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, 2021**

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:

☐ 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))

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, 2021, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. 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, 2021.

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, 2021

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

Applied Therapeutics Reports Third Quarter 2021 Financial Results

Data from pilot trial of AT-007 in SORD deficiency expresses substantial and significant reduction in sorbitol

Data from the ACTION-Galactosemia Kids study demonstrates statistically significant reduction in plasma galactitol

NEW YORK, Nov. 12, 2021 – 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, 2021.

"This quarter we announced positive data in both the Galactosemia pediatric study as well as our pilot SORD Deficiency study, highlighting our execution across programs and expansion into additional indications with AT-007," said Shoshana Shendelman, PhD, CEO, Founder and Chair of the Board of Applied Therapeutics. "We are excited to launch our registrational study in SORD later this year and remain focused on preparations for our anticipated commercial launch in Galactosemia in 2022."

Recent Highlights

- **Reported biomarker data from pilot trial of AT-007 in SORD deficiency.** In October 2021, the Company highlighted results from a pilot open-label study in 8 SORD Deficiency patients. In the study, AT-007 reduced blood sorbitol levels by approximately 66% from baseline through 30 days of treatment with a range of reduction from baseline of 54%-75%. AT-007 was safe and well tolerated in all patients. The Company plans to initiate a registrational study by the end of 2021.

- **Reported pediatric biomarker data from ACTION-Galactosemia Kids.** In October 2021, the Company reported pediatric biomarker data from the ACTION-Galactosemia Kids study. The results demonstrated a substantial reduction in plasma galactitol of approximately 40%, which was statistically significant ($p<0.001$) vs. placebo. Additionally, analysis of the 47 children in the ACTION-Galactosemia Kids study demonstrated a clear correlation between baseline galactitol level and baseline clinical functional outcomes. Children with higher plasma galactitol levels displayed greater disease severity vs. children with lower plasma galactitol levels at baseline. This data is the first demonstration of correlation of a biochemical biomarker with severity of disease in Galactosemia patients. This data will be presented as a late-breaking abstract at the 14th International Congress on Inborn Errors of Metabolism (ICIEM) November 21-24, 2021.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $108.8 million as of September 30, 2021, compared with $125.6 million at June 30, 2021.

- **Research and development expenses** for the three months ended September 30, 2021 were $17.6 million, compared to $19.9 million for the three months ended September 30, 2020. The decrease of $2.3 million was related to a decrease in drug manufacturing and formulation costs of $5.2 million primarily related to the completion and release of AT-001 and AT-007 drug product batches in the three months ended March 31, 2021; an increase in clinical and pre-clinical expense of $2.1 million, primarily related to the progression of the AT-007 ACTION-Galactosemia adult extension study and the AT-007 ACTION-Galactosemia Kids pediatric registrational study; an increase in personnel expenses of $0.6 million due to the increase in headcount in support of our clinical program pipeline; and an increase in regulatory and other expenses of $0.2 million.

- **General and administrative expenses** were $10.8 million for the three months ended September 30, 2021, compared to $10.0 million for the three months ended September 30, 2020. The increase of $0.8 million was primarily related to an increase in commercial expenses of $0.8 million related to the expansion of the commercial department; an increase in other expenses of $0.3 million relating to increased costs of rent and other office expenses; an increase in stock-based compensation of $0.2 million; an increase in insurance expenses of $0.1 million related to increased insurance costs; and a decrease in legal and professional fees $0.6 million due to lower external legal fees.

- **Net loss** for the third quarter of 2021 was $28.4 million, or $1.09 per basic and diluted common share, compared to a net loss of $29.8 million, or $1.33 per basic and diluted common share, for the third quarter 2020.

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 CNS rare metabolic diseases, including Galactosemia, SORD Deficiency and PMM2-CDG. The Company is also developing AT-001, a novel potent ARI, for the treatment of Diabetic Cardiomyopathy, or DbCM, a fatal fibrosis of the heart. 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.

To learn more, please visit www.appliedtherapeutics.com and follow the company on Twitter @Applied_Tx.

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 Company's plan to initiate a registrational study in SORD by the end of 2021, (ii) the anticipated commercial launch in Galactosemia in 2022, (iii) AT-007 potential to be the first disease-modifying therapy for SORD Deficiency, (iv) the timing of the initiation and completion of our clinical trials, (v) the likelihood that data from our clinical trials will support future development of our product candidates and (vi) the likelihood of obtaining regulatory approval of our product candidates. 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.
Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
OPERATING EXPENSES:				
Research and development	$ 17,597	$ 19,945	$ 46,846	$ 47,974
General and administrative	10,833	10,020	31,658	22,744
Total operating expenses	28,430	29,965	78,504	70,718
LOSS FROM OPERATIONS	(28,430)	(29,965)	(78,504)	(70,718)
OTHER INCOME (EXPENSE), NET:				
Interest income (expense), net	76	131	321	435
Other income (expense)	(64)	(10)	(242)	11
Total other income (expense), net	12	121	79	446
Net loss	$ (28,418)	$ (29,844)	$ (78,425)	$ (70,272)
Net loss attributable to common stockholders—basic and diluted	$ (28,418)	$ (29,844)	$ (78,425)	$ (70,272)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.09)	$ (1.33)	$ (3.08)	$ (3.22)
Weighted-average common stock outstanding—basic and diluted	26,177,079	22,426,203	25,472,590	21,790,207

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

	As of September 30, 2021 (Unaudited)	As of December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 70,207	$ 57,466
Investments	38,595	39,363
Prepaid expenses and other current assets	8,141	5,764
Total current assets	116,943	102,593
Operating lease right-of-use asset	1,404	1,712
Security deposits and leasehold improvements	200	201
TOTAL ASSETS	$ 118,547	$ 104,506
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	$ 436	$ 406
Accounts payable	9,170	640
Accrued expenses and other current liabilities	21,237	20,189
Total current liabilities	30,843	21,235
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	1,003	1,332
Total noncurrent liabilities	1,003	1,332
Total liabilities	31,846	22,567
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 26,214,399 shares and 22,493,661 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	3	2
Additional paid-in capital	326,108	242,780
Accumulated other comprehensive loss	(254)	(112)
Accumulated deficit	(239,156)	(160,731)
Total stockholders' equity	86,701	81,939
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 118,547	$ 104,506