Applied Therapeutics Reports Second Quarter 2020 Financial Results

August 11, 2020

NEW YORK, Aug. 11, 2020 (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 second quarter ended June 30, 2020.

"The second quarter was an exciting time for the Company, as we continued to advance our late stage programs towards regulatory submission and commercial launch," said Shoshana Shendelman, PhD, Founder, CEO and Chair of the Board of Applied Therapeutics. "As we move through the rest of the year, we remain focused on our commitment to bringing drugs to patients in urgent need of treatment across multiple diseases, which we believe will ultimately drive shareholder value."

Recent Highlights

- **Presented Data on AT-007 for Treatment of Galactosemia at the Galactosemia Foundation 2020 Virtual Conference.** In July 2020, we presented data and provided an overview of the AT-007 Galactosemia development program at the Galactosemia Foundation 2020 Virtual Conference, a unique platform that brings together patients and families with Galactosemia alongside researchers and physicians.
- **Announced Start of AT-007 Pediatric Galactosemia Study; Released Additional 40mg/kg Data from Adult Galactosemia Study.** June 2020, we announced additional supportive biomarker efficacy and safety data for AT-007 in Galactosemia at 40 mg/kg. The data announced showed once-daily 40 mg/kg AT-007 resulted in plasma galactitol reduction of 55% and a rapid, sustained and statistically significant reduction in galactitol vs. placebo. 40mg/kg was safe and well-tolerated with no drug-related adverse events reported, and no compensatory increase in galactose or other metabolites, such as Gal-1p. We also announced initiation of the AT-007 pediatric trial, ACTION-Galactosemia Kids, in children age 2 to 17.
- **Presented Data on AT-001 for the Treatment of Diabetic Cardiomyopathy at 2020 American Diabetes Association (ADA) Virtual Scientific Sessions.** In June 2020, we presented data at the ADA 80th Scientific Sessions. The presentations included comprehensive data on our aldose reductase inhibitor program and mechanistic data on the role of aldose reductase during hyperglycemia. The presentations included data on the structural basis and rational drug design behind our next generation aldose reductase inhibitors, as well as data elucidating the mechanisms by which AT-001 prevents cellular damage responsible for diabetic complications.
- **Appointed Dr. Chuck Silberstein, MD, MBA, CFA as Chief Financial Officer and Head of Business Development.** In May 2020, we announced the appointment of Dr. Silberstein, formerly Senior Vice President of Corporate Business Development at Allergan plc, as Chief Financial Officer and Head of Business Development. Along with broad corporate strategy and business development skills, Dr. Silberstein brings more than 20 years of investment and capital markets experience to Applied Therapeutics.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $138.5 million as of June 30, 2020 compared with $154.3 million at March 31, 2020.
- **Research and development expenses** for the three months ended June 30, 2020 were $20.8 million, compared to $4.3 million for the three months ended June 30, 2019. For the three months ended June 30, 2020, the increase of $16.5 million was primarily due to an increase in clinical and pre-clinical expense of $7.5 million, primarily related to the progression of the AT-007 ACTION-Galactosemia, and the AT-001 Phase 3 ARISE-HF clinical studies, as well as the commencement of the ACTION-Galactosemia Kids pediatric registrational study; an increase in drug manufacturing and formulation costs of $9.2 million primarily related to the timing of raw material deliveries in support of the 2020 manufacturing campaigns and the completion and release of AT-001 and AT-007 drug product batches; an increase in personnel expenses of $0.2 million due to the increase in headcount in support of our clinical program pipeline; and an increase in regulatory and other expenses of $0.4 million relating to an increase in license fees during the three months ended June 30, 2020. This was partially offset by a decrease in stock-based compensation of $0.8 million due to the increased modification expense recognized during the three months ended June 30, 2019 relating to the acceleration of certain options vesting following the IPO.
- **General and administrative expenses** General and administrative expenses were $7.5 million for the three months ended June 30, 2020, compared to $4.2 million for the three months ended June 30, 2019. For the three months ended June 30, 2020, the increase of $3.3 million was primarily related to the increase in personnel expenses of $1.3 million due to the

increase in headcount, $1.1 million related to an increase in legal and professional fees due to increased costs associated with being a public company, $0.8 million related to the establishment of a commercial department, $0.5 million related to increased insurance costs, and $0.3 million in other expenses relating to increased costs of rent and other office expenses. This was partially offset by the decrease of $0.7 million in stock-based compensation expense, due to the additional modification expense recognized in April 2019 for acceleration of certain options vesting following the IPO.

- **Net loss** for the second quarter of 2020 was $28.1 million, or $1.27 per basic and diluted common share, compared to a net loss of $ 8.4 million, or $ 0.60 per basic and diluted common share, for the second quarter 2019.

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 Galactosemia, a rare pediatric metabolic disease. The Company initiated a pivotal Phase 1/2 clinical trial in June 2019, read out positive top-line biomarker data in adult Galactosemia patients in January 2020 and announced full data from the trial in April 2020. A pediatric Galactosemia study commenced in June 2020 and is currently ongoing. The Company is also developing AT-001, a novel potent ARI that is being developed for the treatment of Diabetic Cardiomyopathy, or DbCM, a fatal fibrosis of the heart. The Company initiated a Phase 3 registrational study in DbCM in September 2019. 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, as well as novel dual PI3k inhibitors in preclinical development for orphan oncology indications.

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) our plans to submit an NDA for potential approval of AT-007 around year-end 2020, which will also include data from the ACTION-Galactosemia Kids trial and the 90-day safety data in adults with Galactosemia, (ii) the design, scope and results of our clinical trials, (iii) the timing of the initiation and completion of our clinical trials, (iv) the likelihood that data from our clinical trials will support future development of our product candidates, and (v) the likelihood of obtaining regulatory approval of our product candidates and qualifying for any special designations, such as orphan drug designation. 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 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, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain regulatory approval of our current and future product candidates, (viii) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (ix) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (x) the implementation of our business model and strategic plans for our business and product candidates, (xi) our intellectual property position and the duration of our patent rights, (xii) developments or disputes concerning our intellectual property or other proprietary rights, (xiii) our expectations regarding government and third-party payor coverage and reimbursement, (xiv) our ability to compete in the markets we serve, (xv) the impact of government laws and regulations and liabilities thereunder, (xvi) 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 (xviii) 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.
Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,	Six Months Ended June 30,

	2020	2019	2020	2019
OPERATING EXPENSES:				
Research and development	$ 20,758	$ 4,254	$ 28,028	$ 11,128
General and administrative	7,522	4,183	12,725	6,037
Total operating expenses	28,280	8,437	40,753	17,165
LOSS FROM OPERATIONS	(28,280)	(8,437)	(40,753)	(17,165)
OTHER INCOME (EXPENSE), NET:				
Interest income (expense), net	183	—	304	(1)
Other income (expense)	38	—	21	—
Total other income (expense), net	221	—	325	(1)
Net loss	$ (28,059)	$ (8,437)	$ (40,428)	$ (17,166)
Net loss attributable to common stockholders—basic and diluted	$ (28,059)	$ (8,437)	$ (40,428)	$ (17,166)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.27)	$ (0.60)	$ (1.88)	$ (1.76)
Weighted-average common stock outstanding—basic and diluted	22,062,030	13,945,939	21,451,344	9,776,582

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

	As of June 30, 2020 (Unaudited)	As of December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 100,854	$ 18,850
Investments	37,644	20,004
Prepaid expenses and other current assets	10,026	7,301
Total current assets	148,524	46,155
Operating lease right-of-use asset	1,849	2,035
Security deposits and leasehold improvements	199	199
TOTAL ASSETS	$ 150,572	$ 48,389
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	372	356
Accounts payable	5,649	8,793
Accrued expenses and other current liabilities	12,855	4,950
Total current liabilities	18,876	14,099
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	1,492	1,683
Total noncurrent liabilities	1,492	1,683
Total liabilities	20,368	15,782
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 and 100,000,000 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 22,331,142 shares and 18,531,560 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	237,429	99,378
Accumulated other comprehensive loss	(29)	(2)
Accumulated deficit	(107,198)	(66,770)

Total stockholders' equity	130,204	32,607
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 150,572	$ 48,389

Source: Applied Therapeutics