

**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): **August 12, 2022**

APPLIED THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-38898
(Commission File Number)

81-3405262
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 August 12, 2022, Applied Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 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 August 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: August 12, 2022

By: /s/ Shoshana Shendelman

Name: Shoshana Shendelman

Title: President and Chief Executive Officer



Applied Therapeutics Reports Second Quarter 2022 Financial Results

Completed public equity offering with gross proceeds of \$30 million

Granted orphan medicinal product designation by the EMA for AT-007 for treatment of Galactosemia

Continued progress in three registrational Phase 3 trials in areas of high unmet medical need, with multiple clinical milestones expected in 2H 2022, including Galactosemia 12 month data analysis, SORD Deficiency biomarker data, and DbCM full enrollment

NEW YORK, August 12, 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 second quarter ended June 30, 2022.

“In the second quarter we continued our progress across our three registrational Phase 3 trials in Galactosemia, SORD Deficiency and Diabetic Cardiomyopathy,” said Shoshana Shendelman, PhD, Founder, CEO and Chair of the Board of Applied Therapeutics. “As we look towards the second half of this year, we are excited about the milestones ahead. We expect to complete our 12 month analysis in the pediatric Galactosemia study in September, and plan to announce full enrollment in both SORD Deficiency and DbCM soon. We expect these catalysts to bring us closer to our goal of delivering meaningful new treatments to patients in need.”

Recent Highlights

- **Completed underwritten public offering of equity.** In June 2022, the Company closed a public offering of its common stock and warrants with gross proceeds of \$30 million, before deducting the underwriting discounts and commissions and offering expenses payable by the Company.
- **Granted Orphan Medicinal Product Designation by the EMA for AT-007 for Galactosemia.** In June 2022, the European Medicines Agency (EMA) designated orphan medicinal product for AT-007 (gavorestat) for the treatment of Galactosemia. Applied Therapeutics plans to meet with the EMA to discuss a potential Marketing Authorization Application (MAA) submission in Europe for conditional approval based on available biomarker data or for full approval based on expected clinical outcomes data.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled \$67.7 million as of June 30, 2022, compared with \$80.8 million at December 31, 2021.
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- **Research and development expenses** for the three months ended June 30, 2022 were \$15.4 million, compared to \$14.8 million for the three months ended June 30, 2021. The \$0.6 million increase was due to an increase in clinical and pre-clinical expense of \$2.2 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 \$0.3 million due to the increase in headcount in support of our clinical program pipeline; an increase in stock-based compensation of \$0.3 million due to new stock option and restricted stock grants; offset by a decrease in drug manufacturing and formulation costs of \$2.2 million and a decrease in regulatory and other expenses of \$19,000.
- **General and administrative expenses** were \$6.1 million for the three months ended June 30, 2022, compared to \$11.1 million for the three months ended June 30, 2021. The decrease of \$4.9 million was due to a decrease in legal and professional fees of \$0.5 million due to lower external legal fees; a decrease in commercial expenses of \$2.5 million related to a decrease in spend for commercial operations; a decrease in personnel expenses of \$0.4 million related to a decrease in headcount; a decrease in stock-based compensation of \$0.7 million relating to options being forfeited during the current period as well as decrease in headcount; a decrease in insurance expenses of \$0.1 million related to decreased insurance costs; and a decrease in other expenses of \$0.7 million relating to decreased costs of other office expenses.
- **Net loss** for the second quarter of 2022 was \$25.9 million, or \$0.96 per basic and diluted common share, compared to a net loss of \$25.8 million, or \$0.99 per basic and diluted common share, for the second quarter 2021. The net loss for the second quarter of 2022 included \$4.4 million in a non-cash expense due to a mark-to-market adjustment on warrant liabilities issued as part of the June 2022 public offering.

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," including, but not limited to, 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. 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, 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 June 30, 2022 (Unaudited)	As of December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 55,728	\$ 53,888
Investments	11,994	26,935
Prepaid expenses and other current assets	9,176	7,571
Total current assets	76,898	88,394
Operating lease right-of-use asset	1,081	1,298
Security deposits and leasehold improvements	199	200
TOTAL ASSETS	\$ 78,178	\$ 89,892
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	\$ 462	\$ 442
Accounts payable	8,691	9,461
Accrued expenses and other current liabilities	17,787	16,559
Warrant liability	24,775	—
Total current liabilities	51,715	26,462
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	655	891
Total noncurrent liabilities	655	891
Total liabilities	52,370	27,353
STOCKHOLDERS' EQUITY:		
Common stock, \$0.0001 par value; 100,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 46,253,524 shares issued and outstanding as of June 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 June 30, 2022 and December 31, 2021; 0 shares issued and outstanding as of June 30, 2022 and December 31, 2021	-	-
Additional paid-in capital	341,090	328,958
Accumulated other comprehensive gain/(loss)	6	(107)
Accumulated deficit	(315,293)	(266,315)
Total stockholders' equity	25,808	62,539
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 78,178	\$ 89,892

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
OPERATING EXPENSES:				
Research and development	\$ 15,396	\$ 14,802	\$ 30,426	\$ 29,250
General and administrative	6,125	11,073	14,196	20,824
Total operating expenses	<u>21,521</u>	<u>25,875</u>	<u>44,622</u>	<u>50,074</u>
LOSS FROM OPERATIONS	<u>(21,521)</u>	<u>(25,875)</u>	<u>(44,622)</u>	<u>(50,074)</u>
OTHER INCOME (EXPENSE), NET:				
Interest income	111	169	187	245
Change in fair value of warrant liabilities	(4,357)	—	(4,357)	—
Other expense	(90)	(122)	(186)	(178)
Total other income (expense), net	<u>(4,336)</u>	<u>47</u>	<u>(4,356)</u>	<u>67</u>
Net loss	<u>\$ (25,857)</u>	<u>\$ (25,828)</u>	<u>\$ (48,978)</u>	<u>\$ (50,007)</u>
Net loss attributable to common stockholders—basic and diluted	<u>\$ (25,857)</u>	<u>\$ (25,828)</u>	<u>\$ (48,978)</u>	<u>\$ (50,007)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.96)</u>	<u>\$ (0.99)</u>	<u>\$ (1.84)</u>	<u>\$ (1.99)</u>
Weighted-average common stock outstanding—basic and diluted	<u>26,901,069</u>	<u>26,082,525</u>	<u>26,560,185</u>	<u>25,114,508</u>