# 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): **June 7, 2019**

# 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.) |

| **340 Madison Avenue, 19th Fl.**<br>**New York, NY 10173** | **10173** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

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

**Not Applicable**
(Former name or former address, if changed since last report.)

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 (see General Instruction A.2. below):

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))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock | APLT | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in 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

**Item 8.01. Other Events.**

On June 7, 2019, Applied Therapeutics, Inc. (the "Company") issued a press release announcing it will present data highlighting AT-001 for treatment of Diabetic Cardiomyopathy at the American Diabetes Association 79th Annual Scientific Sessions (June 7-11, 2019), 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 June 7, 2019. |

**SIGNATURES**

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.**

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

Dated: June 7, 2019

**EXHIBIT 99.1**

**Applied Therapeutics to Present Data Highlighting AT-001 for the Treatment of Diabetic Cardiomyopathy in Late Breaking Session at the American Diabetes Association 79th Annual Scientific Sessions**

*AT-001, a novel, potent and selective aldose reductase inhibitor, is expected to start a pivotal study later this year*

**NEW YORK, June 7, 2019 -** Applied Therapeutics Inc. (Nasdaq:APLT), a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates against validated molecular targets in indications of high unmet medical need, today announced that it will present data at the American Diabetes Association 79th Scientific Sessions in San Francisco (June 7-11, 2019) on AT-001, a novel, potent and selective aldose reductase inhibitor (ARI) in clinical development for Diabetic Cardiomyopathy (DbCM). The Late Breaking Science poster, entitled "Phase 1/2 Safety and Proof of Biological Activity Study of AT-001, an Aldose Reductase Inhibitor in Development for Diabetic Cardiomyopathy" highlights a recently completed Phase 1/2 study in approximately 120 patients with type 2 diabetes, a subset of which had DbCM.

"Diabetic complications, such as Diabetic Cardiomyopathy, continue to grow despite advancements in glucose control. It's imperative that therapies are developed to treat or prevent diabetic complications through mechanisms other than glycemic modification. " said Riccardo Perfetti, MD, PhD. "We are excited to be presenting our data at the prominent 'Late Breaking' session at ADA, and are thrilled by the recognition from the congress and the clinical community. Targeting aldose reductase with a potent and selective inhibitor presents an opportunity to potentially halt disease progression and prevent worsening of heart failure in DbCM patients. We look forward to initiating our pivotal program for AT-001 in DbCM later this year."

**Phase 1/2 Safety and Proof of Biological Activity Study of AT-001, an Aldose Reductase Inhibitor in Development for Diabetic Cardiomyopathy**

(Late Breaking Abstract — oral poster presentation Sunday June 9, 12-1pm)

- AT-001 was well tolerated at all doses tested
- Target engagement was confirmed by potent aldose reductase (AR) inhibition as evidenced by significant reductions in sorbitol, a pharmacodynamic biomarker of AR activity
- AT-001 improved selectivity and affinity for AR resulted in potent AR inhibition

**About Diabetic Cardiomyopathy**

Diabetic Cardiomyopathy (DbCM) is a rapidly progressing degenerative disorder of the heart muscle in people with 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**

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 2/3 pivotal 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, which is expected to advance into a Phase 1 clinical trial in 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 likelihood data will support future development and the expected timing of 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. Other 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 section titled "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.

**Contacts**

Investors:
Maeve Conneighton
(212) 600-1902 or

appliedtherapeutics@argotpartners.com

Media:
media@appliedtherapeutics.com