



aTyr Pharma Announces Second Quarter 2024 Results and Provides Corporate Update

August 13, 2024

Phase 3 EFZO-FIT™ study of efzofitimod in pulmonary sarcoidosis enrollment completed with 268 patients; topline data from this 52-week study expected in the third quarter of 2025.

Ended the second quarter 2024 with \$81.4 million in cash, cash equivalents, restricted cash and investments.

SAN DIEGO, Aug. 13, 2024 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: ATYR) ("aTyr" or the "Company"), a clinical stage biotechnology company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced second quarter 2024 results and provided a corporate update.

"The second quarter of 2024 was a milestone quarter for aTyr, as we completed enrollment in our global pivotal Phase 3 EFZO-FIT™ study of efzofitimod in patients with pulmonary sarcoidosis, a major form of interstitial lung disease (ILD)," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "This landmark study is the largest interventional study ever to be conducted in sarcoidosis and presents an opportunity to deliver a potentially transformative therapy to sarcoidosis patients who have been waiting more than 60 years for a new drug to be approved for this disease. We look forward to releasing topline data from this study in the third quarter of 2025."

Second Quarter 2024 and Subsequent Period Highlights

- **Completed enrollment in the global pivotal Phase 3 EFZO-FIT™ study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis.** This is a randomized, double-blind, placebo-controlled, 52-week study consisting of three parallel cohorts randomized equally to either 3.0 mg/kg or 5.0 mg/kg of efzofitimod or placebo dosed intravenously monthly for a total of 12 doses. The study enrolled 268 patients with pulmonary sarcoidosis at 85 centers in 9 countries, exceeding the targeted enrollment. Topline data from the study are expected in the third quarter of 2025. Patients who complete the study and wish to receive treatment with efzofitimod outside of the clinical trial are eligible to participate in an Individual Patient Expanded Access Program (EAP).
- **Continued enrollment in the Phase 2 EFZO-CONNECT™ study to evaluate the efficacy, safety and tolerability of efzofitimod in patients with systemic sclerosis (SSc, or scleroderma)-related ILD (SSc-ILD).** This proof-of-concept study is a randomized, double-blind, placebo-controlled, 28-week study consisting of three parallel cohorts randomized 2:2:1 to either 270 mg or 450 mg of efzofitimod or placebo dosed intravenously monthly for a total of 6 doses. The study intends to enroll up to 25 patients with SSc-ILD and is open for enrollment at multiple centers in the U.S. Patients who complete the study and wish to receive ongoing treatment with efzofitimod are eligible to participate in a 24-week open-label extension (OLE), which was recently incorporated into the study protocol. Based on current enrollment projections, the Company expects to report interim data from the study in the second quarter of 2025.
- **Presented a poster describing efzofitimod's mechanism of action at the American Thoracic Society (ATS) 2024 International Conference.** The findings further demonstrated that neuropilin-2 (NRP2), efzofitimod's binding partner, is an important new immune target in ILD and that efzofitimod modulates myeloid cells to confer its anti-inflammatory benefit.
- **Entered into a research agreement with Stanford Medicine to explore the role of the Company's anti-NRP2 antibodies in glioblastoma multiforme (GBM).** Michael Lim, M.D., Chair of the Department of Neurosurgery at Stanford Medicine, will serve as the principal investigator for the study, which aims to explore the role anti-NRP2 antibodies in combination with chemotherapy to evaluate their role in reversing immune evasion in GBM, the most common type of primary brain cancer.
- **Appointed Jayant Aphale, Ph.D., as Vice President, Technical Operations.** Dr. Aphale has more than 30 years of experience working in technical operations and manufacturing for novel therapeutic and vaccine products at biotechnology and pharmaceutical companies. Dr. Aphale will serve as a member of the Company's executive leadership team, overseeing manufacturing activities at contract development and manufacturing organizations and implementing strategies related to the continuous improvement of commercial manufacturing, supply chain management, process development of new products and product life cycle management.

Second Quarter 2024 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, cash equivalents, restricted cash and investments as of June 30, 2024, were \$81.4 million.
- **R&D Expenses:** Research and development expenses were \$14.0 million for the second quarter 2024, which consisted primarily of clinical trial costs for the Phase 3 EFZO-FIT™ and Phase 2 EFZO-CONNECT™ studies, manufacturing costs for the efzofitimod program and research and development costs for the efzofitimod and discovery programs.
- **G&A Expenses:** General and administrative expenses were \$3.3 million for the second quarter 2024.

About Efzofitmod

Efzofitmod is a first-in-class biologic immunomodulator in clinical development for the treatment of interstitial lung disease (ILD), a group of immune-mediated disorders that can cause inflammation and fibrosis, or scarring, of the lungs. Efzofitmod is a tRNA synthetase derived therapy that selectively modulates activated myeloid cells through neuropilin-2 to resolve inflammation without immune suppression and potentially prevent the progression of fibrosis. aTyr is currently investigating efzofitmod in the global Phase 3 EFZO-FIT™ study in patients with pulmonary sarcoidosis, a major form of ILD, and in the Phase 2 EFZO-CONNECT™ study in patients with systemic sclerosis (SSc, or scleroderma)-related ILD. These forms of ILD have limited therapeutic options and there is a need for safer and more effective, disease-modifying treatments that improve outcomes.

About aTyr

aTyr is a clinical stage biotechnology company leveraging evolutionary intelligence to translate tRNA synthetase biology into new therapies for fibrosis and inflammation. tRNA synthetases are ancient, essential proteins that have evolved novel domains that regulate diverse pathways extracellularly in humans. aTyr's discovery platform is focused on unlocking hidden therapeutic intervention points by uncovering signaling pathways driven by its proprietary library of domains derived from all 20 tRNA synthetases. aTyr's lead therapeutic candidate is efzofitmod, a first-in-class biologic immunomodulator in clinical development for the treatment of interstitial lung disease, a group of immune-mediated disorders that can cause inflammation and progressive fibrosis, or scarring, of the lungs. For more information, please visit www.atyrpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are usually identified by the use of words such as “aims” “anticipates,” “believes,” “designed,” “expects,” “intends,” “may,” “plans,” “potential,” “project,” “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 include, among others, statements regarding the expected size of, and number and nationality of patients to be enrolled in, the EFZO-FIT™ and EFZO-CONNECT™ studies; the design and benefits of our EAP for efzofitmod for patients with pulmonary sarcoidosis; the potential therapeutic benefits and applications of efzofitmod; the results and ultimate trajectory of our research agreement with Stanford Medicine; and timelines and plans with respect to certain development activities and development goals, including our expectation that our Phase 3 EFZO-FIT™ study of efzofitmod in patients with pulmonary sarcoidosis will report topline results in the third quarter of 2025 and expectation that our Phase 2 EFZO-CONNECT™ study will report interim data in the second quarter of 2025. 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, strategies or prospects will be attained or achieved. All forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. 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 related to our reliance on third-party partners and the potential that such partners may not perform as anticipated, the fact that NRP2 and tRNA synthetase biology is not fully understood, uncertainty regarding the ultimate long-term impact of evolving macroeconomic and geopolitical conditions, the risk of delays in our clinical trials, risks associated with the discovery, development and regulation of our product candidates, including the risk that results from clinical trials or other studies may not support further development, 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, the fact that our collaboration agreements are subject to early termination, 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.

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ATYR PHARMA INC. Condensed Consolidated Statements of Operations (in thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,	June 30,	June 30,	June 30,
	2024	2023	2024	2023
	(unaudited)			
Revenues:				
License and collaboration agreement revenues	\$ —	\$ —	\$ 235	\$ —
Total revenues	—	—	235	—
Operating expenses:				
Research and development	13,973	9,840	27,337	19,219
General and administrative	3,342	3,718	6,849	7,126
Total operating expenses	17,315	13,558	34,186	26,345
Loss from operations	(17,315)	(13,558)	(33,951)	(26,345)
Total other income (expense), net	1,009	1,216	2,158	2,051

Consolidated net loss	(16,306)	(12,342)	(31,793)	(24,294)
Net (gain) loss attributable to noncontrolling interest in Pangu BioPharma Limited	<u>—</u>	<u>4</u>	<u>(4)</u>	<u>5</u>
Net loss attributable to aTyr Pharma, Inc.	\$ (16,306)	\$ (12,338)	\$ (31,797)	\$ (24,289)
Net loss per share, basic and diluted	\$ (0.23)	\$ (0.22)	\$ (0.46)	\$ (0.50)
Shares used in computing net loss per share, basic and diluted	72,284,351	55,143,805	69,204,401	48,557,347

ATYR PHARMA INC.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents, restricted cash and available-for-sale investments	\$ 81,378	\$ 101,650
Other receivables	1,628	2,436
Property and equipment, net	5,184	5,531
Operating lease, right-of-use assets	5,942	6,727
Financing lease, right-of-use assets	1,490	1,788
Prepaid expenses and other assets	<u>10,317</u>	<u>2,521</u>
Total assets	\$ 105,939	\$ 120,653
Accounts payable and accrued expenses	\$ 10,664	\$ 15,088
Current portion of operating lease liability	656	831
Current portion of financing lease liability	517	497
Long-term operating lease liability, net of current portion	11,514	12,339
Long-term financing lease liability, net of current portion	1,164	1,428
Total stockholders' equity	<u>81,424</u>	<u>90,470</u>
Total liabilities and stockholders' equity	\$ 105,939	\$ 120,653

Source: aTyr Pharma, Inc.