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 12, 2020**

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**	**10017**
(Address of Principal Executive Offices)	(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:

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(s)**	**Name of each exchange on which registered**
Common Stock	APLT	The Nasdaq Global Market

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. ☒

Item 2.02. Results of Operations and Financial Condition.

On November 12, 2020, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020. 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:

The following exhibit is attached with this current report on Form 8-K:

Exhibit No.	Description
99.1	Press Release, dated November 12, 2020.

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 12, 2020

By: */s/ Charles Silberstein*
Name: Charles Silberstein, M.D.
Title: Chief Financial Officer

Exhibit 99.1

Applied Therapeutics Reports Third Quarter 2020 Financial Results

Continued enrollment in the ARISE-HF Phase 3 global registrational study of AT-001 in Diabetic Cardiomyopathy (fatal heart disease affecting ~17% diabetics)

On track to initiate rare disease franchise expansion programs in SORD Deficiency and PMM2-CDG studies in the first half of 2021

Continued collaboration with FDA to restart the ACTION-Galactosemia Kids pediatric study

NEW YORK, November 12, 2020 - 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 reported financial results for the third quarter ended September 30, 2020.

"In the third quarter we continued to execute on our Diabetic Cardiomyopathy program, with strong enrollment in our ARISE-HF global Phase 3 registrational study, and new data presented on AT-001 mechanism of action and improvement in cardiac energetics," said Shoshana Shendelman, PhD, Founder, CEO and Chair of the Board of Applied Therapeutics. "As we move towards the end of the year, we'll continue to prepare for new rare disease clinical programs in SORD Deficiency and PMM2-CDG, which we plan to start in 2021. While the delay to our Galactosemia pediatric study has been disappointing to families, we continue to work productively with FDA to restart the trial as soon as possible, and we believe the program will be in a stronger position for approval due to close collaboration with the agency. We thank the Galactosemia community for their continuing support."

Recent Highlights

- **Shared data on AT-001 at the American Heart Association scientific sessions** demonstrating that AT-001 normalizes cardiac energetics and improves cardiac function in a mouse model of Diabetic Cardiomyopathy (DbCM).
- **Executed a licensing and research collaboration agreement with the University of Miami on SORD Deficiency** (genetically identified by the Miami clinical team in a May 2020 Nature publication). SORD Deficiency is a debilitating hereditary neuropathy affecting over 3,000 patients in the US.
- **The pediatric Galactosemia clinical study (ACTION-Galactosemia kids) remains on partial clinical hold as the Company continues to work collaboratively with FDA to restart the study.** The rationale for partial hold is not safety related, and the issues being addressed relate to design and operational aspects of the trial. The Company plans to submit an NDA no later than Q3 2021.
- **Presented Data on AT-007 for the Treatment of Galactosemia at the American Society of Human Genetics (ASHG) 2020 Annual Meeting.** In October 2020, we presented two poster presentations covering AT-007 in Galactosemia at the ASHG 2020 Annual Meeting. The presentations included animal model efficacy data and adult clinical data on the safety and biomarker efficacy of AT-007.
- **Announced Pediatric Rare Disease Designation and Orphan Drug Designation for AT-007 for the treatment of PMM2-CDG.** PMM2-CDG is a debilitating rare disease caused by deficiency in the critical enzyme phosphomannomutase-2, required for systemic glycosylation of proteins. PMM2-CDG causes multiple organ failure and severe disability, resulting in approximately 20% mortality in the first four years of life. There are currently no drugs approved to treat PMM2-CDG.

- **Presented Data on AT-001 for Treatment of Diabetic Cardiomyopathy at 56th Annual Meeting of the European Association for the Study of Diabetes (EASD).** In September 2020, we presented two poster presentations covering AT-001, a next generation aldose reductase inhibitor (ARI), in Phase 3 development for Diabetic Cardiomyopathy at the 56th Annual EASD Meeting. The presentations included data on the safety and specificity of AT-001, as well as data on mechanistic protection from cellular damage during hyperglycemia.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $116.5 million as of September 30, 2020, compared with $38.9 million at December 31, 2019.
- **Research and development expenses** for the three months ended September 30, 2020 were $19.9 million, compared to $7.5 million for the three months ended September 30, 2019. For the three months ended September 30, 2020, the increase of $12.5 million was primarily due to an increase in clinical and pre-clinical expense of $4.6 million, primarily related to the progression of the AT-007 ACTION-Galactosemia adult extension study, the AT-007 ACTION-Galactosemia Kids pediatric registrational study and the AT-001 Phase 3 ARISE-HF clinical study; an increase in drug manufacturing and formulation costs of $7.2 million primarily related to raw material deliveries in support of the 2020 manufacturing campaigns and the completion and release of AT-001 and AT-007 drug product batches; an increase in personnel expenses of $0.2 million due to the increase in headcount in support of our clinical program pipeline; an increase in stock-based compensation of $0.1 million due to new stock option and restricted stock unit grants during the three months ended September 30, 2020; and an increase in regulatory and other expenses of $0.4 million relating to an increase in clinical consulting fees during the three months ended September 30, 2020.
- **General and administrative expenses** were $10.0 million for the three months ended September 30, 2020, compared to $3.3 million for the three months ended September 30, 2019. For the three months ended September 30, 2020, the increase of $6.7 million was primarily related to the increase in personnel expenses of $1.2 million and an increase in stock-based compensation of $1.0 million due to the increase in headcount, $1.0 million related to an increase in legal and professional fees due to increased operations and costs associated with being a public company, $2.4 million related to the establishment of a commercial department, $0.2 million related to increased insurance costs, and $0.9 million in other expenses relating to increased costs of rent and other office expenses.
- **Net loss** for the third quarter of 2020 was $29.8 million, or $1.33 per basic and diluted common share, compared to a net loss of $10.7 million, or $0.63 per basic and diluted common share, for the third quarter 2019.

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-007, is a novel central nervous system penetrant aldose reductase inhibitor (ARI) for the treatment of Galactosemia, a rare pediatric metabolic disease. The Company initiated a pivotal Phase 1/2 clinical trial in June 2019, read out positive top-line biomarker data in adult Galactosemia patients in January 2020 and announced full data from the trial in April 2020. A pediatric Galactosemia study commenced in June 2020. The Company is also developing AT-001, a novel potent 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. 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, as well as novel dual PI3k inhibitors in preclinical development for orphan oncology indications.

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 timing of our NDA submission for potential approval of AT-007, which will include data from the ACTION-Galactosemia Kids trial and the 90-day safety data in adults with Galactosemia, (ii) the design, scope and results of our clinical trials, (iii) the timing of the initiation and completion of our clinical trials, (iv) the likelihood that data from our clinical trials will support future development of our product candidates, and (v) the likelihood of obtaining regulatory approval of our product candidates and qualifying for any special designations, such as orphan drug designation. 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, (i) our plans to develop and commercialize our product candidates, (ii) the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs, (iii) our ability to take advantage of expedited regulatory pathways for any of our product candidates, (iv) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, (v) our ability to successfully acquire or license additional product candidates on reasonable terms, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain regulatory approval of our current and future product candidates, (viii) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (ix) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (x) the implementation of our business model and strategic plans for our business and product candidates, (xi) our intellectual property position and the duration of our patent rights, (xii) developments or disputes concerning our intellectual property or other proprietary rights, (xiii) our expectations regarding government and third-party payor coverage and reimbursement, (xiv) our ability to compete in the markets we serve, (xv) the impact of government laws and regulations and liabilities thereunder, (xvi) developments relating to our competitors and our industry, (xvii) the impact of the COVID-19 pandemic on the timing and progress of our ongoing clinical trials and our business in general and (xviii) other factors that may impact our financial results. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. 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
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
OPERATING EXPENSES:				
Research and development	$ 19,945	$ 7,453	$ 47,974	$ 18,582
General and administrative	10,020	3,294	22,744	9,331
Total operating expenses	29,965	10,747	70,718	27,913
LOSS FROM OPERATIONS	(29,965)	(10,747)	(70,718)	(27,913)
OTHER INCOME (EXPENSE), NET:				
Interest income (expense), net	131	34	435	33
Other income (expense)	(10)	—	11	—
Total other income (expense), net	121	34	446	33
Net loss	$ (29,844)	$ (10,713)	$ (70,272)	$ (27,880)
Net loss attributable to common stockholders—basic and diluted	$ (29,844)	$ (10,713)	$ (70,272)	$ (27,880)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.33)	$ (0.63)	$ (3.22)	$ (1.98)
Weighted-average common stock outstanding—basic and diluted	22,426,203	17,095,870	21,790,207	14,085,579

Applied Therapeutics, Inc.
Balance Sheet
(in thousands, except share and per share data)

	As of September 30, 2020 (Unaudited)	As of December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 48,679	$ 18,850
Investments	67,826	20,004
Prepaid expenses and other current assets	6,380	7,301
Total current assets	122,885	46,155
Operating lease right-of-use asset	1,754	2,035
Security deposits and leasehold improvements	199	199
TOTAL ASSETS	$ 124,838	$ 48,389
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	380	356
Accounts payable	1,945	8,793
Accrued expenses and other current liabilities	18,177	4,950
Total current liabilities	20,502	14,099
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	1,396	1,683
Total noncurrent liabilities	1,396	1,683
Total liabilities	21,898	15,782
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 22,456,686 shares and 18,531,560 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	240,074	99,378
Accumulated other comprehensive loss	(94)	(2)
Accumulated deficit	(137,042)	(66,770)
Total stockholders' equity	102,940	32,607
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 124,838	$ 48,389