

**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): September 24, 2026

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 obligation 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	ATYR	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 8.01 Other Events.

On September 24, 2026, aTyr Pharma, Inc. (the Company) announced that it has reached alignment with the U.S. Food and Drug Administration (FDA) on the protocol for a Phase 3 study of its lead therapeutic candidate, efzofitmod, in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease (Planned Phase 3 Study). The Company expects to focus on regulatory submissions in the U.S. and Europe as it initiates study-related activities in the fourth quarter of 2026.

The Planned Phase 3 Study will be a global, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of efzofitmod in patients with moderate to severe pulmonary sarcoidosis. The 54-week Planned Phase 3 Study will consist of two parallel cohorts randomized equally to either 5.0 mg/kg efzofitmod or placebo dosed intravenously once every 3 weeks for a total of 17 doses. The Planned Phase 3 Study is intended to enroll up to approximately 372 patients with symptomatic pulmonary sarcoidosis with restrictive lung disease who are receiving a stable dose of ≤ 5.0 mg daily oral corticosteroid and/or a background immunosuppressant. All background treatment will remain stable throughout the duration of the Planned Phase 3 Study. The primary endpoint of the Planned Phase 3 Study will be change from baseline in forced vital capacity (FVC) at week 48 and the key secondary endpoint will be change from baseline in the King's Sarcoidosis Questionnaire (KSQ)-Lung score at week 48.

The Planned Phase 3 Study design is supported by data from a subgroup analysis of the Phase 3 EFZO-FIT™ study that showed that patients with pulmonary sarcoidosis with restrictive lung disease (defined as FVC percent predicted $\leq 80\%$ with a normal FEV1/FVC ratio) who were treated with 5.0 mg/kg efzofitmod experienced a clinically meaningful benefit in FVC and improvements in multiple patient-reported outcomes, including the KSQ-Lung score, compared to placebo. These findings were presented at the World Association of Sarcoidosis and Other Granulomatous Disorders 2026 Congress.

Future development of efzofitmod in the Planned Phase 3 Study in pulmonary sarcoidosis will require the Company to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements.

Forward-Looking Statements

This Current Report on Form 8-K (this Current Report) 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 "anticipate," "believes," "can," "could," "designed," "expects," "intends," "may," "plans," "potential," "upcoming," "will," and variations of such words or similar expressions. The Company intends these forward-looking statements to be covered by such safe harbor provisions for forward-looking statements and is making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements include, among others, statements regarding the Company's continued development of efzofitmod in pulmonary sarcoidosis, including the additional capital that the Company expects to be necessary for future development; timelines and plans with respect to certain regulatory and development milestones, activities and goals, including the Company's plans to initiate study-related activities in the fourth quarter of 2026 for the Planned Phase 3 Study; the proposed design of the Planned Phase 3 Study of efzofitmod in pulmonary sarcoidosis, including the dosing regimen, enrollment expectations, targeted endpoints, and strategy to focus on a more limited patient population; and the Company's interpretation of the results of the Phase 3 EFZO-FIT™ study and the meaning of those interpretations for the Planned Phase 3 Study. These forward-looking statements also reflect the Company's current views about the Company's plans, intentions, expectations, strategies and prospects, which are based on the information currently available to the Company and on assumptions the Company has made. Although the Company believes that its plans, intentions, expectations, strategies and prospects, as reflected in or suggested by these forward-looking statements, are reasonable, the Company 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 Company management that, although the Company believes 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 the Company's control including, without limitation, uncertainty related to interactions with the FDA in general, risks that the results from the Planned Phase 3 Study may not ultimately support FDA approval of efzofitmod in pulmonary sarcoidosis, uncertainty regarding geopolitical and macroeconomic events, risks associated with the discovery, development and regulation of efzofitmod, the risks associated with targeting a more limited patient population in the Planned Phase 3 Study of efzofitmod in pulmonary sarcoidosis, the risk that the Company or future partners

may cease or delay preclinical or clinical development activities for efzofitimod for a variety of reasons (including difficulties or delays in patient enrollment in planned clinical trials), the possibility that future collaborations could be terminated early, and the risk that the Company may not be able to raise the additional funding required for the Company's business and product development plans, as well as those risks set forth in the Company's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and in its other SEC filings. Except as required by law, the Company assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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: September 24, 2026

