

**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): **August 17, 2020 (August 14, 2020)**

APPLIED THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of
Incorporation)

001-38898

(Commission File Number)

81-3405262

(I.R.S. Employer Identification No.)

545 Fifth Avenue, Suite 1400

New York, NY 10017

(Address of Principal Executive Offices)

10017

(Zip Code)

Registrant's telephone number, including area code: **(212) 220-9226**

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

Common Stock

Trading Symbol(s)

APLT

**Name of each exchange on which
registered**

The 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.

As previously disclosed, on June, 15, 2020, Applied Therapeutics, Inc. (the “Company”) announced the initiation of the ACTION-Galactosemia Kids pediatric registrational study of AT-007 for treatment of galactosemia (the “ACTION-Kids Study”) to evaluate safety, pharmacokinetics, and reduction in the toxic biomarker, galactitol. The study is comprised of two parts: a placebo-controlled dose range finding segment evaluating up to seven days of consecutive dosing to determine the optimal dose in children, followed by a placebo-controlled 90 day study evaluating safety and biomarker efficacy.

On August 14, 2020, the Company received a letter from the U.S. Food and Drug Administration (the “FDA”) that placed a partial clinical hold on the ACTION-Kids Study and requested that the Company provide the FDA additional technical information relating to ensuring that every patient in the study has access to the prospect of direct benefit of the drug. The partial clinical hold does not relate to concerns regarding the safety profile of AT-007. The study is currently in the dose range finding segment, and the partial clinical hold does not introduce any disruption to ongoing treatment. The adult ACTION-Galactosemia study, which is in the long-term extension phase, is not affected by the partial clinical hold.

The Company will work closely with FDA to resume the study as soon as possible and plans to submit the supporting technical information requested by the FDA promptly. The FDA has 30 days thereafter to review the information and to notify the Company if the ACTION-Kids Study may be resumed.

Based on this anticipated pediatric study delay, the Company plans to submit a new drug application in the first quarter of 2021.

This Form 8-K contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, included herein regarding strategy, future operations, prospects, plans and objectives of management, including words such as “may,” “will,” “expect,” “anticipate,” “plan,” “intend,” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are forward-looking statements. These include, without limitation, statements regarding (i) the timing of the initiation and completion, including with respect to any disruptions or delays, of our clinical trials, (ii) the likelihood of obtaining regulatory approval of our product candidates, including the length of the partial clinical hold on the ACTION-Kids Study, (iii) our plan to submit a new drug application in the first quarter of 2021 and (iii) the overall timing of our clinical development plan. Forward-looking statements in this Form 8-K involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we, therefore cannot assure you that our plans, intentions, expectations or strategies will be attained or achieved. Such risks and uncertainties include, without limitation, the uncertainties inherent in the initiation, execution and completion of clinical trials, in the timing of availability of trial data, in the results of the clinical trials, in the actions of regulatory agencies, in the commercialization and acceptance of new therapies as well as the impact of the COVID-19 pandemic on these plans and expectations. Factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this Form 8-K are discussed in our filings with the U.S. Securities and Exchange Commission, including the “Risk Factors” contained therein. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances 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.

APPLIED THERAPEUTICS, INC.

Dated: August 17, 2020

By: /s/ Charles Silberstein

Name: Charles Silberstein, M.D.

Title: Chief Financial Officer
