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):**March 18, 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** (Address of Principal Executive Offices)	**10017** (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 March 18, 2021, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and full year ended December 31, 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 March 18, 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: March 18, 2021

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

Exhibit 99.1

Applied Therapeutics Reports Fourth Quarter and Year-end 2020 Financial Results

AT-007 ACTION-Galactosemia Kids pediatric clinical study recently resumed following discussions with FDA

On track to submit NDA for AT-007 in Galactosemia no later than Q3 2021; Commercial preparations underway

ARISE-HF Phase 3 global registrational study of AT-001 in Diabetic Cardiomyopathy on track to complete enrollment in mid-2021

On track to initiate rare disease franchise expansion programs in SORD Deficiency and PMM2-CDG studies in the first half of 2021; Company to host Rare Disease Forum on Tuesday, March 23rd

NEW YORK, March 18, 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 fourth quarter and full year ended December 31, 2020.

"The fourth quarter was a productive period of internal planning and execution," said Shoshana Shendelman, PhD, Founder, CEO and Chair of the Board of Applied Therapeutics. "We are excited for what lies ahead in 2021, where our focus will be on advancing our late stage assets toward commercialization while initiating clinical development of our two new rare disease programs."

Recent Highlights

- **Announced Restart of Pediatric Galactosemia Study**. In February 2021, the Company announced that the FDA lifted the clinical hold on the AT-007 ACTION-Galactosemia Kids pediatric clinical study, and the study resumed immediately. Applied Therapeutics worked closely with FDA to modify the trial, with the shared goal of ensuring that all patients have the opportunity to receive clinical benefit, and remains on target to submit an NDA no later than Q3 2021.

- **Announced the Launch of a Galactosemia Awareness and Education Initiative.** Galactosemia Together is the first and only industry-led Galactosemia awareness and education campaign. Developed in partnership with the Galactosemia community, this initiative aims to address gaps in education by providing updated, reliable and credible resources to help connect, educate and support those families impacted by this disease.

- **Announced Magnetic Resonance Spectroscopy (MRS) Data from ACTION-Galactosemia Study.** In December 2020, the Company shared MRS data on reduction of galactitol levels in the brain of Galactosemia patients treated with AT-007 in the ACTION-Galactosemia adult study. Overall, plasma reduction in galactitol correlated with brain reduction in galactitol. At the two doses which demonstrated statistically significant reduction in plasma galactitol, 20 and 40mg/kg, 3 out of 4 patients displayed substantial galactitol reduction ranging from 61.94% to 69.80% reduction from baseline.

- **Closed Public Offering of 3,000,000 Shares of Common Stock at a Price to the Public of $23.00 Per Share.** In February 2021, the Company completed an underwritten public offering of 3,450,000 shares of common stock, including the exercise in full of the underwriters' option to purchase 450,000 additional shares of common stock at a price of $23.00 per share, resulting in aggregate net proceeds of approximately $74.3 million.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $96.8 million as of December 31, 2020, compared with $38.9 million at December 31, 2019. This does not include approximately $74.3 million in aggregate net proceeds the Company received from the underwritten public offering of common stock in February 2021.

- **Research and development expenses for the year ended December 31, 2020** were $61.8 million, compared to $32.4 million for the year ended December 31, 2019. The increase of $29.4 million related to an increase in clinical and pre-clinical expense of $11.3 million, primarily related to the progression of the AT-007 ACTION-Galactosemia adult extension and the AT-001 Phase 3 ARISE-HF clinical studies, as well as the commencement and progression of the AT-007 ACTION-Galactosemia Kids pediatric registrational study; an increase in drug manufacturing and formulation expenses of $15.4 million primarily related to the commencement of the 2020 manufacturing campaigns and the associated raw material deliveries and AT-007 and AT-001 drug product batch releases; an increase in personnel expenses of $0.6 million due to the increase in headcount in support of our clinical program pipeline; a decrease in stock-based compensation of $0.2 million due to the stock option modification expense recognized during the year ended December 31, 2019 for the acceleration of certain options vesting following the IPO; offset by an increase in expense recognized during the year ended December 31, 2020 due to new stock option and restricted stock grants; and an increase of regulatory and other expenses of $2.3 million primarily related to University of Miami license fees and increased clinical consulting fees recognized during the year ended December 31, 2020.

- **General and administrative expenses** were 32.7 million for the year ended December 31, 2020, compared to $13.2 million for the year ended December 31, 2019. The increase of $19.4 million was an increase in professional and legal fees of $4.1 million due to increased operations and costs associated with being a public company for a full year; an increase of $5.7 million related to the establishment of a commercial department; an increase in personnel expenses of $4.2 million and an increase in stock-based compensation of $2.0 million due to an increase in headcount; an increase of insurance expenses of $1.8 million related to increased D&O insurance costs; and an increase in other expenses of $1.6 million, primarily relating to increased costs of rent and other office expenses.

- **Net loss** for the year ended December 31, 2020 was $94.0 million, or $4.28 per basic and diluted common share, compared to a net loss of $45.5 million, or $3.55 per basic and diluted common share, for the year ended December 31, 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 timing of our rare disease franchise expansion programs in SORD Deficiency and PMM2-CDG, (iii) the timing and effectiveness of our Galactosemia awareness and education campaign, (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.

Contacts

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Applied Therapeutics, Inc.
Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2020	**2019**
OPERATING EXPENSES:		
Research and development	$ 61,788	$ 32,350
General and administrative	32,678	13,232
Total operating expenses	94,466	45,582
LOSS FROM OPERATIONS	(94,466)	(45,582)
OTHER INCOME (EXPENSE), NET:		
Interest income (expense), net	559	93
Other income (expense)	(54)	(24)
Total other income (expense), net	505	69
Net loss	$ (93,961)	$ (45,513)
Net loss attributable to common stockholders—basic and diluted	$ (93,961)	$ (45,513)
Net loss per share attributable to common stockholders—basic and diluted	$ (4.28)	$ (3.55)
Weighted-average common stock outstanding—basic and diluted	21,966,326	12,831,221

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

	As of December 31, 2020	As of December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 57,466	$ 18,850
Investments	39,363	20,004
Prepaid expenses and other current assets	5,764	7,301
Total current assets	102,593	46,155
Operating lease right-of-use asset	1,712	2,035
Security deposits and leasehold improvements	201	199
TOTAL ASSETS	$ 104,506	$ 48,389
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	$ 406	$ 356
Accounts payable	640	8,793
Accrued expenses and other current liabilities	20,189	4,950
Total current liabilities	21,235	14,099
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	1,332	1,683
Total noncurrent liabilities	1,332	1,683
Total liabilities	22,567	15,782
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 22,493,661 shares and 18,531,560 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	242,780	99,378
Accumulated other comprehensive loss	(112)	(2)
Accumulated deficit	(160,731)	(66,770)
Total stockholders' equity	81,939	32,607
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 104,506	$ 48,389