# Applied Therapeutics Reports Third Quarter 2023 Financial Results

November 9, 2023

*Regulatory submissions on track for govorestat (AT-007) for the treatment of Classic Galactosemia to US FDA and EMA in 4Q 2023*

*Two Upcoming Phase 3 Trial Readouts, with ARISE-HF Trial of AT-001 (caficrestat) in Diabetic Cardiomyopathy on track for data readout in 4Q 2023 and INSPIRE Trial of AT-007 trial in Sorbitol Dehydrogenase (SORD) Deficiency in 1Q 2024*

NEW YORK, Nov. 09, 2023 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2023.

"We have continued to make progress across our late-stage pipeline and have several key regulatory and clinical inflection points expected later this quarter and in early 2024," said Shoshana Shendelman, PhD, Founder, Chief Executive Officer, and Chair of the Board. "We are working expeditiously to submit our regulatory filings for govorestat (AT-007) for the treatment of Classic Galactosemia in both the U.S. and in Europe and look forward to providing updates as those submissions occur. In tandem, we are soon approaching Phase 3 readouts for our ARISE-HF Trial of AT-001 (caficrestat) in Diabetic Cardiomyopathy (DbCM) and our INSPIRE Trial of AT-007 trial in Sorbitol Dehydrogenase (SORD) Deficiency, which are expected in 4Q23 and in 1Q24, respectively."

**Recent Highlights**

- **On Track to Submit NDA to the U.S. FDA and MAA to the EMA for Govorestat (AT-007) for the Treatment of Classic Galactosemia in the Fourth Quarter of 2023.** The Company is working to submit a New Drug Application (NDA) to the United States Food and Drug Administration (U.S. FDA) for govorestat for the treatment of Galactosemia. As previously announced, the Company held a successful pre-NDA meeting with the FDA regarding the govorestat Galactosemia program. Based on discussions with the FDA, the Company believes they are aligned with the FDA and plans to submit an NDA for govorestat (AT-007) for the treatment of Galactosemia in the fourth quarter of this year. Regarding regulatory submission plans in Europe, the Company and its European commercial partner, Advanz Pharma, expect to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) this quarter.
- **Hosted an Expert Forum on Diabetic Cardiomyopathy with Leading Cardiologists.** In November 2023, the Company hosted a KOL discussion on Diabetic Cardiomyopathy (DbCM) led by James Januzzi, MD, Hutter Family Professor of Medicine, Harvard Medical School, Director, Dennis and Marilyn Barry Fellowship in Cardiology Research, Massachusetts General Hospital Gregory Lewis, MD, Director, Cardiopulmonary Exercise Testing Laboratory and Section Head, Heart Failure, Massachusetts General Hospital. 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. A replay of the webcast event can be accessed here.
- **Presented Baseline Data from Ongoing Phase 3 ARISE-HF Study of AT-001 (caficrestat) in Diabetic Cardiomyopathy at the 2023 European Association for the Study of Diabetes Annual Meeting.** In September 2023, the Company presented baseline data at the 2023 European Association for the Study of Diabetes (EASD) Annual Meeting from the ongoing Phase 3 ARISE-HF study of AT-001 (caficrestat) in DbCM. Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics, presented the data in an oral Symposium entitled *Diabetic Cardiomyopathy (DbCM): a severe complication of diabetes*. The baseline data presented at EASD showed that patients with DbCM exhibit reduced cardiac functional capacity, resulting in decreased physical capacity, underscoring the negative impact of DbCM on physical function and quality of life in patients. The data supports the development of AT-001 for the treatment of DbCM and the ongoing ARISE-HF Phase 3 global clinical trial.

**Financial Results**

- **Cash and cash equivalents and short-term investments** totaled $37.5 million as of September 30, 2023, compared with $30.6 million at December 31, 2022.
- **Research and development expenses** for the three months ended September 30, 2023 were $10.8 million, compared to $13.1 million for the three months ended September 30, 2022. The decrease of approximately $2.3 million was primarily related to a decrease in clinical and pre-clinical expense of $1.8 million, primarily due to the decrease in expense related to CROs, a decrease in drug manufacturing and formulation costs of $0.5 million primarily due to the release of legacy accrual in the three months ended September 30, 2023; an increase in personnel expenses of $10,000; a decrease in stock-based compensation of $0.4 million due to decrease in headcount which resulted in options and restricted stock units

being forfeited; and an increase in regulatory and other expenses of $0.4 million.

- **General and administrative expenses** were $4.7 million for the three months ended September 30, 2023, compared to $6.2 million for the three months ended September 30, 2022. The decrease of approximately $1.5 million was primarily related to an increase in legal and professional fees of $0.7 million due to higher external legal fees; a decrease in commercial expenses of $0.8 million related to a decrease in spend for commercial operations and release of legacy accruals for the three months ended September 30, 2023; a decrease in personnel expenses of $0.4 million related to a decrease in headcount; a decrease in stock-based compensation of $0.6 million relating to options and restricted stock units being forfeited during the current period as well as decrease in headcount; a decrease in insurance expenses of $0.4 million related to decreased insurance costs; and a decrease in other expenses of $0.1 million.
- **Net loss** for the third quarter of 2023 was $42.4 million, or $0.47 per basic and diluted common share, compared to a net loss of $19.1 million, or $0.40 per basic and diluted common share, for the third 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) the timing of data readouts for our ARISE-HF and INSPIRE trials, (ii) the timing of our plans to submit an NDA and MAA for 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) 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.

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**Applied Therapeutics, Inc.**
**Condensed Balance Sheets**
**(in thousands, except share and per share data)**

| | As of September 30, 2023 | As of December 31, 2022 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 37,457 | $ 16,657 |
| Investments | — | 13,923 |
| Prepaid expenses and other current assets | 7,031 | 6,728 |
| Total current assets | 44,488 | 37,308 |
| Operating lease right-of-use asset | 510 | 857 |
| Security deposits and leasehold improvements | 197 | 198 |
| TOTAL ASSETS | $ 45,195 | $ 38,363 |
| **LIABILITIES AND STOCKHOLDERS' (DEFICIT)/EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Current portion of operating lease liabilities | $ 491 | $ 477 |
| Accounts payable | 6,005 | 4,534 |
| Accrued expenses and other current liabilities | 12,245 | 14,756 |
| Warrant liabilities | 36,763 | 13,657 |
| Total current liabilities | 55,504 | 33,424 |
| NONCURRENT LIABILITIES: | | |
| Noncurrent portion of operating lease liabilities | 44 | 414 |
| Clinical holdback - long-term portion | 691 | 464 |
| Total noncurrent liabilities | 735 | 878 |
| Total liabilities | 56,239 | 34,302 |
| STOCKHOLDERS' (DEFICIT)/EQUITY: | | |
| Common stock, $0.0001 par value; 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 77,133,516 shares issued and outstanding as of September 30, 2023 and 48,063,358 shares issued and outstanding as of December 31, 2022 | 7 | 5 |
| Preferred stock, par value $0.0001; 10,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022 | — | — |
| Additional paid-in capital | 419,856 | 352,828 |
| Accumulated other comprehensive gain | — | 51 |
| Accumulated deficit | (430,907) | (348,823) |
| Total stockholders' (deficit)/equity | (11,044) | 4,061 |
| TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT)/EQUITY | $ 45,195 | $ 38,363 |

**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, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| REVENUE: | | | | |
| License Revenue | $ — | $ — | $ 10,660 | $ — |
| Total Revenue | — | — | 10,660 | — |
| OPERATING EXPENSES: | | | | |
| Research and development | $ 10,785 | $ 13,116 | $ 38,602 | $ 43,542 |
| General and administrative | 4,710 | 6,240 | 15,585 | 20,436 |
| Total operating expenses | 15,495 | 19,356 | 54,187 | 63,978 |
| LOSS FROM OPERATIONS | (15,495) | (19,356) | (43,527) | (63,978) |
| OTHER INCOME (EXPENSE), NET: | | | | |
| Interest income | 392 | 227 | 1,020 | 414 |
| Change in fair value of warrant liabilities | (27,277) | 36 | (39,611) | (4,321) |
| Other income (expense): | 10 | (8) | 34 | (194) |
| Total other income (expense), net | (26,875) | 255 | (38,557) | (4,101) |
| Net loss | $ (42,370) | $ (19,101) | $ (82,084) | $ (68,079) |

| | | | | |
|---|---|---|---|---|
| Net loss attributable to common stockholders—basic and diluted | $ (42,370) | $ (19,101) | $ (82,084) | $ (68,079) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (0.47) | $ (0.40) | $ (1.09) | $ (2.02) |
| Weighted-average common stock outstanding—basic and diluted | 90,669,969 | 48,000,183 | 75,482,234 | 33,785,386 |