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): **January 4, 2023**

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))

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. ☒

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 1.01. Entry Into a Material Definitive Agreement.

On January 3, 2022, Applied Therapeutics, Inc., a Delaware corporation (the "Company"), entered into an Exclusive License and Supply Agreement (the "Agreement") with Mercury Pharma Group Limited (trading as Advanz Pharma Holdings), a company organized and existing under the laws of England and Wales ("ADVANZ PHARMA"), a UK headquartered global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines in Europe. Pursuant to the Agreement, the Company granted ADVANZ PHARMA the exclusive right and license to commercialize drug products containing AT-007 (also known as govorestat), the Company's proprietary Aldose Reductase Inhibitor (ARI) (the "Licensed Product"), for use in treatment of sorbitol dehydrogenase deficiency ("SORD") and galactosemia in humans (each, a "Licensed Indication") in the European Economic Area, Switzerland and the United Kingdom (the "Territory"). The Company also grants ADVANZ PHARMA a right of negotiation and "most-favored nation" rights with respect to acquiring the European commercialization rights for any additional indications for which the Licensed Product may be developed in the future (or any other products the Company may develop solely to the extent used for the Licensed Indications).

ADVANZ PHARMA is required to use commercially reasonable efforts to launch and commercialize the Licensed Products in the major markets in the Territory in each Licensed Indication following, and subject to, receipt of marketing authorization therein. Under the Agreement, ADVANZ PHARMA agrees to pay the Company (i) an upfront payment of EUR 10 million (approx. USD $10.6 million), and certain development milestone payments upon clinical trial completions and receipt of marketing authorization in the Territory, as well as certain commercial milestone payments, totaling EUR 134 million (approx. USD $142.2 million) in the aggregate, and (ii) royalties of 20% of net sales of the Licensed Product. Such royalty rate will be payable on a country-by-country basis until the later of (i) the expiration of the licensed patents covering the composition of matter of AT-007, or (ii) 10 years after the European Medicines Agency's grant of marketing authorization for the Licensed Product. The royalties are subject to certain deductions, including certain secondary finishing costs, certain step-in establishment costs and a portion of fees for any potential third party patent licenses if applicable in the future. Following the initial term of the license, as described above, the royalty rate shall be reduced to 10% and shall continue in perpetuity unless the Agreement is terminated in various circumstances in accordance with its terms.

Certain of the patents licensed to ADVANZ PHARMA under the Agreement are sub-licensed from the University of Miami and Columbia University, and thus remain subject to certain obligations of the Company (including royalty obligations) to such institutions.

Under the Agreement, the Company remains responsible for development of the Licensed Product, and must conduct such development through grant of marketing authorizations in the Licensed Indications in the Territory and as otherwise required under such marketing authorization, in accordance with any timeframe required by regulatory authorities. The Company retains sole responsibility for the conduct of all clinical trials (subject in some circumstances to cost-sharing with ADVANZ PHARMA), unless the Company provides ADVANZ PHARMA prior consent to conduct certain studies following marketing authorization, or ADVANZ PHARMA exercises certain step-in rights (as described below). The Company also agrees to manufacture and supply the Licensed Product in bulk form to ADVANZ PHARMA. ADVANZ PHARMA is responsible for secondary packaging and release for the Territory.

The Agreement includes indemnification obligations on the part of both parties for third-party claims arising out of, among other things, a breach of the Agreement; an election by the other party not to initiate a recall; gross negligence or willful misconduct; and violation of applicable laws. In addition, both parties have agreed to indemnification obligations for third party liability product liability claims and certain exclusions from liability disclaimers, such as for breaches of confidentiality, death or personal injury caused by negligence or willful default.

In certain circumstances, including in the event of specified supply shortages, bankruptcy and certain other financial events, a force majeure event lasting more than three months, or termination as a result of the Company's gross negligence or willful misconduct, ADVANZ PHARMA may exercise certain step-in rights. Such step-in rights include the ability for ADVANZ PHARMA to perform its own supply arrangements, and in some cases, specified development rights in the Licensed Indications in the Territory and assignment of certain contract rights. In all such circumstances, ADVANZ PHARMA must continue to pay royalties and milestone payments. ADVANZ PHARMA may recoup certain of its manufacturing and development establishment costs, and deduct such costs from royalties.

The Company may terminate the Agreement upon certain specified events, including ADVANZ PHARMA's failure to launch or achieve certain sales threshold for the Licensed Product in major markets within a certain timeframe, or if ADVANZ PHARMA challenges a licensed patent, and either party may terminate the Agreement upon the other party's material breach or insolvency, certain material safety issues or a force majeure event of the other party lasting longer than six months. ADVANZ PHARMA may also terminate the agreement if the Licensed Product does not receive marketing authorization for use in a Licensed Indication in any country in the Territory by a specified date, or in the event of the Company's gross negligence or willful misconduct (subject to a cure period).

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: January 4, 2023

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