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 13, 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 5th 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:

☐ 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 March 13, 2020, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and full year ended December 31, 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:

The following exhibits are attached with this current report on Form 8-K:

Exhibit No.	Description
99.1	Press Release, dated March 13, 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: March 13, 2020

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

Exhibit 99.1

Applied Therapeutics Reports Fourth Quarter and Year-end 2019 Financial Results

NEW YORK, March 13, 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 fourth quarter and full year ended December 31, 2019.

“This past year was a transformative time for Applied Therapeutics. In addition to our transition to a public company, we completed two additional financings, and made significant progress in our clinical development programs in Diabetic Cardiomyopathy and Galactosemia - both devastating diseases with no treatment options available,” said Shoshana Shendelman, Ph.D., Founder, CEO and Chair of the Board of Applied Therapeutics. “With positive results from our pivotal Phase 2 ACTION-Galactosemia study in hand, we plan to move quickly towards regulatory filing, while preparing for Galactosemia commercial launch and growing our organization. On our Diabetic Cardiomyopathy program, we remain on track to fully enroll our Phase 3 registrational study this year, as we continue to advance this potential blockbuster opportunity. Throughout 2020 we’ll continue to move additional candidates into the clinic, while expanding our pipeline – delivering on our core strategy of applying technological advances to high unmet need indications.”

Recent Highlights

- **Closed $143.4 Million Underwritten Public Offering.** In January 2020, we completed an underwritten public offering of common stock at a price to the public of $45.50 per share, resulting in gross proceeds of approximately $143.4 million.

- **Announced Positive Topline Results of Pivotal Phase 2 ACTION-Galactosemia Study.** In January 2020, we announced positive topline results from the Pivotal Phase 2 portion of the ACTION-Galactosemia study of AT-007, a central nervous system (CNS) penetrant Aldose Reductase inhibitor (ARI), in adult Galactosemia patients. AT-007 treatment resulted in a statistically significant and robust reduction in plasma galactitol vs placebo in adult Galactosemia patients, and AT-007 was well tolerated, with no drug-related adverse events noted. We plan to utilize recent FDA guidance permitting biomarker-based development in low prevalence, slowly progressing rare metabolic diseases, such as Galactosemia, and expect to file for regulatory approval in the second half of 2020. We plan to present the full data from the ACTION-Galactosemia trial at the Society for Inherited Metabolic Disorders Annual Meeting, being held April 26 – 29 in Austin, Texas.

- **Presented Pre-Clinical Data Highlighting AT-001 for Treatment of Diabetic Cardiomyopathy at the World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC).** In December 2019, we presented pre-clinical data on AT-001, a novel, potent and selective Aldose Reductase inhibitor (ARI) in Phase 3 clinical development for Diabetic Cardiomyopathy at WCIRDC in Los Angeles, California. The data showed a head to head comparison of AT-001 vs a first-generation ARI and highlights the improvements over these prior ARIs.

- **Presented Study Design and Rationale for the ARISE-HF Pivotal Study of AT-001 for Treatment of Diabetic Cardiomyopathy at the 16th Annual Global Cardiovascular Clinical Trialist's Forum (CVCT).** In December 2019, we presented the study design and rationale for our ongoing ARISE-HF study at CVCT in Washington, D.C. ARISE-HF is a Phase 3 pivotal study examining effects of AT-001 on functional capacity (as measured by peak V02) in patients with Diabetic Cardiomyopathy at high risk of progression. We expect to announce topline data from the ARISE-HF trial in 2021.

- **Presented Clinical Data Highlighting AT-001 for the Treatment of Diabetic Cardiomyopathy at the American Heart Association (AHA) Scientific Sessions 2019.** In November 2019, we presented clinical data on AT-001 at AHA 2019 in Philadelphia, Pennsylvania. The data presented support our clinical rationale for development of AT-001 in Diabetic Cardiomyopathy by showing a reduction in NTproBNP, an important cardiac stress biomarker shown to correlate with long term heart failure outcomes and a strong preliminary indicator of efficacy in this patient population.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $38.9 million as of December 31, 2019, compared with $18.8 million at December 31, 2018. This does not include approximately $143.4 million in gross process we received from an underwritten public offering of common stock in January 2020.

- **Research and development expenses** for the year-ended December 31, 2019 were $32.4 million, compared to $11.5 million for the year ended December 31, 2018. The increase of approximately $20.9 million was primarily related to increased activity on our clinical trials, including an increase in clinical and pre-clinical expenses of $12.4 million and drug manufacturing and formulation expenses of $4.1 million, an increase in personnel expenses of $4.6 million that is allocated to research and development, offset by a decrease in regulatory and other expenses of $0.2 million.

- **General and administrative expenses** were $13.2 million for the year ended December 31, 2019, compared to $2.0 million for the year ended December 31, 2018. The increase of approximately $11.2 million was primarily related to the increase of personnel expenses of $4.4 million due to the portion of the chief executive officer's salary that is allocated to general and administrative and the hiring of other personnel, including the chief financial officer, and an increase in professional and legal fees of $3.5 million due to the closing of multiple financings and increased IP work, and an increase in other expenses of $3.2 million, primarily due to recruiting efforts for the chief medical officer and rent.

- **Net loss** for year ended December 31, 2019 was $45.5 million, or $3.55 per basic and diluted common share, compared to a net loss of $16.5 million, or $3.01 per basic and diluted common share, for the year ended December 31, 2018.

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 Phase 1/2 clinical trial in June 2019 and read out positive top-line biomarker data in adult Galactosemia patients in January of 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, expected to advance into a Phase 1 study in 2020, 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) our plan to move quickly towards regulatory filing following our pivotal Phase 2 ACTION-Galactosemia study, while preparing for Galactosemia commercial launch and growing our organization, (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, and (iv) 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 and (xvii) 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

	Year Ended December 31,	
	2019	**2018**
OPERATING EXPENSES:		
Research and development	$ 32,350	$ 11,471
General and administrative	13,232	2,047
Total operating expenses	45,582	13,518
LOSS FROM OPERATIONS	(45,582)	(13,518)
OTHER INCOME (EXPENSE), NET:		
Interest income (expense), net	93	(1,642)
Loss on extinguishment of debt	—	(221)
Other income (expense)	(24)	(1,140)
Total other income (expense), net	69	(3,003)
Net loss	$ (45,513)	$ (16,521)
Net loss attributable to common stockholders—basic and diluted	$ (45,513)	$ (16,521)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.55)	$ (3.01)
Weighted-average common stock outstanding—basic and diluted	12,831,221	5,483,149

	As of December 31, 2019	As of December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 18,850	$ 18,748
Prepaid expenses and other current assets	7,301	1,498
Investments	20,004	—
Total current assets	46,155	20,246
Operating lease right-of-use asset	2,035	—
Security deposits and leasehold improvements	199	—
TOTAL ASSETS	$ 48,389	$ 20,246
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	356	—
Accounts payable	8,793	3,015
Accrued expenses and other current liabilities	4,950	1,413
Total current liabilities	14,099	4,428
CURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	1,683	—
Total liabilities	15,782	4,428
Series A convertible preferred stock, $0.0001 par value; 0 shares and 3,093,898 shares authorized at December 31, 2019 and December 31, 2018, respectively; 0 shares and 3,093,898 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $7,000 at December 31, 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 December 31, 2019 and December 31, 2018, respectively; 0 shares and 4,001,848 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively; liquidation preference of $0 and $29,964 as of December 31, 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 December 31, 2019 and December 31, 2018, respectively; 18,531,560 shares and 5,513,531 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	1	—
Additional paid-in capital	99,378	1,665
Accumulated other comprehensive loss	(2)	—
Accumulated deficit	(66,770)	(21,257)
Total stockholders' equity (deficit)	32,607	(19,592)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'	$ 48,389	$ 20,246