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 8, 2019**

APPLIED THERAPEUTICS, INC.
(Exact name of registrant as specified in charter)

Delaware	**001-38898**	**81-3405262**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
340 Madison Avenue, 19th Fl. **New York, NY 10173** (Address of Principal Executive Offices)		**10173** (Zip Code)

Registrant's telephone number, including area code: **(212) 220-9319**

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:

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

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

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

o 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 x

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. x

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	APLT	The Nasdaq Stock Market LLC

Item 8.01 Other Events.

On August 8, 2019, Applied Therapeutics, Inc. issued a press release announcing the completion of the Single Ascending Dose (SAD) healthy volunteer portion of the Phase 1/2 study of AT-007 Galactosemia, which press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 8, 2019

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 8, 2019

By: /s/ Mark Vignola
Name: Mark Vignola, Ph.D.
Title: Chief Financial Officer

Applied Therapeutics Reports AT-007 SAD Data from Healthy Volunteer Portion of Phase 1/2 ACTION-Galactosemia Study

NEW YORK, August 8, 2019 - Applied Therapeutics, Inc. (Nasdaq: APLT), a clinical-stage biopharmaceutical company developing novel drug candidates in indications of high unmet medical need, today announced the completion of the Single Ascending Dose (SAD) healthy volunteer portion of the Phase 1/2 study of AT-007 in Galactosemia (ACTION-Galactosemia).

The results show that AT-007 was well tolerated, with no drug-related adverse events or dose-limiting toxicities reported. The SAD study treated 4 cohorts of 8 subjects each and explored doses from 0.5mg/kg to 20mg/kg. In addition to safety, AT-007 demonstrated a linear pharmacokinetic (PK) profile, favorable exposure, and half-life consistent with once-daily dosing.

“We are encouraged by the favorable safety profile in healthy volunteers, and we look forward to advancing AT-007 through the MAD study in healthy volunteers and to the Phase 2 portion of the study in patients with Galactosemia,” said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. “Developing drugs for high unmet indications, such as Galactosemia, is critical to our mission at Applied, and we are committed to developing a potential new therapy for patients with no available treatment options.”

AT-007 will advance in parallel to a Phase 1b Multiple Ascending Dose (MAD) study in healthy volunteers (up to 7 consecutive days of treatment), and a Phase 2 study in adults with Galactosemia. Galactosemia patients will be eligible for treatment up to 28 days total (single dose followed by 27 consecutive days of dosing). In addition to safety and PK, the study will determine the ability of AT-007 to suppress toxic accumulation of galactitol in Galactosemia patients. Applied Therapeutics plans to employ recent FDA guidance permitting biomarker-based development in low prevalence, slowly progressing rare metabolic diseases, such as Galactosemia.

“AT-007 marks our second program to move through the clinic, and we are excited to see additional data in support of our technology and development strategy,” said Shoshana Shendelman, PhD, Founder and Chief Executive Officer of Applied Therapeutics. “We look forward to presenting additional data on our Galactosemia program at the American Society for Human Genetics conference this fall.”

About Galactosemia

Galactosemia is a rare metabolic disease that affects how the body processes a simple sugar called galactose, and for which there is no known cure or approved treatment available. Galactose is found in foods, but the human body also naturally produces galactose on its own, so dietary restriction can’t prevent complications of disease. It is estimated that the U.S. Galactosemia population is approximately 2,800 patients, based on newborn screening data identifying 2,500 infants through 2014, and the estimated birth rate of 80 patients per year. High levels of galactose circulating in the blood and tissues

of Galactosemia patients enables Aldose Reductase to convert galactose to a toxic metabolite, called galactitol, which causes long-term complications ranging from CNS dysfunction to cataracts.

About AT-007

AT-007 is a central nervous system (CNS) penetrant Aldose Reductase inhibitor (ARI) in Phase 1/2 development for treatment of Galactosemia. AT-007 has been studied in in an animal model of Galactosemia, which demonstrated that AT-007 reduces toxic galactitol levels and prevents disease complications. Applied Therapeutics is planning a biomarker based development program in patients with Galactosemia, based on the recently released draft industry guidance on drug development for low prevalence, slowly progressing rare metabolic diseases. The company received Orphan Designation for AT-007 for Galactosemia in May 2019.

About Applied Therapeutics Inc.

Applied Therapeutics is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates against validated molecular targets in indications of high unmet medical need. The company's lead drug candidate, AT-001, is a novel aldose reductase inhibitor (ARI) that is being developed for the treatment of Diabetic Cardiomyopathy, or DbCM, a fatal fibrosis of the heart. The company plans to initiate a Phase 3 registrational study in DbCM in 2019. Applied Therapeutics is also developing AT-007, a central nervous system penetrant ARI, for the treatment of Galactosemia, a rare pediatric metabolic disease, and initiated a Phase 1/2 clinical trial in June 2019. The preclinical pipeline also includes AT-003, an ARI designed to cross through the back of the eye when dosed orally, for the treatment of diabetic retinopathy, expected to advance into a Phase 1 study in 2020.

Forward-Looking Statements

This press release 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 in this press release 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 the (i) our cash runway and acceleration of our clinical development plan, (ii) the likelihood data will support future development of our product candidates, (iii) qualification for exemptions resulting from the receipt of orphan drug designation and (iii) the expected timing of the initiation of our clinical trials. Forward-looking statements in this release 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. Factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release 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.

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Galactosemia Patients/ Families:

If you are a patient or family member interested in receiving information regarding participation in the Phase 1/2 clinical trial, please email: galactosemia@appliedtherapeutics.com.