# 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 10, 2023**

# 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**<br>**New York, NY 10017**<br>(Address of Principal Executive Offices) | **10017**<br>(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 August 10, 2023, Applied Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2023. 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 10, 2023. |
| 104 | Cover Page Interactive Data File - the cover page iXBRL tags are 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 10, 2023

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

**Exhibit 99.1**

**Applied Therapeutics Reports Second Quarter 2023 Financial Results**

*Regulatory progress for govorestat (AT-007) for the treatment of Classic Galactosemia, with potential NDA submission based on discussions with the FDA as well as EMA Marketing Authorization Application planned in Fall 2023*

*Phase 3 INSPIRE Trial of govorestat in Sorbitol Dehydrogenase (SORD) Deficiency and ARISE-HF Trial of AT-001 in Diabetic Cardiomyopathy on track for data readouts in 2H 2023*

**NEW YORK, August 10, 2023** - 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 second quarter ended June 30, 2023.

"In the second quarter we continued to advance our programs across Galactosemia, SORD Deficiency and Diabetic Cardiomyopathy," said Shoshana Shendelman, PhD, Founder, Chief Executive Officer, and Chair of the Board. "As we move into the second half of this year, our efforts will focus on regulatory progress in Galactosemia and SORD Deficiency, and on Phase 3 clinical readouts in SORD Deficiency and DbCM. We remain steadfast in our commitment to bring govorestat (AT-007) and caficrestat (AT-001) to patients with these devastating diseases in need of treatment."

**Recent Highlights**

- **Regulatory Progress on Govorestat (AT-007) for the Treatment of Classic Galactosemia.** The Company announced that the United States Food and Drug Administration (US FDA) granted a Pre-New Drug Application (Pre-NDA) meeting to be held this summer to discuss a potential NDA submission for govorestat (AT-007) for the treatment of Galactosemia. The Company believes that the clinical efficacy demonstrated to date, combined with galactitol biomarker data and a favorable safety profile, may support an NDA submission, and is seeking feedback from the FDA and alignment on the details of the submission. If the FDA is in agreement on the potential path forward to approval, the Company will plan to submit an NDA in the fall. The Company expects to provide a further update following the meeting. Regarding regulatory submission plans in Europe, Applied Therapeutics and its European commercial partner, Advanz Pharma, met with the European Medicines Agency (EMA) rapporteurs, and plan to proceed with an EMA Marketing Authorization Application (MAA) submission as expeditiously as possible. The EMA submission is anticipated in the fall in order to provide sufficient time for approval of the Pediatric Investigational Plan (PIP), as well as incorporation of rapporteur comments and suggestions from the meeting.

- **Presented Baseline Data from Ongoing Phase 3 ARISE-HF Study of AT-001 (caficrestat) in Diabetic Cardiomyopathy at the 2023 Annual Meeting of the American Diabetes Association (ADA).** In June 2023, the Company presented baseline data at the 2023 Annual Meeting of the ADA from the ongoing Phase 3 ARISE-HF study of AT-001 (caficrestat) in Diabetic Cardiomyopathy (DbCM). The data, presented in an oral symposium and two poster presentations, demonstrated a strong statistical correlation between elevations in the cardiac stress biomarker NT-proBNP, reduced cardiac functional capacity, and physical activity, underscoring the negative impact of DbCM on physical function and quality of life in patients. The ongoing ARISE-HF Phase 3 global clinical trial is evaluating the safety and efficacy of AT-001 (caficrestat) in improving or preventing worsening of cardiac functional capacity in Diabetic Cardiomyopathy (DbCM). The Company expects topline data from the study in the fourth quarter of 2023.

- **Presented Baseline Data, Clinical Trial Design, and 3-month Sorbitol Reduction Interim Analysis from Phase 3 INSPIRE Study of Govorestat (AT-007) in SORD Deficiency and new supporting preclinical data at 2023 Peripheral Nerve Society Annual Meeting.** Also in June 2023, the Company presented baseline data and 3-month sorbitol reduction interim data from the Phase 3 INSPIRE study of govorestat for the treatment of Sorbitol Dehydrogenase (SORD) Deficiency, as well as new preclinical data supporting the ongoing Phase 3 study, at the 2023 Annual Meeting of the Peripheral Nerve Society. The preclinical data, showcased in an oral presentation at the Annual Meeting of the Peripheral Nerve Society, demonstrated that sorbitol accumulation is a disease driver in patient-derived cells as well as in animal models, including a newly presented rat model. The oral presentations also included the trial design of the Phase 3 INSPIRE study.

- **Orphan Medicinal Product Designation Granted by EMA to Govorestat in SORD Deficiency.** In May 2023, the Company announced that the European Medicines Agency (EMA) granted Orphan Medicinal Product Designation to govorestat for the treatment of SORD Deficiency. Orphan Medicinal Product Designation provides certain benefits and incentives in the EU, including protocol assistance, fee reductions, and ten years of market exclusivity once the medicine is on the market.

- **New Preclinical Data Published in the Journal of Clinical Investigation Showing Reduction of Sorbitol in SORD-Deficient Patient-Derived Cells and Drosophila Disease Model Treated with Govorestat.** Also in May 2023, the Company announced that new data was published in the Journal of Clinical Investigation evaluating govorestat treatment in patient-derived fibroblasts, patient iPSC-derived motor neurons, and SORD-deficient drosophila. The data demonstrated that govorestat treatment significantly reduced sorbitol levels in the patient-derived cells and SORD-deficient drosophila, and also mitigated synaptic degeneration and significantly improved synaptic transduction, locomotor activity, and mitochondrial function in the SORD-deficient drosophila.

**Financial Results**

- **Cash and cash equivalents and short-term investments** totaled $35.6 million as of June 30, 2023, compared with $30.6 million at December 31, 2022.

- **Research and development expenses** for the three months ended June 30, 2023 were $11.9 million, compared to $15.4 million for the three months ended June 30, 2022. The decrease of approximately $3.5 million was primarily related to a decrease in clinical and pre-clinical expense of $3.7 million, primarily due to the decrease in expense related to CROs, offset by the progression of the SORD Phase 3 registrational study; an increase in drug manufacturing and formulation costs of $0.4 million primarily related to purchase of raw materials in the three months ended June 30, 2023; a decrease in personnel expenses of $0.2 million due to the decrease in headcount; a decrease in stock-based compensation of $36,000 due to decrease in headcount which resulted in options and restricted stock units being forfeited; and a decrease in regulatory and other expenses of $0.1 million.

- **General and administrative expenses** were $5.3 million for the three months ended June 30, 2023, compared to $6.1 million for the three months ended June 30, 2022. The decrease of approximately $0.8 million was primarily related to an increase in legal and professional fees of $0.2 million due to higher external legal fees; a decrease in commercial expenses of $13,000 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 $0.4 million relating to options being forfeited during the current period as well as decrease in headcount; a decrease in insurance expenses of $0.3 million related to decreased insurance costs; and a decrease in other expenses of $30,000 relating to decreased costs of other office expenses.

- **Net loss** for the second quarter of 2023 was $29.6 million, or $0.37 per basic and diluted common share, compared to a net loss of $25.9 million, or $0.96 per basic and diluted common share, for the second quarter 2022.

**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, govorestat, 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 the 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 plans to request a pre-NDA meeting or submit an NDA or MAA for approval and (ii) the anticipated cash runway of the Company. 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) our ability to achieve the anticipated benefits from the agreements entered into in connection with our partnership with Advanz Pharma 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 June 30, 2023 (Unaudited) | As of December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 35,616 | $ 16,657 |
| Investments | — | 13,923 |
| Prepaid expenses and other current assets | 7,205 | 6,728 |
| Total current assets | 42,821 | 37,308 |
| Operating lease right-of-use asset | 628 | 857 |
| Security deposits and leasehold improvements | 197 | 198 |
| TOTAL ASSETS | $ 43,646 | $ 38,363 |
| **LIABILITIES AND STOCKHOLDERS' (DEFICIT)/EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Current portion of operating lease liabilities | $ 486 | $ 477 |
| Accounts payable | 4,687 | 4,534 |
| Accrued expenses and other current liabilities | 16,023 | 14,756 |
| Warrant liability | 25,992 | 13,657 |
| Total current liabilities | 47,188 | 33,424 |
| NONCURRENT LIABILITIES: | | |
| Noncurrent portion of operating lease liabilities | 170 | 414 |
| Clinical holdback - long-term portion | 622 | 464 |
| Total noncurrent liabilities | 792 | 878 |
| Total liabilities | 47,980 | 34,302 |
| STOCKHOLDERS' (DEFICIT)/EQUITY: | | |
| Common stock, $0.0001 par value; 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 62,119,466 shares issued and outstanding as of June 30, 2023 and 48,063,358 shares issued and outstanding as of December 31, 2022 | 6 | 5 |
| Preferred stock, par value $0.0001; 10,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 0 shares issued and outstanding as of June 30, 2023 and December 31, 2022 | — | — |
| Additional paid-in capital | 384,197 | 352,828 |
| Accumulated other comprehensive gain/(loss) | — | 51 |
| Accumulated deficit | (388,537) | (348,823) |
| Total stockholders' (deficit)/equity | (4,334) | 4,061 |
| TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT)/EQUITY | $ 43,646 | $ 38,363 |

**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, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| REVENUE: | | | | |
| License Revenue | $ — | $ — | $ 10,660 | $ — |
| Total Revenue | — | — | 10,660 | — |
| OPERATING EXPENSES: | | | | |
| Research and development | $ 11,883 | $ 15,396 | $ 27,818 | $ 30,426 |
| General and administrative | 5,293 | 6,125 | 10,876 | 14,196 |
| Total operating expenses | 17,176 | 21,521 | 38,694 | 44,622 |
| LOSS FROM OPERATIONS | (17,176) | (21,521) | (28,034) | (44,622) |
| OTHER INCOME (EXPENSE), NET: | | | | |
| Interest income | 408 | 111 | 628 | 187 |
| Change in fair value of warrant liabilities | (12,804) | (4,357) | (12,335) | (4,357) |
| Other expense | (5) | (90) | 27 | (186) |
| Total other expense, net | (12,401) | (4,336) | (11,680) | (4,356) |
| Net loss | $ (29,577) | $ (25,857) | $ (39,714) | $ (48,978) |
| Net loss attributable to common stockholders—basic and diluted | $ (29,577) | $ (25,857) | $ (39,714) | $ (48,978) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (0.37) | $ (0.96) | $ (0.59) | $ (1.84) |
| Weighted-average common stock outstanding—basic and diluted | 79,041,695 | 26,901,069 | 67,762,501 | 26,560,185 |