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): **September 4, 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**	**10173**
(Address of Principal Executive Offices)	(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:

☐ 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 8.01. Other Events.

On September 4, 2019, Applied Therapeutics, Inc. issued a press release announcing the initiation of a Phase 3 registrational trial for AT-001, an aldose reductase inhibitor, in Diabetic Cardiomyopathy, 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:

The following exhibits are attached with this current report on Form 8-K:

Exhibit No.	Description
99.1	Press Release, issued by Applied Therapeutics, Inc., dated September 4, 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: September 4, 2019

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

Exhibit 99.1

Applied Therapeutics Announces Initiation of Phase 3 Registrational Trial of AT-001 in Diabetic Cardiomyopathy (ARISE-HF)

NEW YORK, Sept 4, 2019 — Applied Therapeutics Inc. (Nasdaq:APLT), a clinical-stage biopharmaceutical company developing novel drug candidates against validated molecular targets in indications of high unmet medical need, today announced the initiation of a Phase 3 registrational trial for AT-001, a novel, potent and selective aldose reductase inhibitor (ARI), in Diabetic Cardiomyopathy (DbCM). The study, called ARISE-HF, will investigate AT-001's ability to improve or prevent the decline of functional capacity in patients with DbCM at high risk of progression to overt heart failure.

Aldose reductase (AR) activity has been implicated as a strong contributing factor to pathogenesis in DbCM, a fatal fibrosis of the heart that occurs in both type 1 and type 2 diabetic patients, which leads to decreased contractility and decreased heart function, eventually resulting in overt heart failure. DbCM affects 17 — 24 percent of people with diabetes, or approximately 77 million patients worldwide.

ARISE-HF is a double-blind, placebo controlled, Phase 3 registrational trial expected to enroll approximately 675 type 2 diabetic patients with DbCM at high risk of progression to overt heart failure. ARISE-HF will assess AT-001's ability to improve or prevent decline in exercise tolerance as measured by maximum amount of oxygen a person can utilize during intense exercise (peak VO2) over 15 months of treatment. The ARISE-HF trial will be conducted at approximately 70 centers in North America and Europe. Patients will be randomized 1:1:1 to either placebo, low dose AT-001 (1000mg), or high dose AT-001 (1500mg), taken twice daily. Additional supportive secondary and exploratory endpoints include percent of patients progressing to overt heart failure, quality of life metrics (modified KCCQ), echocardiographic measurements and cardiac stress biomarkers, including NTproBNP. At the conclusion of the core trial, patients may continue into a 12-month placebo-controlled extension study to assess potential impact on cardiovascular death and hospitalization.

"We are excited to announce the initation of ARISE-HF, our pivotal trial in Diabetic Cardiomyopathy," said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. "Diabetic Cardiomyopathy continues to be a growing issue for patients with diabetes, despite advancements in glucose control. Targeting aldose reductase with a potent and selective aldose reductase inhibitor presents an opportunity to potentially halt disease progression and prevent worsening of heart failure in DbCM patients. These patients have been left behind for far too long, and advancement of our program into this final phase of development is a major step forward."

About Diabetic Cardiomyopathy

Diabetic Cardiomyopathy (DbCM) is a rapidly progressing degenerative disorder of the heart in patients with both type 1 and type 2 diabetes. There are no approved therapies for this fatal condition, which affects 17 — 24 percent of people with diabetes, or approximately 77 million patients worldwide. Hyperglycemia, a symptom that characterizes diabetes, triggers the enzyme Aldose Reductase to convert excess glucose into sorbitol and fructose, both of which can lead to cell death in the heart muscle. When this happens, the heart fibroses, or "hardens," such that the organ is unable to circulate

blood through the body effectively. Approximately 25 percent of patients with DbCM progress to overt heart failure or death within 1.5 years of diagnosis.

About AT-001

AT-001 is an investigational oral, novel, potent Aldose Reductase inhibitor in clinical development for the treatment of Diabetic Cardiomyopathy. AT-001 has been studied in a Phase 1/2 study in approximately 120 patients with type 2 diabetes, a subset of which had DbCM.

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 initiated a Phase 3 registrational study in DbCM in September 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 (i) the design, scope and results of our clinical trials, (ii) the timing of the initiation and completion of our clinical trials, (iii) the likelihood that data from our clinical trials will support future development of our product candidates, (iv) the likelihood of obtaining regulatory approval of our product candidates and qualifying for any special designations, such as orphan drug designation, (v) our cash runway and the timing of our clinical development plan. 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.

Investors:
Maeve Conneighton
(212) 600-1902 or
appliedtherapeutics@argotpartners.com

Media:

media@appliedtherapeutics.com