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): **November 13, 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 2.02. Results of Operations and Financial Condition.

On November 13, 2019, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Form 8-K, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 13, 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: November 13, 2019

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

Exhibit 99.1

Applied Therapeutics Reports Third Quarter 2019 Financial Results

NEW YORK, November 13, 2019 - Applied Therapeutics, Inc. (Nasdaq: APLT), a clinical-stage biopharmaceutical company developing novel drug candidates in indications of high unmet medical need, today reported financial results for the third quarter ended September 30, 2019.

"The third quarter was a critical period of progress at Applied, and we are extremely pleased to have met all of our objectives," said Shoshana Shendelman, PhD, Founder, Chief Executive Officer and Chair of the Board of Applied Therapeutics. "We are now in the final phase of development on both of our lead programs, having initiated our Phase 3 registrational study of AT-001 in Diabetic Cardiomyopathy (ARISE-HF) and transitioned into the Phase 2 portion of our Galactosemia trial (ACTION-Galactosemia) in the third quarter. We continue to maintain our momentum and remain on track to report pivotal data on our Galactosemia program by year end. Recently, we had an opportunity to broaden our shareholder base and strengthen the balance sheet through a private placement, providing us with additional cash runway as we move beyond development and into commercialization of our lead assets."

Recent Highlights

- **Closed $20M Private Placement.** In November 2019, we announced the close of a private placement of common stock, resulting in gross proceeds of approximately $20 million.
- **Presented Data Highlighting AT-007 for the Treatment of Galactosemia at the ASHG Annual Meeting.** In October 2019, our Chief Medical Officer, Riccardo Perfetti, MD, PhD, gave an oral platform presentation highlighting AT-007 for the treatment of Galactosemia at the American Society of Human Genetics (ASHG) 2019 Annual Meeting in Houston. We also hosted an Educational Symposium featuring a panel of Galactosemia experts.
- **Presented Preclinical and Clinical Data on AT-001 in Diabetic Cardiomyopathy (DbCM) at the EASD and HFSA Annual Meetings. In September 2019, we presented preclinical and clinical proof of concept data on AT-001 in DbCM** at the Heart Failure Society of America (HFSA) 23rd Annual Scientific Meeting in Philadelphia. In addition, we presented a preclinical poster on AT-001 at the 55th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Barcelona, demonstrating that AT-001 significantly reduces cardiac damage in an animal model of DbCM. These data further support the development rationale and clinical proof of concept for AT-001 in DbCM.

- **Initiated Phase 3 Registrational Trial of AT-001 in Diabetic Cardiomyopathy (ARISE-HF).** In September 2019, we announced the initiation of ARISE-HF, a Phase 3 registrational trial for AT-001 in Diabetic Cardiomyopathy (DbCM). 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 peak VO2 over 15 months of treatment. 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.

- **Reported Single and Multiple Ascending Dose Data from Healthy Volunteer Portion of Phase 1/2 ACTION-Galactosemia Trial Evaluating AT-007.**In August 2019, we announced the completion of the Single Ascending Dose healthy volunteer portion of the Phase 1/2 study of AT-007 in Galactosemia. In October, at the ASHG meeting, we provided an update on Multiple Ascending Dose portion of the study. AT-007 was well tolerated, with no drug-related adverse events or dose-limiting toxicities reported. The study, referred to as ACTION-Galactosemia, was initiated in June 2019 and is designed to investigate the safety and pharmacokinetics (PK) of AT-007, a central nervous system (CNS) penetrant Aldose Reductase (AR) inhibitor in healthy volunteers, and biomarker effects in adult subjects with Galactosemia. Data from the adult Galactosemia patient portion of the trial is expected in the fourth quarter of 2019. We plan to employ recent FDA guidance permitting biomarker-based development in low prevalence, slowly progressing rare metabolic diseases, such as Galactosemia.

Financial Results

- **Cash and cash equivalents and short-term investments**totaled $33.0 million as of September 30, 2019, compared with $18.8 million at December 31, 2018. Subsequent to the close of the quarter, we closed a private placement of common stock resulting in net proceeds of approximately $20 million.

- **Research and development expenses** for the three months ended September 30, 2019 were $7.5 million, compared to $2.7 million for the three months ended September 30, 2018. The increase of approximately $4.8 million was primarily related to the progressing of our clinical trials through development, including an increase in clinical and pre-clinical expenses of $4.0 million and personnel expenses of $1.0 million due to the hiring of research and development personnel, including the Chief Medical Officer in August 2018. These increases are offset by a decrease in drug manufacturing and formulation expenses of $0.1 million and decrease in regulatory and other expenses of $0.1 million.

- **General and administrative expenses** were $3.3 million for the three months ended September 30, 2019, compared to $0.6 million for the three months ended September 30, 2018. The increase of approximately $2.7 million was primarily related to personnel expenses of $1.0 million due to the increase in headcount, including the hiring of the Chief Financial Officer, professional fees of $0.9 million due to increased legal and consulting fees, and other expenses of $0.8 million, primarily due to public relations efforts, travel expenses and recruiting efforts.

- **Net loss** for the third quarter of 2019 was $10.7 million, or $0.63 per basic and diluted common share, compared to a net loss of $4.3 million, or $0.78 per basic and diluted common share, for the third quarter of 2018.

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.

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Applied Therapeutics, Inc.
Statement of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
OPERATING EXPENSES:				
Research and development	$ 7,453	$ 2,726	$ 18,582	$ 6,111
General and administrative	3,294	598	9,331	1,418
Total operating expenses	10,747	3,324	27,913	7,529
LOSS FROM OPERATIONS	(10,747)	(3,324)	(27,913)	(7,529)
OTHER INCOME (EXPENSE), NET:				
Interest income (expense), net	34	(584)	33	(1,400)
Other expense	—	(373)	—	(873)
Total other income (expense), net	34	(957)	33	(2,273)
Net loss	$ (10,713)	$ (4,281)	$ (27,880)	$ (9,802)
Net loss attributable to common stockholders —basic and diluted	$ (10,713)	$ (4,281)	$ (27,880)	$ (9,802)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.63)	$ (0.78)	$ (1.98)	$ (1.79)
Weighted-average common stock outstanding —basic and diluted	17,095,870	5,497,871	14,085,579	5,473,414

Applied Therapeutics, Inc.
Balance Sheet

	As of September 30, 2019 (Unaudited)	As of December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,065	$ 18,748
Prepaid expenses and other current assets	4,080	1,498
Investments	19,889	—
Total current assets	37,034	20,246
Other assets	230	—
TOTAL ASSETS	$ 37,264	$ 20,246
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	1,688	3,015
Accrued expenses and other current liabilities	4,829	1,413
Total current liabilities	6,517	4,428
Total liabilities	6,517	4,428
Series A convertible preferred stock, $0.0001 par value; 0 shares and 3,093,898 shares authorized at September 30, 2019 and December 31, 2018, respectively; 0 shares and 3,093,898 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $7,000 at September 30, 2019 and December 31, 2018, respectively	—	6,254
Series B convertible preferred stock, $0.0001 par value; 0 shares and 7,790,052 shares authorized as of September 30, 2019 and December 31, 2018, respectively; 0 shares and 4,001,848 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $29,964 as of September 30, 2019 and December 31, 2018, respectively	—	29,156
STOCKHOLDERS' EQUITY (DEFICIT):		
Common stock, $0.0001 par value; 100,000,000 and 20,441,982 shares authorized as of September 30, 2019 and December 31, 2018, respectively; 17,134,190 shares and 5,513,531 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1	—
Additional paid-in capital	79,872	1,665
Accumulated other comprehensive loss	11	—
Accumulated deficit	(49,137)	(21,257)
Total stockholders' equity (deficit)	30,747	(19,592)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 37,264	$ 20,246