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): **May 12, 2022**

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 May 12, 2022, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 May 12, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: May 12, 2022

By: */s/ Shoshana Shendelman*
Name: Shoshana Shendelman
Title: President and Chief Executive Officer

Exhibit 99.1

Applied Therapeutics Reports First Quarter 2022 Financial Results

Continued progress in three Phase 3 trials in areas of high unmet medical need, with multiple clinical milestones expected in 2022

NEW YORK, May 12, 2022 - 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 first quarter ended March 31, 2022.

"We made significant progress in the first quarter across all three of our Phase 3 programs" said Shoshana Shendelman, PhD, Founder and CEO of Applied Therapeutics. "We are pleased to have reached alignment with the FDA on Galactosemia, and are excited about the expected milestones in the year ahead."

Recent Highlights

- **Provided Regulatory Update on Galactosemia Program.** In January 2022, the Company announced that the FDA would require clinical outcomes data for approval. Clinical outcomes are assessed in the pediatric clinical study every 6 months by a firewalled committee until the study reaches statistical significance. The Company met with the FDA in April 2022, and the FDA confirmed that the pediatric study as it is currently designed would support an NDA submission if statistical significance is reached. The 6-month clinical outcomes were assessed by the firewalled data monitoring committee, and it was determined that the safety/benefit profile supports continuing the study. The next committee evaluation will be following completion of the 12-month clinical outcomes assessments.

- **Presented Data on AT-007 Treatment in SORD Deficiency at the 2022 Annual Meeting of the Peripheral Nerve Society.** In May 2022, the Company presented data highlighting the effect of AT-007 treatment on sorbitol levels. In a pilot study in patients with SORD Deficiency, sorbitol level correlated with disease severity, and AT-007 treatment substantially reduced sorbitol levels. In a Drosophila model of disease, elevated sorbitol resulted in neuronal damage and decline in mobility, and AT-007 treatment prevented the disease phenotype by inhibiting sorbitol production. Taken together, this data significantly advances the understanding of the disease and potential for treatment with AT-007.

- **Presented Data on Galactosemia Disease Progression at the 2022 43rd Annual Meeting of the Society for Inherited Metabolic Disorders.** In April 2022, the Company presented data featuring baseline disease characteristics of 47 pediatric patients with Classic Galactosemia, illustrating the high burden of disease associated with Galactosemia, including neurological complications, due to high galactitol levels. In addition, data presented at the meeting illustrated that higher galactitol levels, but not higher Gal-1p levels, were associated with greater disease severity overall and on each of the four quadrants of CNS function. Together, these data underscore the urgent need to bring a treatment to people living with Galactosemia.

- **Presented Data on Galactosemia Disease Progression at the 2022 Annual Clinical Genetics Meeting of the American College of Medical Genetics and Genomics.** In March 2022, the Company presented data featuring the first therapeutic interventional clinical trial in pediatric patients with Classic Galactosemia, demonstrating that AT-007 significantly reduces toxic galactitol in ACTION-Galactosemia children.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $55.7 million as of March 31, 2022, compared with $80.8 million at December 31, 2021.

- **Research and development expenses** for the three months ended March 31, 2022 were $15.0 million, compared to $14.4 million for the three months ended March 31, 2021. The increase of $0.6 million was primarily due to an increase in clinical and pre-clinical expense of $5.1 million, primarily related to the progression of the SORD pivotal trial, progression of the AT-007 ACTION-Galactosemia long-term extension adult study, and progression of the AT-007 ACTION-Galactosemia Kids pediatric registrational study; an increase in personnel expenses of $0.8 million due to the increase in headcount in support of our clinical program pipeline; an increase in regulatory and other expenses of $0.2 million; an increase in stock-based compensation of $0.1 million due to new stock option and restricted stock grants; and offset by a decrease in drug manufacturing and formulation costs of $5.6 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.

- **General and administrative expenses** were $8.1 million for the three months ended March 31, 2022, compared to $9.8 million for the three months ended March 31, 2021. The decrease of $1.7 million was due to a decrease in commercial expenses of $0.6 million related to a decrease in spend relating to commercial operations; a decrease in other expenses of $0.3 million relating to decreased costs of other office expenses; a decrease in stock-based compensation of $1.0 million relating to options being forfeited during the current period; a decrease in legal and professional fees of $0.2 million due to lower external legal fees; offset by an increase in personnel expenses of $0.2 million related to an increase in headcount; and an increase in insurance expenses of $0.1 million related to increased insurance costs.

- **Net loss** for the first quarter of 2022 was $23.1 million, or $0.88 per basic and diluted common share, compared to a net loss of $24.2 million, or $1.00 per basic and diluted common share, for the first quarter 2021.

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) our NDA submission for potential approval of AT-007, (ii) the timing of the completion of our the statistical analysis of clinical outcomes, (iii) the timing of expected milestones, (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. 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

Investors:
Maeve Conneighton
(212) 600-1902 or
appliedtherapeutics@argotpartners.com

Media:
media@appliedtherapeutics.com

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

	Three Months Ended March 31,	
	2022	**2021**
OPERATING EXPENSES:		
Research and development	$ 15,030	$ 14,448
General and administrative	8,071	9,751
Total operating expenses	23,101	24,199
LOSS FROM OPERATIONS	(23,101)	(24,199)
OTHER INCOME (EXPENSE), NET:		
Interest income (expense), net	76	76
Other income (expense)	(96)	(56)
Total other income (expense), net	(20)	20
Net loss	$ (23,121)	$ (24,179)
Net loss attributable to common stockholders—basic and diluted	$ (23,121)	$ (24,179)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.88)	$ (1.00)
Weighted-average common stock outstanding—basic and diluted	26,215,514	24,135,735

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

	As of March 31, 2022 (Unaudited)	As of December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 38,214	$ 53,888
Investments	17,437	26,935
Prepaid expenses and other current assets	7,913	7,571
Total current assets	63,564	88,394
Operating lease right-of-use asset	1,190	1,298
Security deposits and leasehold improvements	199	200
TOTAL ASSETS	$ 64,953	$ 89,892
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	$ 453	$ 442
Accounts payable	5,922	9,461
Accrued expenses and other current liabilities	15,842	16,559
Total current liabilities	22,217	26,462
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	773	891
Total noncurrent liabilities	773	891
Total liabilities	22,990	27,353
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 26,215,514 shares issued and outstanding as of March 31, 2022 and December 31, 2021	3	3
Preferred stock, par value $0.0001; 10,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 0 shares issued and outstanding as of March 31, 2022 and December 31, 2021	-	-
Additional paid-in capital	331,476	328,958
Accumulated other comprehensive loss	(80)	(107)
Accumulated deficit	(289,436)	(266,315)
Total stockholders' equity	41,963	62,539
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 64,953	$ 89,892