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): **February 15, 2024**

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

Delaware	**001-38898**	**81-3405262**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	APLT	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.

On February 15, 2024, Applied Therapeutics, Inc. (the "Company") announced positive interim 12-month results from the ongoing Phase 3 INSPIRE trial, in which the primary endpoints and several key secondary endpoints were achieved. The INSPIRE trial is a Phase 3 double-blind placebo-controlled registrational study evaluating the effect of once-daily (QD) oral govorestat (AT-007) in 56 patients aged 16-55 with SORD Deficiency in the US and Europe.

SORD Deficiency is a debilitating, hereditary axonal neuropathy caused by mutations in the Sorbitol Dehydrogenase gene, leading to an inability to metabolize the sugar sorbitol and resulting in accumulation of high levels of toxic sorbitol, which causes motor neuron degeneration and loss of mobility and motility. Govorestat is a central nervous system penetrant Aldose Reductase Inhibitor, which blocks the conversion of glucose to sorbitol, and has previously been shown to reduce sorbitol levels in patients with SORD Deficiency.

The objective of this pre-specified, 12-month interim analysis was to evaluate early indicators of govorestat treatment effect in order to inform future regulatory discussions and support a potential New Drug Application (NDA) submission, due to the urgent need for treatment and absence of any other options for patients with SORD Deficiency. The 12-month interim analysis was comprised of a clinical efficacy primary endpoint based on correlation of sorbitol with composite clinical outcome measures, and a pharmacodynamic (PD) biomarker primary endpoint based on sorbitol reduction.

Interim Analysis Results:

- Demonstrated statistically significant correlation between sorbitol level and the prespecified CMT-FOM composite clinical endpoint (10-meter walk-run test, 4 stair climb, sit to stand test, 6-minute walk test and dorsiflexion) ($p=0.05$).

- Govorestat treatment provided sustained reduction in sorbitol level in patients with SORD Deficiency over 12 months of treatment, which was statistically significant compared to placebo ($p<0.001$).

- Govorestat treatment also resulted in a highly statistically significant effect ($p=0.01$) on the CMT Health Index (CMT-HI), an important patient-reported outcome measure of disease severity and well-being, which was a secondary endpoint in the study. Aspects of the CMT-HI that demonstrated a treatment effect included lower limb function, mobility, fatigue, pain, sensory function, and upper limb function.

- Govorestat was safe and well tolerated, with similar incidence of adverse events between active and placebo-treated groups.

We believe the results from the 12-month interim analysis confirm the role of sorbitol as a key driver of disease severity and progression over time. Clinical outcomes of the ongoing INSPIRE trial are expected to be assessed again at 24 months, where the 10-meter walk run test serves as the primary clinical efficacy endpoint. The Company plans to discuss a potential NDA submission with the U.S. Food and Drug Administration (FDA) based on the clinical data to date.

This report 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 report regarding the strategy, future operations, prospects, plans and objectives of management, including words such as "may," "will," "expect," "anticipate," "plan," "intend," "predicts" 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 Company's plans to request pre-NDA meeting with the neurology division of the FDA regarding potential approval based on the clinical data to date and (ii) the timing of assessment of clinical outcomes of the INSPIRE trial any potential submission. 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, (i) our plans to develop, market and commercialize our product candidates, (ii) the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs, (iii) our ability to take advantage of expedited regulatory pathways for any of our product candidates, (iv) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, (v) our ability to successfully acquire or license additional product candidates on reasonable terms and advance product candidates into, and successfully complete, clinical studies, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain and timing of regulatory approval of our current and future product candidates, (viii) the anticipated indications for our product candidates, if approved, (ix) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (x) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (xi) the implementation of our business model and strategic plans for our business and product candidates, (xii) our intellectual property position and the duration of our patent rights, (xiii) developments or disputes concerning our intellectual property or other proprietary rights, (xiv) our expectations regarding government and third-party payor coverage and reimbursement, (xv) our ability to compete in the markets we serve, (xvi) the impact of government laws and regulations and liabilities thereunder, (xvii) developments relating to our competitors and our industry, (xviii) our ability to achieve the anticipated benefits from the agreements entered into in connection with our partnership with Advanz Pharma and (xiv) other factors that may impact our financial results. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. Factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this report 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: February 15, 2024

By: */s/ Shoshana Shendelman*
Name: Shoshana Shendelman
Title: President and Chief Executive Officer