
**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 15, 2022

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.)

3545 John Hopkins Court, Suite #250
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 15, 2022, aTyr Pharma, Inc. issued a press release announcing financial results for the quarter ended June 30, 2022. 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 15, 2022 |
| 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 15, 2022



IMMEDIATE RELEASE

Contact:

Ashlee Dunston
Director, Investor Relations and Corporate Communications
adunston@atyrpharma.com

aTyr Pharma Announces Second Quarter 2022 Results and Provides Corporate Update

First sites initiated in Phase 3 EFZO-FIT™ study in patients with pulmonary sarcoidosis.

FDA granted Fast Track designation for efzofitmod for the treatment of pulmonary sarcoidosis.

Ended the second quarter 2022 with \$89.3 million in cash, restricted cash, cash equivalents and investments.

Company to host conference call and webcast today, May 15th, at 5:00 p.m. EDT / 2:00 p.m. PDT.

SAN DIEGO – August 15, 2022 – aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced second quarter 2022 results and provided a corporate update.

“We are pleased with our second quarter progress as we announced our plans to initiate EFZO-FIT™, a Phase 3 study of efzofitmod in patients with pulmonary sarcoidosis,” said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “This global pivotal study is a major milestone for the sarcoidosis community and is projected to be the largest interventional study for patients with sarcoidosis to date. We are on track to enroll the first patient in this study this quarter.”

Second Quarter 2022 and Subsequent Period Highlights

- In May 2022, announced plans to initiate the global pivotal EFZO-FIT™ study, a global pivotal Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of efzofitmod in patients with pulmonary sarcoidosis. This is a 52-week study consisting of three parallel cohorts randomized equally to either 3.0 mg/kg or 5.0 mg/kg of efzofitmod or placebo dosed intravenously once a month for a total of 12 doses. The study intends to enroll 264 subjects with pulmonary sarcoidosis at multiple centers in North America, Europe and Japan. The trial design will incorporate a forced steroid taper. The primary endpoint of the study is steroid reduction. Secondary endpoints include measures of lung function and sarcoidosis symptoms.
- Accomplished several operational milestones for the EFZO-FIT™ study since its announcement in May 2022, including multiple interactions with regulatory authorities in the United States, European Union and Japan along with the submission of study protocol and clinical trial applications to regulatory authorities, ethics committees and institutional review boards. Site selection, qualification and initiations for several sites have occurred, as well as an investigator meeting for U.S. sites. The company is on track to enroll the first patient in the study in the third quarter of 2022.
- Received U.S. Food and Drug Administration (FDA) Fast Track designation for efzofitmod for the treatment of pulmonary sarcoidosis. Fast Track designation helps facilitate development and expedite the review of drugs to treat serious or life-threatening diseases with unmet medical need. Fast Track designation provides certain benefits, including more frequent interactions with the FDA throughout

the development program, as well as eligibility for accelerated approval, priority review and rolling review.

- Presented clinical data from the recently completed Phase 1b/2a study of efzofitimod in patients with pulmonary sarcoidosis at the American Thoracic Society (ATS) 2022 International Conference in San Francisco, California.
- Announced fibroblast growth receptor 4 (FGFR4) as the target receptor for a fragment of the Alanyl-tRNA Synthetase (AARS) in a poster presented at the Keystone Symposia on Tissue Fibrosis and Repair: Mechanisms, Human Disease and Therapeutics. FGFR4 is known to play a role in diseases related to inflammation and fibrosis, including conditions where unchecked fibrosis can precede the development of certain cancers. The company intends to interrogate the interaction between this fragment of AARS and FGFR4 and the implications for disease in order to explore this synthetase fragment as a potential pipeline candidate.

Second Quarter 2022 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, restricted cash, cash equivalents and investments as of June 30, 2022, were \$89.3 million.
- **R&D Expenses:** Research and development expenses were \$9.1 million for the second quarter of 2022, which consisted of product development and manufacturing costs for the efzofitimod and ATYR2810 programs, as well as startup costs for the Phase 3 EFZO-FIT™ study.
- **G&A Expenses:** General and administrative expenses were \$3.4 million for the second quarter of 2022.
- **Shares Outstanding:** Common shares outstanding were 28,127,458 as of June 30, 2022.

Conference Call and Webcast Details

aTyr will host a conference call and webcast today at 5:00 p.m. EDT / 2:00 p.m. PDT to discuss its financial results and provide a corporate update. Interested parties may access the call by registering [here](#) in order to obtain a dial in, personalized passcode and webcast information. 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 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 and adaptive immune response 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 <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," "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 statements regarding the trial design of EFZO-FIT™ and the expected number of patients to be enrolled in the study; our plans to enroll the first patient in the EFZO-FIT™ study in the third quarter of 2022; our plan to interrogate the interaction between AARS-1 and FGFR4 and explore such synthetase fragment as a potential pipeline candidate; 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. 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, the fact that NRP2 and tRNA synthetase biology is not fully understood, uncertainty regarding the COVID-19 pandemic, and geopolitical conflicts, including 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the

SEC on August 15, 2022 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
(in thousands, except share and per share data)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|-------------|------------------------------|-------------|
| | 2022 | 2021 | 2022 | 2021 |
| | (unaudited) | | | |
| Operating expenses: | | | | |
| Research and development | \$ 9,135 | \$ 7,655 | \$ 18,031 | \$ 12,171 |
| General and administrative | 3,449 | 2,790 | 6,931 | 5,476 |
| Total operating expenses | 12,584 | 10,445 | 24,962 | 17,647 |
| Loss from operations | (12,584) | (10,445) | (24,962) | (17,647) |
| Total other income (expense), net | 163 | 53 | 387 | 100 |
| Consolidated net loss | (12,421) | (10,392) | (24,575) | (17,547) |
| Net loss attributable to noncontrolling interest in Pangu BioPharma Limited | 1 | 1 | 2 | 5 |
| Net loss attributable to aTyr Pharma, Inc. | \$ (12,420) | \$ (10,391) | \$ (24,573) | \$ (17,542) |
| Net loss per share, basic and diluted | \$ (0.44) | \$ (0.64) | \$ (0.88) | \$ (1.16) |
| Shares used in computing net loss per share, basic and diluted | 28,063,387 | 16,128,473 | 27,941,560 | 15,121,721 |

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

| | June 30, 2022 | December 31, 2021 |
|--|--------------------------|------------------------------|
| | (unaudited) | |
| Cash, cash equivalents, restricted cash and available-for-sale investments | \$ 89,287 | \$ 107,911 |
| Other receivables | 426 | 435 |
| Property and equipment, net | 558 | 543 |
| Operating lease, right-of-use assets | 827 | 1,267 |
| Financing lease, right-of-use assets | 368 | — |
| Prepaid expenses and other assets | 4,550 | 5,381 |
| Total assets | \$ 96,016 | \$ 115,537 |
| Accounts payable, accrued expenses and other liabilities | \$ 8,284 | \$ 5,033 |
| Current portion of operating lease liability | 906 | 980 |
| Current portion of financing lease liability | 70 | — |
| Long-term operating lease liability, net of current portion | — | 398 |
| Long-term financing lease liability, net of current portion | 298 | — |
| Total stockholders' equity | 86,458 | 109,126 |
| Total liabilities and stockholders' equity | \$ 96,016 | \$ 115,537 |

