

**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): September 14, 2020

AEGLEA BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37722
(Commission
File Number)

46-4312787
(IRS Employer
Identification No.)

**805 Las Cimas Parkway
Suite 100
Austin, TX**
(Address of principal executive offices)

78746
(Zip Code)

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

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 Par Value Per Share	AGLE	The Nasdaq Stock Market LLC (Nasdaq Global Market)

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 8.01 Other Events.

On September 14, 2020, Aeglea BioTherapeutics, Inc. (the "Company") announced updated guidance on the enrollment completion of its Phase 3 PEACE (Pegzilarginase Effect on Arginase 1 Deficiency Clinical Endpoints) trial to evaluate the safety and efficacy of pegzilarginase in patients with Arginase 1 Deficiency given the impact of COVID-19.

The Company expects to complete enrollment in the Phase 3 PEACE trial by January 2021 and anticipates that topline data from the trial will be available in the middle of 2021. The anticipated pace of reopening of sites impacted by COVID-19 has slowed in some locations limiting patient access. To date, the Company has enrolled over 50% of the trial and expects to be approximately 75% enrolled in the next few weeks based on the patients currently consented and in screening. The Company has nearly twice as many patients as needed for the trial at our active sites with a high level of patient and physician engagement.

The Company has continued patient finding activities and to date has identified more than 250 patients in the global addressable markets, primarily in the U.S. and Europe.

Forward Looking Statements

This current report 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 to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what the Company expects. Examples of forward-looking statements include, among others, statements the Company makes regarding its cash forecasts, the timing and success of its clinical trials and related data, the timing and expectations for regulatory submissions and approvals, timing and results of meetings with regulators, the timing of announcements and updates relating to the Company's clinical trials and related data, its ability to enroll patients into its clinical trials, the expected impact of the COVID-19 pandemic on the Company's operations and clinical trials, success in collaborations, potential addressable markets of the Company's product candidates and the potential therapeutic benefits and economic value of the Company's product candidates. Further information on potential risk factors that could affect our business and its financial results are detailed in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 filed with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. The Company undertakes 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.

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: September 14, 2020

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