

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): May 9, 2023**

**ATYR PHARMA, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37378**  
(Commission File Number)

**20-3435077**  
(IRS Employer  
Identification No.)

**10240 Sorrento Valley Road, Suite 300**  
**San Diego, CA**  
(Address of Principal Executive Offices)

**92121**  
(Zip Code)

**Registrant's telephone number, including area code: (858) 731-8389**

**Not Applicable**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	LIFE	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On May 9, 2023, aTyr Pharma, Inc. issued a press release announcing financial results for the three months ended March 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information under this Item 2.02, including Exhibit 99.1 hereto is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release, dated May 9, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURE**

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Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ATYR PHARMA, INC.**

By: /s/ Jill M. Broadfoot  
Jill M. Broadfoot  
Chief Financial Officer

Date: May 9, 2023



**IMMEDIATE RELEASE**

**Contact:**

Ashlee Dunston  
Director, Investor Relations and Corporate Communications  
[adunston@atyrpharma.com](mailto:adunston@atyrpharma.com)

**aTyr Pharma Announces First Quarter 2023 Results and Provides Corporate Update**

*Phase 3 EFZO-FIT™ study of efzofitimod in patients with pulmonary sarcoidosis currently enrolling in the U.S., Europe and Japan.*

*Phase 2 proof-of-concept study of efzofitimod in patients with SSc-ILD expected to initiate in the third quarter of 2023.*

*Company to host multiple presentations for efzofitimod at the upcoming American Thoracic Society (ATS) 2023 International Conference.*

*February follow-on common stock offering generated \$48.1 million in net proceeds.*

*Ended the first quarter 2023 with \$117.6 million in cash, cash equivalents and investments.*

SAN DIEGO – May 9, 2023 – aTyr Pharma, Inc. (Nasdaq: LIFE) (“aTyr” or the “Company”), a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced first quarter 2023 results and provided a corporate update.

“We are pleased with the start to the year and the progress we have made with our efzofitimod clinical development program for interstitial lung disease (ILD),” said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “Our global pivotal Phase 3 EFZO-FIT™ study in patients with pulmonary sarcoidosis, the most prevalent form of ILD, continues to enroll in the U.S., Europe and Japan, and we are on track with our plans to initiate a Phase 2 study in patients with systemic sclerosis (SSc, or scleroderma)-associated ILD (SSc-ILD), a major form of connective tissue disease-related ILD, in the third quarter of this year.”

“We finished the first quarter of 2023 with \$117.6 million in cash, cash equivalents and investments. With our current cash position and the opportunity for additional milestone payments from our partner Kyorin Pharmaceutical Co., Ltd., we believe we are well capitalized to complete and read out our two efzofitimod clinical trials.”

**First Quarter 2023 and Subsequent Period Highlights**

- **Continued 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 intends to enroll up to 264 subjects with pulmonary sarcoidosis. Enrollment is in progress at centers in the U.S., Europe and Japan.

- **Progressed plans to initiate a Phase 2 proof-of-concept study to evaluate the efficacy, safety and tolerability of efzofitimod in patients with SSc-ILD.** This study will be 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 is expected to enroll 25 patients at multiple centers in the U.S. The primary objective of the study will be to evaluate the efficacy of multiple doses of intravenous efzofitimod on pulmonary, cutaneous and systemic manifestations in patients with SSc-ILD. The study is expected to initiate in the third quarter of 2023.
- **Announced the publication of the first review article for efzofitimod in the peer-reviewed journal *Sarcoidosis, Vasculitis and Diffuse Lung Diseases*.** In the article, titled, “Efzofitimod: a novel anti-inflammatory agent for sarcoidosis,” the authors, led by Robert P. Baughman, M.D., Professor of Medicine at the University of Cincinnati Medical Center, describe the mechanism for efzofitimod as it relates to the granulomatous inflammation central to the pathophysiology of sarcoidosis and review the preclinical and clinical data generated for efzofitimod that support its anti-inflammatory properties and the potential for it to be a novel therapeutic approach to immune-mediated fibrotic lung diseases such as pulmonary sarcoidosis.
- **Announced multiple presentations for efzofitimod at the upcoming American Thoracic Society (ATS) 2023 International Conference.** The conference is scheduled to take place May 19 – 24, 2023, in Washington, D.C.
  - o **Respiratory Innovation Summit – Showcase Five: Fibrosis Innovators** on Saturday, May 20, 2023, at 3:45 p.m.
  - o **Mini Symposium 9209 – Efzofitimod, a Novel Immunomodulator for Pulmonary Sarcoidosis, Modulates Patient Inflammatory Responses Through Myeloid Cells** on Monday, May22, 2023, at 3:15 p.m.
  - o **Thematic Poster P645 – Exposure-Efficacy Analysis Supports Proof of Concept for Efzofitimod in Pulmonary Sarcoidosis** on Tuesday, May 23, 2023, from 11:30 a.m. to 1:15 p.m.
  - o **Industry Theater Presentation – Efzofitimod: An Emerging Treatment for Sarcoidosis?** on Tuesday, May 23, 2023, at 1:30 p.m.

## First Quarter 2023 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, restricted cash, cash equivalents and investments as of March 31, 2023, were \$117.6 million. During the first quarter of 2023, the Company raised net proceeds of \$48.1 million through the public offering of common stock. Based on the Company's current operational plans and existing cash, the Company maintains its prior guidance and believes its cash runway will extend into 2026.
- **R&D Expenses:** Research and development expenses were \$9.4 million for the first quarter 2023, which consisted primarily of clinical trial costs for the Phase 3 EFZO-FIT™ study, manufacturing costs for the efzofitmod program and research and development costs for the efzofitmod and discovery programs.
- **G&A Expenses:** General and administrative expenses were \$3.4 million for the first quarter 2023.

## About Efzofitmod

aTyr is developing efzofitmod as a potential therapeutic for patients with fibrotic lung disease. Efzofitmod, a fusion protein comprised of the immunomodulatory domain of histidyl-tRNA synthetase fused to the FC region of a human antibody, is a selective modulator of neuropilin-2 that downregulates innate immune responses in inflammatory disease states. aTyr's lead indication for efzofitmod is pulmonary sarcoidosis, a major form of interstitial lung disease. Clinical proof-of-concept for efzofitmod was recently established in a Phase 1b/2a multiple-ascending dose, placebo-controlled study of efzofitmod in patients with pulmonary sarcoidosis, which demonstrated safety and a consistent dose response and trends of benefit of efzofitmod compared to placebo on key efficacy endpoints, including steroid reduction, lung function, clinical symptoms and inflammatory biomarkers. aTyr is currently conducting EFZO-FIT™, a Phase 3 study of efzofitmod in pulmonary sarcoidosis patients.

## About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform. aTyr's research and development efforts are concentrated on a newly discovered area of biology, the extracellular functionality and signaling pathways 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 and their extracellular targets. aTyr's primary focus is efzofitmod, a clinical-stage product candidate which binds to the neuropilin-2 receptor and is designed to downregulate immune engagement in fibrotic lung disease. For more information, please visit [www.atyrpharma.com](http://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 "believes,"

“expects,” “intends,” “may,” “plans,” “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 statements regarding our belief that we will have sufficient cash to fund both of our efzofitmod clinical trials and the company’s operations into 2026; the expected size of, and number of patients to be enrolled in, the EFZO-FIT™ study; the potential therapeutic benefits and applications of efzofitmod and our discovery programs; and timelines and plans with respect to certain development activities and development goals, including our expectation that our Phase 2 proof-of-concept study of efzofitmod in patients with SSc-ILD will begin in the third quarter of 2023. 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. 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, our assumptions and expectations underlying our belief that we will have sufficient cash runway into 2026 may not be accurate, the fact that NRP2 and tRNA synthetase biology is not fully understood, uncertainty regarding macroeconomic and geopolitical conflicts, 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 and in our subsequent 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.**  
**Consolidated Statements of Operations**  
(in thousands, except share and per share data)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
	<b>(unaudited)</b>	
Operating expenses:		
Research and development	\$ 9,379	\$ 8,896
General and administrative	3,408	3,482
Total operating expenses	12,787	12,378
Loss from operations	(12,787)	(12,378)
Total other income (expense), net	835	224
Consolidated net loss	(11,952)	(12,154)
Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	1	1
Net loss attributable to aTyr Pharma, Inc.	\$ (11,951)	\$ (12,153)
Net loss per share, basic and diluted	\$ (0.29)	\$ (0.44)
Shares used in computing net loss per share, basic and diluted	41,897,706	27,818,379



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

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
	<b>(unaudited)</b>	
Cash, cash equivalents, restricted cash and available-for-sale investments	\$ 117,575	\$ 69,311
Other receivables	1,625	11,775
Property and equipment, net	5,167	3,059
Operating lease, right-of-use assets	6,942	7,250
Financing lease, right-of-use assets	1,948	1,248
Prepaid expenses and other assets	3,581	3,143
<b>Total assets</b>	<b>\$ 136,838</b>	<b>\$ 95,786</b>
Accounts payable, accrued expenses and other liabilities	\$ 12,853	\$ 12,968
Current portion of operating lease liability	381	630
Current portion of financing lease liability	420	264
Long-term operating lease liability, net of current portion	11,916	9,633
Long-term financing lease liability, net of current portion	1,570	1,007
Total stockholders' equity	109,698	71,284
<b>Total liabilities and stockholders' equity</b>	<b>\$ 136,838</b>	<b>\$ 95,786</b>

