

aTyr Pharma Announces Second Quarter 2018 Operating Results and Provides Corporate Update

August 14, 2018

Conference Call Today at 5:00 p.m. ET / 2:00 p.m. PT

SAN DIEGO, Aug. 14, 2018 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel immunological pathways, today announced operating results for the second quarter ended June 30, 2018.

"We have made important advancements in the development of our lead product candidate, ATYR1923, during the recent months," said Sanjay Shukla, M.D., M.S., President and CEO of aTyr. "We have completed our Phase 1 clinical trial for ATYR1923 and are poised to initiate a clinical trial by the end of this year in patients with interstitial lung disease. Our research activities have substantially increased our translational knowledge and furthered our understanding of neuropilin-2 as a target to accelerate the clinical development of ATYR1923."

Clinical Highlights & Upcoming Milestones

- In June 2018, aTyr announced results of its Phase 1, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, immunogenicity and pharmacokinetics (PK) of intravenous ATYR1923 in 36 healthy volunteers.
 - ATYR1923 was generally well-tolerated with no significant adverse events and its PK profile supports the potential for a once-monthly dosing regimen.
- In the fourth quarter of 2018, aTyr plans to initiate a Phase 1b/2a multiple-ascending dose, placebo-controlled, firstin-patient study with ATYR1923 for the treatment of patients with immune-mediated interstitial lung disease.
 - The study will be designed to evaluate safety, tolerability, and immunogenicity of multiple doses of ATYR1923 and to evaluate several established functional pulmonary endpoints, imaging endpoints, patient reported outcome measures and potential biomarkers.

Research Highlights

- In May 2018, aTyr presented a mechanistic update on the Resokine pathway at the American Academy of Immunology Annual Meeting in Austin, TX.
 - Identification of a T cell Immunomodulatory Domain in HistidyI-tRNA Synthetase.
- In May 2018, aTyr presented preclinical data in a lung injury model demonstrating that ATYR1923 improves lung function and reduces inflammation in rats after bleomycin induced lung injury at the 2018 American Thoracic Society Annual Meeting in San Diego, CA.
 - Preclinical Characterization of ATYR1923 (iMod.Fc), an Immune-Modulatory Therapeutic with Potentially Broad Application in Interstitial Lung Diseases.
- In July 2018, aTyr presented positive lung and skin findings with ATYR1923 in a translational animal model at the Scleroderma Foundation National Patient Education Conference in Philadelphia, PA.
 - ATYR1923 Ameliorates Dermal and Pulmonary Fibrosis in a Murine Model of Sclerodermatous Chronic Graft vs. Host Disease.
- In July 2018, the publication titled "*Bi-allelic Mutations in the Phe-tRNA Synthetase Associated with Multi-system Pulmonary Disease Supports Non-Translation Functior*" was published in the American Journal of Human Genetics.
 - This was a collaborative effort between aTyr, The Scripps Research Institute, Hong Kong University of Science and Technology, Pangu Biopharma and Columbia University among others.
- In August 2018, the publication titled "Tyrosyl-tRNA Synthetase Stimulates Thrombopoietin-Independent Hematopoiesis Accelerating Recovery from Thrombocytopenia" was published in the Proceedings of the National Academy of Sciences.
 - This research was supported in part by aTyr in collaboration with The Scripps Research Institute and Kyoto University among others.

• In July 2018, aTyr appointed Jill Broadfoot as Chief Financial Officer.

Second Quarter 2018 Financial Results and Cash Position

Research and development expenses were \$6.5 million and \$8.4 million for the three months ended June 30, 2018 and 2017, respectively. The decrease of \$1.9 million was due primarily to a \$1.7 million decrease related to lower product manufacturing costs and a \$1.0 million decrease related to the completion of clinical studies related to our initial product candidate, ATYR1940, partially offset by a \$0.3 million increase related to ATYR1923 clinical studies. Research and development expenses for the three months ended June 30, 2018 included \$0.6 million of employee severance and other termination benefits and \$0.3 million of non-cash stock-based compensation related to the restructuring plan announced in May 2018 (the "Restructuring Plan").

General and administrative expenses were \$3.5 million for both the three months ended June 30, 2018 and 2017. General and administrative expenses for the three months ended June 30, 2018 included \$0.3 million of employee severance and other termination benefits and \$0.1 million of non-cash stock-based compensation related to the Restructuring Plan.

Year-to-Date 2018 Financial Results

Research and development expenses were \$12.6 million and \$17.6 million for the six months ended June 30, 2018 and 2017, respectively. The decrease of \$5.0 million was due primarily to a \$2.9 million decrease related to the completion of clinical studies related to ATYR1940 and a \$2.3 million decrease related to lower product manufacturing costs, partially offset by a \$0.7 million increase related to ATYR1923 clinical studies. Research and development expenses for the six months ended June 30, 2018 included \$0.6 million of employee severance and other termination benefits and \$0.3 million of non-cash stock-based compensation related to the Restructuring Plan.

General and administrative expenses were \$7.5 million for both the six months ended June 30, 2018 and 2017. General and administrative expenses for the six months ended June 30, 2018 included \$0.3 million of employee severance and other termination benefits and \$0.1 million of non-cash stock-based compensation related to the Restructuring Plan.

As of June 30, 2018, aTyr had \$64.3 million in cash, cash equivalents and investments and 41.3 million shares of common stock outstanding on an if-converted basis (includes 29.9 million shares of common stock and 11.4 million shares of common stock if converted from Class X Preferred stock).

Conference Call and Webcast Details

aTyr Pharma will host a conference call and webcast today at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time to discuss the results and the recent announcements. Interested parties may access the call by dialing toll-free (844) 358-9116 from the US, or (209) 905-5951 internationally and using conference ID 4039179. Links to a live audio webcast and replay may be accessed on the aTyr website events page at: http://investors.atyrpharma.com/events-and-webcasts. An audio replay will be available for at least 90 days following the event.

About ATYR1923

aTyr scientists successfully engineered the first fusion protein with a Resokine protein, ATYR1923, designed to enhance the immuno-modulatory properties *in vivo*. aTyr is developing ATYR1923 as a potential therapeutic for patients with immune-mediated interstitial lung diseases. aTyr announced data from a first-in-human Phase 1 clinical trial of ATYR1923 in June 2018. This randomized, double-blind, placebo-controlled study investigated the safety, tolerability, immunogenicity, and pharmacokinetics (PK) of intravenous ATYR1923 in 36 healthy volunteers. The results indicate that the drug was generally well-tolerated at all dose levels tested, with no significant adverse events and the observed PK profile supports the potential for a once-monthly dosing regimen. aTyr expects to initiate a multi-ascending dose, placebo-controlled Phase 1b/2a study in patients with interstitial lung disease in the fourth quarter of 2018.

About the Resokine Pathway

The Resokine pathway is comprised of extracellular proteins derived from the histidyl tRNA synthetase (HARS) gene family. The gene for HARS gives rise to a number of splice variants, many of which have lost their catalytic activity, but which retain the N-terminal domain of 59 amino acids. This domain was appended to HARS during evolution of multicellular organisms and is not essential for protein synthetic activity but is retained with high homology across mammalian species. Proteins derived from the HARS gene, both full-length and splice variants, are present in human circulation and appear to play a role in modulating immune responses. We refer to the extracellular HARS proteins as Resokine, to differentiate them from the intracellular enzyme involved in protein synthesis.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel immunological pathways. aTyr's research and development efforts are concentrated on a newly discovered area of biology, the extracellular functionality of tRNA synthetases. aTyr has built a global intellectual property estate directed to a potential pipeline of protein compositions derived from 20 tRNA synthetase genes. aTyr is focused on the therapeutic translation of the Resokine pathway, comprised of extracellular proteins derived from the histidyl tRNA synthetase gene family. ATYR1923 is a clinical-stage product candidate, based on the Resokine pathway, which binds to the neuropilin-2 receptor and is designed to down-regulate immune engagement in interstitial lung diseases and other immune-mediated diseases. For more information, please visit http://www.atyrpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Litigation Reform Act. Forward-looking statements are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by such safe harbor provisions for forward-looking statements and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements regarding the potential therapeutic benefits and applications of our product candidates; our ability to successfully advance our pipeline or product candidates, undertake certain development activities (such as the initiation of clinical trials, clinical trial enrollment, the conduct of clinical trials and the announcement of top-line results) and accomplish certain development goals, and the timing of such events; the

anticipated benefits and cost-savings relating to the corporate restructuring; and the scope and strength of our intellectual property portfolio. These forward-looking statements also reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects, as reflected in or suggested by these forward-looking statements, are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in these forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks associated with the discovery, development and regulation of our product candidates, the risk that we may cease or delay preclinical or clinical development activities for any of our existing or future product candidates for a variety of reasons (including difficulties or delays in patient enrollment in planned clinical trials), and the risk that we may not be able to raise the additional funding required for our business and product development plans, as well as those risks set forth in our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and in our other SEC filings. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

ATYR PHARMA INC.

Condensed Consolidated Statements of Operations

(unaudited, in thousands, except share and per share data)

	Three Month	ns Ended	Six Months	Ended
	June 30,		June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 6,484	\$ 8,420	\$ 12,634	\$ 17,624
General and administrative	3,476	3,487	7,546	7,494
Total operating expenses	9,960	11,907	20,180	25,118
Loss from operations	(9,960) (11,907) (20,180) (25,118)
Total other expense, net	(452) (231) (899) (425)
Net loss	\$ (10,412) \$ (12,138) \$ (21,079) \$ (25,543)
Net loss per share attributable to common stock holders, basic and diluted	\$ (0.35) \$ (0.51) \$ (0.71) \$(1.07)
Weighted average common stock shares outstanding, basic and diluted	29,842,721	23,810,112	2 29,819,224	23,774,736

ATYR PHARMA INC.

Condensed Consolidated Balance Sheets

(in thousands)

	June 30, 2018 (unaudited)		December 31, 2017	
Cash, cash equivalents and available-for-sale investments	•	64,329	\$	85,119
Other assets		1,758		1,956
Property and equipment, net		2,221		2,280
Total assets	\$	68,308	\$	89,355
Accounts payable and accrued expenses	\$	3,367	\$	5,379
Current portion of long-term loans, net of debt issuance costs and discount		7,717		5,012
Term loans, net of current portion and debt issuance costs and discount		11,848		14,719
Stockholders' equity		45,376		64,245
Total liabilities and stockholders' equity	\$	68,308	\$	89,355

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Primary Logo

Source: aTyr Pharma, Inc.