Applied Therapeutics Reports First Quarter 2023 Financial Results

May 11, 2023

Demonstrated Long-term Clinical Benefit of Govorestat in ACTION-Galactosemia Kids Trial

Strengthened Balance Sheet with $30 Million Private Placement of Equity

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 in 2023

NEW YORK, May 11, 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 first quarter ended March 31, 2023.

"We are committed to bringing transformative therapies to patients with debilitating diseases and no treatment options, including Galactosemia, SORD Deficiency and Diabetic Cardiomyopathy," said Shoshana Shendelman, PhD, Founder and CEO of Applied Therapeutics. "We look forward to discussing our recent Galactosemia data with regulatory agencies and potentially moving towards approval of govorestat for Galactosemia later this year. We are also excited about our upcoming data readouts in SORD Deficiency and Diabetic Cardiomyopathy. Our recent financing helps to strengthen the balance sheet to support advancement of our clinical programs towards commercialization."

Recent Highlights

- **Announced Long-term Clinical Benefit of Govorestat (AT-007) in the Phase 3 ACTION-Galactosemia Kids Trial.** In April 2023, the Company announced consistent long-term clinical benefit from the ACTION-Galactosemia Kids Phase 3 study of govorestat. Treatment with govorestat demonstrated consistent and sustained clinical benefit on activities of daily living, behavioral symptoms, cognition, adaptive behavior and tremor. Consistent with prior reported data, improvement in galactitol levels was sustained throughout the trial with no impact on Gal-1p or galactose, further establishing the causal role of galactitol in disease pathogenesis. The Company believes that there is compelling evidence of clinical efficacy and plans to request a pre-NDA meeting, with a potential NDA submission in the second half of 2023. The Company also plans to submit an MAA in mid-2023 for potential European approval.

- **Closed $30 Million Private Placement of Equity, Strengthening the Company's Balance Sheet.** In April 2023, the Company announced the sale of shares of the Company's common stock and pre-funded warrants to purchase common stock in a private placement led by Venrock, resulting in approximately $30 million of gross proceeds, before deducting placement agent commissions and other offering expenses, to the Company. The Company believes that the capital raised in the private placement, in addition to current cash and potential milestones expected from the Advanz European licensing partnership, is expected to fund the business through the middle of 2024.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $22.9 million as of March 31, 2023, compared with $30.6 million at December 31, 2022. The Company raised an additional $30 million of gross proceeds, before deducting placement agent commissions and other offering expenses, through a private placement in April 2023.

- **Research and development expenses** for the three months ended March 31, 2023 were $15.9 million, compared to $15.0 million for the three months ended March 31, 2022. The increase of approximately $0.9 million was primarily related to an increase in clinical and pre-clinical expense of $0.3 million, primarily due to the progression of the SORD Phase 3 registrational study; an increase in drug manufacturing and formulation costs of $1.0 million primarily related to purchase of raw materials in the three months ended March 31, 2023; a decrease in personnel expenses of $0.2 million due to the decrease in headcount; an increase in stock-based compensation of $6,000 due to new restricted stock grants; and a decrease in regulatory and other expenses of $0.2 million.

- **General and administrative expenses** were $5.6 million for the three months ended March 31, 2023, compared to $8.1 million for the three months ended March 31, 2022. The decrease of approximately $2.5 million was primarily related to a decrease in legal and professional fees of $0.1 million due to lower external legal fees; a decrease in commercial expenses of $1.1 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 $29,000 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 $0.3 million relating to decreased costs of other office expenses.

- **Net loss** for the first quarter of 2023 was $10.1 million, or $0.18 per basic and diluted common share, compared to a net loss of $23.1 million, or $0.88 per basic and diluted common share, for the first 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.

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

	As of March 31, 2023	As of December 31, 2022
ASSETS		

CURRENT ASSETS:		
Cash and cash equivalents	$ 22,917	$ 16,657
Investments	—	13,923
Prepaid expenses and other current assets	6,146	6,728
Total current assets	29,063	37,308
Operating lease right-of-use asset	743	857
Security deposits and leasehold improvements	198	198
TOTAL ASSETS	$ 30,004	$ 38,363
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	$ 483	$ 477
Accounts payable	5,555	4,534
Accrued expenses and other current liabilities	14,025	14,756
Warrant liability	13,188	13,657
Total current liabilities	33,251	33,424
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	291	414
Clinical holdback - long-term portion	534	464
Total noncurrent liabilities	825	878
Total liabilities	34,076	34,302
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 200,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 48,113,561 shares issued and outstanding as of March 31, 2023 and 48,063,358 shares issued and outstanding as of December 31, 2022	5	5
Preferred stock, par value $0.0001; 10,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Additional paid-in capital	354,883	352,828
Accumulated other comprehensive gain/(loss)	—	51
Accumulated deficit	(358,960)	(348,823)
Total stockholders' equity	(4,072)	4,061
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 30,004	$ 38,363

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

	Three Months Ended March 31,	
	2023	**2022**
REVENUE:		
License Revenue	$ 10,660	$ —
Total Revenue	10,660	—
OPERATING EXPENSES:		
Research and development	$ 15,935	$ 15,030
General and administrative	5,583	8,071
Total operating expenses	21,518	23,101
LOSS FROM OPERATIONS	(10,858)	(23,101)
OTHER INCOME (EXPENSE), NET:		
Interest income	221	76
Change in fair value of warrant liabilities	469	—
Other expense	31	(96)
Total other income, net	721	(20)
Net loss	$ (10,137)	$ (23,121)
Net loss attributable to common stockholders—basic and diluted	$ (10,137)	$ (23,121)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.18)	$ (0.88)
Weighted-average common stock outstanding—basic and diluted	56,357,983	26,215,514