine below medical guidance of 200 μM, safety and pharmacokinetics.

"Patients with ARG1-D face chronic hyperargininemia that results in significant morbidity and early mortality. The PEACE trial is designed to determine the ability of pegzilarginase to reduce elevated plasma arginine levels beyond current management," said James Wooldridge, M.D., chief medical officer of Aeglea. "Thoughtful input from the FDA and EMA, and our extensive analysis of Phase 1/2 data, resulted in a trial that is designed to provide an assessment of the treatment effects of pegzilarginase that are important to patients, clinicians and regulators. Furthermore, we appreciate the growing support from the patient and clinical community as we prepare to advance this important trial."

Throughout the PEACE trial, patients will be monitored for adverse events. Upon completion of the 24-week treatment period, patients will qualify to participate in a long-term extension study of pegzilarginase.

Conference Call & Webcast Details
Aeglea will hold a clinical update conference call today, Tuesday, December 11, 2018 at 5:00 p.m. ET. To access the live conference call via phone, please dial 1-877-709-8155 (toll free) within the United States, or 1-201-689-8881 internationally. A replay of the call will be available through December 18, 2018 by dialing 1-877-660-6853 within the United States or 1-201-612-7415 internationally. The conference ID is 13685662.

To access the live and archived webcast of the presentation, please visit the Presentations & Events section of the Aeglea BioTherapeutics investor relations website. Please connect to the website at least 15 minutes prior to the presentation to allow for any software download that may be necessary.

About Pegzilarginase in Arginase 1 Deficiency
Pegzilarginase is an enhanced human arginase that enzymatically depletes the amino acid arginine. Aeglea is developing pegzilarginase for the treatment of patients with Arginase 1 Deficiency, a rare debilitating disease presenting in childhood with persistent hyperargininemia, severe progressive neurological abnormalities and early mortality. Pegzilarginase is intended for use as an enzyme replacement therapy in patients to reduce elevated blood arginine levels. The Company's interim Phase 1/2 data demonstrated clinical improvements and rapid and sustained lowering of plasma arginine in Arginase 1 Deficiency patients.

About Aeglea BioTherapeutics
Aeglea is a clinical-stage biotechnology company that designs and develops innovative human enzyme therapeutics for patients with rare genetic diseases and cancer. The Company is developing pegzilarginase, its lead investigational therapy, for the treatment of Arginase 1 Deficiency, as monotherapy in arginine-dependent cancers and in combination with an immune checkpoint inhibitor for small cell lung cancer. In addition, Aeglea has an active research pipeline of other human enzyme-based approaches in both therapeutic areas. For more information, please visit http://aegleabio.com.

Safe Harbor / Forward Looking Statements
This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, (i) the potential clinical and therapeutic benefits and economic value of our lead product candidate, pegzilarginase or other product, (ii) the initiation of patient dosing in the Phase 3 PEACE trial, (iii) the ability of pegzilarginase to achieve applicable endpoints in the Phase 3 PEACE trial, (iv) the ability for patients who participate in the Phase 3 PEACE trial to participate in a long-term extension study, (v) the availability of data from the Phase 3 PEACE trial, and (vi) the potential for data from the Company's clinical trials of pegzilarginase to support a marketing application, as well as the timing of these events Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 filed with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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