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): October 4, 2022

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.)**

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 October 4, 2022, Aeglea BioTherapeutics, Inc. (the "Company") announced that it had initiated dosing in the third cohort of the Phase 1/2 clinical trial of pegtarviliase, formerly AGLE-177, for the treatment of Classical Homocystinuria. Patients in this third cohort are receiving 1.35 mg/kg of pegtarviliase once weekly administered via subcutaneous injection. The Company also announced that it received a letter from the U.S. Food and Drug Administration (the "FDA") regarding the Company's recently submitted protocol amendment for the Phase 1/2 clinical trial of pegtarviliase for the treatment of Homocystinuria. The protocol amendment, among other things, requested the inclusion of adolescent patients at clinical trial sites in the United States. The FDA stated the protocol did not provide adequate justification and evidence to support the prospect of direct clinical benefit for pediatric patients and placed the trial on partial clinical hold for the enrollment of patients less than 18 years of age under this Investigational New Drug ("IND") at this time. The Company intends to address the feedback from the FDA and aims to satisfy the requirements for prospective benefit for future inclusion of pediatric patients under the IND, including in a potential pivotal trial. The partial clinical hold only applies to the IND with the FDA, and the Company believes that the letter should not impact the planned enrollment and dosing of patients aged 18 years and older in the United States or patients aged 12 years and older in the UK and Australia.

This current report on Form 8-K 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 we expect. Examples of forward-looking statements include, among others, statements we make regarding our ability to achieve further cost-savings, the timing of announcements and updates relating to our clinical trials and related data, including the clinical data for our Phase 1/2 trial of pegtarviliase in Homocystinuria, the timing and success of our clinical trials and related data, the timing and expectations for regulatory submissions and approvals, including the Marketing Authorization Application for pegzilarginase in Europe, our ability to obtain regulatory approval for, and commercialize, pegzilarginase, recognize milestone and royalty payments from our agreement with Immedica, our ability to enroll patients into our clinical trials, the expected impact of the COVID-19 pandemic on our operations and clinical trials, success in our collaborations, the length of time that we believe our existing cash resources will fund operations, the potential addressable markets of our product candidates and the potential therapeutic benefits and economic value of our lead product candidate or other product candidates. 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 June 30, 2022 filed with the Securities and Exchange Commission (the "SEC"), and our 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.

SIGNATURE

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

AEGLEA BIOTHERAPEUTICS, INC.

Date: October 4, 2022

By: /s/ Jonathan Alspaugh
Jonathan Alspaugh
Chief Financial Officer