

**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): August 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 August 9, 2023, aTyr Pharma, Inc. issued a press release announcing financial results for the quarter ended June 30, 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

Exhibit No.	Description
99.1	Press Release, dated August 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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: August 9, 2023



IMMEDIATE RELEASE

Contact:

Ashlee Dunston

Director, Investor Relations and Public Affairs

adunston@atyrpharma.com

aTyr Pharma Announces Second Quarter 2023 Results and Provides Corporate Update

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

Phase 2 EFZO-CONNECT™ study of efzofitimid in SSc-ILD expected to initiate in the third quarter of 2023.

Ended the second quarter of 2023 with \$112.0 million in cash, cash equivalents and investments.

SAN DIEGO – August 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 second quarter 2023 results and provided a corporate update.

“Throughout the second quarter we have continued to progress and invest in our clinical development program for our lead therapeutic candidate, efzofitimid, in 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 and our Phase 2 EFZO-CONNECT™ study in patients with systemic sclerosis (SSc, or scleroderma)-associated ILD (SSc-ILD), is expected to enroll the first patient in the third quarter.”

Second Quarter 2023 and Subsequent Period Highlights

- **Continued enrollment in the global pivotal Phase 3 EFZO-FIT™ study to evaluate the efficacy and safety of efzofitimid 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 efzofitimid or placebo dosed intravenously monthly for a total of 12 doses. The study intends to enroll up to 264 subjects with pulmonary sarcoidosis. The study is open for enrollment at nearly all of the centers intended in the U.S., Europe and Japan and is expected to expand to include centers in Brazil.
- **Progressed plans to initiate the Phase 2 EFZO-CONNECT™ study to evaluate the efficacy, safety and tolerability of efzofitimid in patients with SSc-ILD.** This proof-of-concept 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 efzofitimid 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 efzofitimid on pulmonary, cutaneous and systemic manifestations in patients with SSc-ILD. The study is expected to initiate in the third quarter of 2023.

- **Received European Commission orphan drug designation for efzofitimid for the treatment of SSc based on the opinion of the European Medicines Agency (EMA) Committee for Orphan Medicinal Products.** The EMA grants orphan status to products intended for the treatment, prevention or diagnosis of a disease with a prevalence no more than five in 10,000 people in the EU that is life-threatening or chronically debilitating for which either no satisfactory method of diagnosis, prevention, or treatment exists, or if such a method exists, the medicine is of significant benefit to those affected by such condition. EMA orphan drug designation provides certain benefits, including the potential for up to 10 years of marketing exclusivity following regulatory approval in the EU, reduction in regulatory fees and a centralized EU approval process.
- **Announced two posters for efzofitimid accepted for presentation at the upcoming European Respiratory Society (ERS) International Congress 2023.** The conference is scheduled to take place September 9 – 13, 2023, in Milan, Italy. The Company will present new data from a pooled, post hoc analysis from the Phase 1b/2a study of efzofitimid in patients with pulmonary sarcoidosis that further supports efficacy measures in these patients. Additionally, new mechanistic data supports the rationale for efzofitimid as a potential treatment for patients with SSc-ILD.
 - o **Poster PA419** – Efzofitimid: A Novel Therapeutic Candidate for SSc-ILD on Sunday, September 10, 2023, from 8:00 a.m. to 9:30 a.m. CEST.
 - o **Poster PA1744** – Therapeutic Doses of Efzofitimid Significantly Improve Multiple Pulmonary Sarcoidosis Efficacy Measures on Sunday, September 10, 2023, from 4:00 p.m. to 5:30 p.m. CEST.

Second Quarter 2023 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, restricted cash, cash equivalents and investments as of June 30, 2023, were \$112.0 million. 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 \$9.8 million for the second quarter of 2023, which consisted primarily of clinical trial costs for the Phase 3 EFZO-FIT™ study, manufacturing costs for the efzofitimid program and research and development costs for the efzofitimid and discovery programs.

- **G&A Expenses:** General and administrative expenses were \$3.7 million for the second quarter of 2023.

About Efzofitimod

aTyr is developing efzofitimod as a potential therapeutic for patients with fibrotic lung disease. Efzofitimod, 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 efzofitimod is pulmonary sarcoidosis, a major form of interstitial lung disease. Clinical proof-of-concept for efzofitimod was recently established in a Phase 1b/2a multiple-ascending dose, placebo-controlled study of efzofitimod in patients with pulmonary sarcoidosis, which demonstrated safety and a consistent dose response and trends of benefit of efzofitimod 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 efzofitimod 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 efzofitimod, 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.

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 runway to fund both of our efzofitimod clinical trials and the Company's operations into 2026; the expected size of, and number and nationality of patients to be enrolled in, the EFZO-FIT™ and EFZO-CONNECT™ studies; certain potential benefits of EMA orphan drug designation; the potential therapeutic benefits and applications of efzofitimod 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 efzofitimod in patients with SSc-ILD will initiate 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 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 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(unaudited)			
Operating expenses:				
Research and development	\$ 9,840	\$ 9,135	\$ 19,219	\$ 18,031
General and administrative	3,718	3,449	7,126	6,931
Total operating expenses	13,558	12,584	26,345	24,962
Loss from operations	(13,558)	(12,584)	(26,345)	(24,962)
Total other income (expense), net	1,216	163	2,051	387
Consolidated net loss	(12,342)	(12,421)	(24,294)	(24,575)
Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	4	1	5	2
Net loss attributable to aTyr Pharma, Inc.	\$ (12,338)	\$ (12,420)	\$ (24,289)	\$ (24,573)
Net loss per share, basic and diluted	\$ (0.22)	\$ (0.44)	\$ (0.50)	\$ (0.88)
Shares used in computing net loss per share, basic and diluted	55,143,80	28,063,38	48,557,34	27,941,56
	5	7	7	0

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

	June 30, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents, restricted cash and available-for-sale investments	\$ 112,000	\$ 69,311
Other receivables	1,287	11,775
Property and equipment, net	5,812	3,059
Operating lease, right-of-use assets	7,119	7,250
Financing lease, right-of-use assets	1,894	1,248
Prepaid expenses and other assets	4,635	3,143
Total assets	\$ 132,747	\$ 95,786
Accounts payable, accrued expenses and other liabilities	\$ 11,304	\$ 12,968
Current portion of operating lease liability	621	630
Current portion of financing lease liability	443	264
Long-term operating lease liability, net of current portion	12,802	9,633
Long-term financing lease liability, net of current portion	1,525	1,007
Total stockholders' equity	106,052	71,284
Total liabilities and stockholders' equity	\$ 132,747	\$ 95,786

