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): **August 12, 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** (Address of Principal Executive Offices)		**10173** (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:

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))

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 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

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 August 12, 2019, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 12, 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: August 12, 2019

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

Exhibit 99.1

Applied Therapeutics Reports Second Quarter 2019 Financial Results

NEW YORK, August 12, 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 second quarter ended June 30, 2019.

"During the second quarter, we continued to execute on advancing our robust pipeline of novel drug candidates through the clinic," said Shoshana Shendelman, Founder, Chief Executive Officer and Chair of the Board of Applied Therapeutics. "We initiated our Phase 1/2 trial of AT-007 in Galactosemia in June and reported favorable Single Ascending Dose data from healthy volunteers last week. We look forward to advancing AT-007 through the next portion of the trial, which includes treatment of adults with Galactosemia. In addition, we are preparing for the dosing of the first patient in our registrational Phase 3 trial for our lead asset, AT-001, in Diabetic Cardiomyopathy (DbCM), which we expect to occur in the third quarter."

Recent Highlights

- **Reported Single 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 (SAD) healthy volunteer portion of the Phase 1/2 study of AT-007 in Galactosemia. 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.

- **Presented Phase 1/2 Data Highlighting Safety and Efficacy for AT-001 in DbCM at the American Diabetes Association (ADA) 79th Annual Scientific Sessions in San Francisco.** In June 2019, we presented Phase 1/2 Data Highlighting Safety and Efficacy for AT-001 in DbCM at the ADA Annual Scientific Sessions. The data, presented as part of the Late Breaking session, demonstrated that AT-001 was well tolerated at all dose levels, and target engagement was confirmed by potent AR inhibition as evidenced by significant reductions in sorbitol, a pharmacodynamic biomarker of AR activity. AT-001 also improved selectivity and affinity for AR and resulted in potent AR inhibition.

- **Received FDA Orphan Drug Designation for AT-007 in Galactosemia.** In May 2019, we received orphan drug designation for AT-007 in Galactosemia. The designation allows Applied Therapeutics to qualify for a number of incentives, including: seven years of market exclusivity upon regulatory approval, if received; exemption from FDA application fees for Galactosemia; and tax credits for qualified clinical trials.

- **Presented Phase 1/2 Data Highlighting Safety and Proof of Biological Activity for AT-001 in DbCM at The European Society for Cardiology (ESC) 6th World Congress in Athens, Greece.** In May 2019, we presented two posters at ESC, the first of which was presented in the Late Breaking session and highlighted key data from a recently completed Phase 1/2 study in approximately 120 type 2 diabetic patients describing the safety, pharmacokinetics and proof of biological activity for AT-001 in DbCM. Supporting preclinical data from an animal model of DbCM was also presented, demonstrating that AT-001 prevents or reduces cardiac damage in a relevant disease model.

- **Completed Initial Public Offering.** In May 2019, we completed our IPO, generating approximately $34.6 million in net proceeds, after deducting underwriter discounts and commissions and offering expenses payable by us.

Financial Results

- **Cash and cash equivalents** totaled $41.1 million as of June 30, 2019, compared with $18.8 million at December 31, 2018.

- **Research and development expenses** for the three months ended June 30, 2019 were $4.3 million, compared to $1.9 million for the three months ended June 30, 2018. The increase of approximately $2.4 million was primarily related to costs associated with progressing our clinical trials, including an increase in clinical and pre-clinical expenses of $1.6 million and personnel expenses of $2.1 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 $1.3 million.

- **General and administrative expenses** were $4.2 million for the three months ended June 30, 2019, compared to $0.4 million for the three months ended June 30, 2018. The increase of approximately $3.8 million was primarily related to personnel expenses of $2.2 million due to the increase in headcount, including the hiring of the interim Chief Financial Officer and the Controller, professional fees of $0.9 million due to increased legal and consulting fees, and other expenses of $0.7 million, primarily due to public relations efforts, travel expenses and recruiting efforts.

- **Net loss** for the second quarter of 2019 was $8.4 million, or $0.60 per basic and diluted common share, compared to a net loss of $3.2 million, or $0.58 per basic and diluted common share, for the second 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 plans to initiate a Phase 3 registrational 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, 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 the (i) our cash runway and acceleration of our clinical development plan, (ii) the likelihood data will support future development of our product candidates, (iii) qualification for exemptions resulting from the receipt of orphan drug designation and (iii) the expected timing of the 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. 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.

Investors:

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Applied Therapeutics, Inc.
Statement of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
OPERATING EXPENSES:				
Research and development	$ 4,254	$ 1,937	$ 11,128	$ 3,385
General and administrative	4,183	400	6,037	820
Total operating expenses	8,437	2,337	17,165	4,205
LOSS FROM OPERATIONS	(8,437)	(2,337)	(17,165)	(4,205)
OTHER INCOME (EXPENSE), NET:				
Interest income (expense), net	—	(533)	(1)	(815)
Other expense	—	(315)	—	(501)
Total other income (expense), net	—	(848)	(1)	(1,316)
Net loss	$ (8,437)	$ (3,185)	$ (17,166)	$ (5,521)
Net loss attributable to common stockholders—basic and diluted	$ (8,437)	$ (3,185)	$ (17,166)	$ (5,521)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.60)	$ (0.58)	$ (1.76)	$ (1.01)
Weighted-average common stock outstanding—basic and diluted	13,945,939	5,463,489	9,776,582	5,460,983

Applied Therapeutics, Inc.
Balance Sheet

	As of June 30, 2019 (Unaudited)	As of December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,076	$ 18,748
Prepaid expenses and other current assets	5,708	1,498
Total current assets	46,784	20,246
TOTAL ASSETS	$ 46,784	$ 20,246
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	3,987	3,015
Accrued expenses and other current liabilities	2,793	1,413
Total current liabilities	6,780	4,428
Other liabilities		
Total liabilities	6,780	4,428
Series A convertible preferred stock, $0.0001 par value; 0 shares and 3,093,898 shares authorized at June 30, 2019 and December 31, 2018, respectively; 0 shares and 3,093,898 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $7,000 at June 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 June 30, 2019 and December 31, 2018, respectively; 0 shares and 4,001,848 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $29,964 as of June 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 June 30, 2019 and December 31, 2018, respectively; 17,052,202 shares and 5,513,531 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	1	—
Additional paid-in capital	78,427	1,665
Accumulated deficit	(38,424)	(21,257)
Total stockholders' equity (deficit)	40,004	(19,592)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 46,784	$ 20,246