

**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): **March 28, 2024**

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	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 March 28, 2024, Applied Therapeutics, Inc. (the “Company”) announced that the U.S. Food and Drug Administration (“FDA”) has extended the review period for the New Drug Application (“NDA”) for govorestat (AT-007) for the treatment of Classic Galactosemia by three months. The FDA has set a new Prescription Drug User Fee Act (PDUFA) target action date of November 28, 2024.

The FDA notified the Company that it required additional time to review supplemental analyses of previously submitted data that had been provided by the Company in response to the FDA’s routine information requests and determined that the additional information constitutes a Major Amendment to the NDA. In February 2024, the Company announced that the FDA accepted and granted Priority Review to the NDA. Govorestat was previously granted Pediatric Rare Disease designation, and will qualify for a Priority Review Voucher (PRV) upon approval.

Govorestat is an investigational, novel Aldose Reductase Inhibitor (ARI) being developed for the treatment of several rare diseases. The NDA filing of govorestat is supported by rapid and sustained reduction in galactitol, which resulted in a meaningful benefit on clinical outcomes across pediatric patients, alongside a favorable safety profile. The submission package included clinical outcomes data from the Phase 3 registrational ACTION-Galactosemia Kids study in children aged 2-17 with Galactosemia, the Phase 1/2 ACTION-Galactosemia study in adult patients with Galactosemia, and preclinical data.

If approved, govorestat would be the first medication indicated for the treatment of Galactosemia and would be the Company’s first commercial product. The Company has also submitted a Marketing Authorization Application (“MAA”) for govorestat for the treatment of Classic Galactosemia to the European Medicines Agency (“EMA”), which was validated in December 2023 and is under review by the EMA’s Committee for Medicinal Products for Human Use (CHMP). The Company expects a decision by the EMA in the fourth quarter of 2024.

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 the likelihood that the Company’s ongoing NDA and MMA submissions will be approved and the timing of any approval decision. 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: March 29, 2024

By: /s/ Shoshana Shendelman

Name: Shoshana Shendelman

Title: President and Chief Executive Officer
