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 9, 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** (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))

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 9, 2022, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 9, 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: November 9, 2022

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

Exhibit 99.1

Applied Therapeutics Reports Third Quarter 2022 Financial Results

NEW YORK, November 9, 2022 - Applied Therapeutics, Inc. (NASDAQ: APLT) (the "Company"), 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, 2022.

"In the third quarter, we made significant progress across all three of our late-stage programs," said Shoshana Shendelman, PhD, Founder, CEO and Chair of the Board of Applied Therapeutics. "We remain focused on successful completion of our ongoing Phase 3 trials in Galactosemia, SORD Deficiency and Diabetic Cardiomyopathy, and look forward to sharing data in 2023, with the potential to bring new treatment options to these patients with limited to no available therapies."

Recent Highlights

- **Presented Data on AT-001 Treatment in Diabetic Cardiomyopathy at the 2022 American Heart Association Scientific Sessions.** In November 2022, the Company presented data in multiple sessions featuring mechanistic support for AT-001, a selective Aldose Reductase inhibitor, in a Diabetic Cardiomyopathy (DbCM) mouse model, demonstrating that AT-001 treatment prevents fibrosis and adverse cardiac remodeling, baseline data from the ongoing Phase 3 ARISE-HF study on quality of life impact of disease and correlation of cardiac functional capacity (peak VO2) with physical function and additional DbCM diagnosis and prevalence data.

- **Announced Full Enrollment in the Registrational Phase 3 ARISE-HF Trial of AT-001 in Diabetic Cardiomyopathy.** In October 2022, the Company announced full enrollment in the Phase 3 registrational ARISE-HF trial studying AT-001 in patients with DbCM. The primary endpoint is cardiac functional capacity (as measured by Peak VO2) at 15 months of treatment. The Company continues to expect topline data around year-end 2023 or early 2024, and if positive, the Company plans to submit for potential regulatory approval. Patients will continue in blinded format for an additional 12 months of treatment (up to 27 months total) to produce secondary endpoint data on progression to overt heart failure, hospitalization, morbidity and mortality, which is not anticipated to be required for regulatory approval, but will support long-term market access.

- **Reported Positive Data Trend in AT-007 ACTION-Galactosemia Kids Pediatric Trial.** In October 2022, the Company announced that the ACTION-Galactosemia Kids Phase 3 trial demonstrated a trend in clinical benefit favoring AT-007 vs. placebo. Review of the data at 12 months of treatment by the DMC indicated that while the study primary endpoint has not yet reached statistical significance, a trend exists favoring AT-007 vs. placebo. The clinical benefit at this early time point was most pronounced in patients with significant deficits in clinical performance at baseline. Safety data demonstrated that AT-007 continues to be safe and well tolerated. The study will continue to proceed in blinded format to the next review at 18 months of treatment. In the meantime, the Company will meet with the EMA to discuss potential submission of an MAA based on existing data for conditional approval.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $47.4 million as of September 30, 2022, compared with $80.8 million at December 31, 2021.

- **Research and development expenses** for the three months ended September 30, 2022 were $13.1 million, compared to $17.6 million for the three months ended September 30, 2021. The decrease of $4.5 million was primarily related to a decrease in drug manufacturing and formulation costs of $2.9 million related to the completion and release of AT-007 drug product batches and purchase of raw materials in the three months ended September 30, 2021; a decrease in clinical and pre-clinical expense of $1.7 million, primarily due to reduced clinical trial spend on the AT-007 ACTION-Galactosemia Kids pediatric registrational study and AT-007 ACTION-Galactosemia long-term extension adult study; and a decrease in regulatory and other expenses of $0.4 million. This was partially offset by an increase in personnel expenses of $48,000 due to the increase in headcount in support of our clinical program pipeline; and an increase in stock-based compensation of $0.5 million due to new stock option and restricted stock units grants and due to the incremental stock-based compensation expense recognized as a result of the stock option repricing.

- **General and administrative expenses** were $6.2 million for the three months ended September 30, 2022, compared to $10.8 million for the three months ended September 30, 2021. The decrease of $4.6 million was primarily due to a decrease in legal and professional fees of $0.2 million due to lower external legal fees; a decrease in commercial expenses of $2.8 million related to a decrease in spend for commercial operations; a decrease in personnel expenses of $0.5 million related to a decrease in headcount; a decrease in stock-based compensation of $0.3 million relating to options being forfeited during the current period; a decrease in insurance expenses of $0.3 million related to decreased insurance costs; and a decrease in other expenses of $0.5 million relating to decreased costs of other office expenses.

- **Net loss** for the third quarter of 2022 was $19.1 million, or $0.40 per basic and diluted common share, compared to a net loss of $28.4 million, or $1.09 per basic and diluted common share, for the third 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.

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 timing of topline data, which is expected around year-end 2023 or early 2024, (ii) the company's plans to submit for potential regulatory approval and (iii) the company's plans to meet with the EMA to discuss conditional approval. 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, market 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 and advance product candidates into, and successfully complete, clinical studies, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain and timing of regulatory approval of our current and future product candidates, (viii) the anticipated indications for our product candidates, if approved, (ix) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (x) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (xi) the implementation of our business model and strategic plans for our business and product candidates, (xii) our intellectual property position and the duration of our patent rights, (xiii) developments or disputes concerning our intellectual property or other proprietary rights, (xiv) our expectations regarding government and third-party payor coverage and reimbursement, (xv) our ability to compete in the markets we serve, (xvi) the impact of government laws and regulations and liabilities thereunder, (xvii) 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 (xiv) 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.
Condensed Balance Sheets
(in thousands, except share and per share data)

	As of September 30, 2022 (Unaudited)	As of December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 40,388	$ 53,888
Investments	6,990	26,935
Prepaid expenses and other current assets	8,132	7,571
Total current assets	55,510	88,394
Operating lease right-of-use asset	970	1,298
Security deposits and leasehold improvements	199	200
TOTAL ASSETS	$ 56,679	$ 89,892
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	$ 470	$ 442
Accounts payable	6,973	9,461
Accrued expenses and other current liabilities	14,332	16,559
Warrant liability	24,739	—
Total current liabilities	46,514	26,462
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	536	891
Total noncurrent liabilities	536	891
Total liabilities	47,050	27,353
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 48,058,956 shares issued and outstanding as of September 30, 2022 and 26,215,514 shares issued and outstanding as of December 31, 2021	5	3
Preferred stock, par value $0.0001; 10,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 0 shares issued and outstanding as of September 30, 2022 and December 31, 2021	-	-
Additional paid-in capital	343,995	328,958
Accumulated other comprehensive gain/(loss)	23	(107)
Accumulated deficit	(334,394)	(266,315)
Total stockholders' equity	9,629	62,539
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 56,679	$ 89,892

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
OPERATING EXPENSES:				
Research and development	$ 13,116	$ 17,597	$ 43,542	$ 46,846
General and administrative	6,240	10,833	20,436	31,658
Total operating expenses	19,356	28,430	63,978	78,504
LOSS FROM OPERATIONS	(19,356)	(28,430)	(63,978)	(78,504)
OTHER INCOME (EXPENSE), NET:				
Interest income	227	76	414	321
Change in fair value of warrant liabilities	36	—	(4,321)	—
Other expense	(8)	(64)	(194)	(242)
Total other income (expense), net	255	12	(4,101)	79
Net loss	$ (19,101)	$ (28,418)	$ (68,079)	$ (78,425)
Net loss attributable to common stockholders—basic and diluted	$ (19,101)	$ (28,418)	$ (68,079)	$ (78,425)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.40)	$ (1.09)	$ (2.02)	$ (3.08)
Weighted-average common stock outstanding—basic and diluted	48,000,183	26,177,079	33,785,386	25,472,590