Applied Therapeutics Reports First Quarter 2020 Financial Results

May 11, 2020

NEW YORK, May 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 first quarter ended March 31, 2020.

“The first quarter was a period of tremendous growth and advancement across our clinical programs,” said Shoshana Shendelman, PhD, Founder, CEO and Chair of the Board of Applied Therapeutics. “We also began building out our commercial infrastructure in preparation for future launches, including Galactosemia. The company remains well capitalized as a result of the financing in January, and we look forward to continuing our momentum throughout the rest of this year - launching our pediatric study in Galactosemia, continuing enrollment on the DbCM ARISE-HF study, and advancing additional new programs forward into the clinic.”

Recent Highlights

- **Announced Full Data and Scientific Presentations from the Pivotal Phase 2 ACTION-Galactosemia Trial.** In April 2020, we announced new data and scientific presentations from the pivotal Phase 2 ACTION-Galactosemia trial. The topline data from the trial was originally announced in early January. The full study data, originally planned to be presented at the Society for Inherited Metabolic Disorders conference, showed that once-daily 20mg/kg AT-007 rapidly and sustainably reduced toxic galactitol levels with no accompanying increase in galactose. Additionally, positive trends on MRI outcomes were shown, including indirect measures of edema, neuronal health and brain galactitol levels in AT-007-treated patients. As no drug-related adverse events were seen at the once-daily 20mg/kg dose, a once-daily 40mg/kg dose was subsequently studied in healthy volunteers, and was also shown to be safe and well-tolerated. Evaluation of the 40 mg/kg dose in Galactosemia patients remains ongoing.
- **Announced IND and Investigator-Initiated Studies of AT-001 in Critical COVID-19 Patients.** In April 2020, we announced that a COVID-19 IND has been opened with the FDA for AT-001, a novel potent Aldose Reductase inhibitor. Multiple AT-001 investigator-initiated trials are currently underway to address acute lung inflammation and cardiomyopathy in critical COVID-19 patients. Several New York City hospitals have initiated Emergency Investigational Drug applications for AT-001 use in critical COVID-19 patients. Additional data is being gathered through studies on the effect of AT-001 therapy in critical COVID-19 patients.
- **Appointed Adam Hansard as Chief Commercial Officer.** In March 2020, we announced the appointment of Adam Hansard as Chief Commercial Officer. Mr. Hansard brings extensive commercial and leadership experience across the biotech and pharmaceutical industry to Applied Therapeutics.
- **Closed $143.4 Million Underwritten Public Offering.** In January 2020, we completed an underwritten public offering of common stock at a price to the public of $45.50 per share, resulting in gross proceeds of approximately $143.4 million, before deducting underwriting discounts and commissions and offering expenses.

Financial Results

- **Cash and cash equivalents and short-term investments** totaled $154.3 million as of March 31, 2020, compared with $38.9 million at December 31, 2019.
- **Research and development expenses** for the three months ended March 31, 2020 were $7.3 million, compared to $6.9 million for the three months ended March 31, 2019. The increase of approximately $0.4 million was primarily related to the increase in clinical and pre-clinical expenses of $0.8 million for the advancement of clinical trials, increase in personnel-related costs of $0.2 million and $0.5 million increase in stock-based compensation expense due to an increase in headcount, which were offset by the decrease in drug manufacturing and formulation expenses of $1.0 million and decrease in regulatory and other expenses of $0.1 million.
- **General and administrative expenses** were $5.2 million for the three months ended March 31, 2020, compared to $1.9 million for the three months ended March 31, 2019. The increase of approximately $3.3 million was primarily related to the increase in personnel expenses and stock-based compensation of $0.4 million and $0.5 million, respectively, due to the increase in headcount, including the hiring of the chief financial officer and chief accounting officer, $1.3 million related to an increase in legal and professional fees due to increased costs associated with being a public company, and $1.2 million in other expenses relating to increased costs of insurance, rent, and other office expenses.
- **Net loss** for the first quarter of 2020 was $12.4 million, or $0.59 per basic and diluted common share, compared to a net loss of $8.7 million, or $1.58 per basic and diluted common share, for the first 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 Phase 1/2 clinical trial in June 2019 and read out positive top-line biomarker data in adult Galactosemia patients in January of 2020. 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, expected to advance into a Phase 1 study in 2020, 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 plan to move quickly towards regulatory filing following our pivotal Phase 2 ACTION-Galactosemia study, while preparing for Galactosemia commercial launch and growing our organization, (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.

Contacts

Investors:
Maeve Conneighton
(212) 600-1902 or
appliedtherapeutics@argotpartners.com

Media:
Gleb Sagitov
media@appliedtherapeutics.com

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

	Three Months Ended March 31,	
	2020	**2019**
OPERATING EXPENSES:		
Research and development	$ 7,271	$ 6,874
General and administrative	5,196	1,855
Total operating expenses	12,467	8,729
LOSS FROM OPERATIONS	(12,467)	(8,729)

OTHER INCOME (EXPENSE), NET:		
Interest income (expense), net	122	(1)
Other income (expense)	(24)	—
Total other income (expense), net	98	(1)
Net loss	$ (12,369)	$ (8,730)
Net loss attributable to common stockholders—basic and diluted	$ (12,369)	$ (8,730)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.59)	$ (1.58)
Weighted-average common stock outstanding—basic and diluted	20,840,658	5,513,531

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

	As of March 31, 2020 (Unaudited)	As of December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 92,503	$ 18,850
Prepaid expenses and other current assets	9,432	7,301
Investments	61,806	20,004
Total current assets	163,741	46,155
Operating lease right-of-use asset	1,942	2,035
Security deposits and leasehold improvements	199	199
TOTAL ASSETS	$ 165,882	$ 48,389
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	364	356
Accounts payable	1,606	8,793
Accrued expenses and other current liabilities	6,496	4,950
Total current liabilities	8,466	14,099
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	1,588	1,683
Total noncurrent liabilities	1,588	1,683
Total liabilities	10,054	15,782
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 and 100,000,000 shares authorized as of March 31, 2020 and December 31, 2019, respectively; 21,969,277 shares and 18,531,560 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	234,876	99,378
Accumulated other comprehensive loss	89	(2)
Accumulated deficit	(79,139)	(66,770)
Total stockholders' equity	155,828	32,607
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 165,882	$ 48,389

Source: Applied Therapeutics