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): April 21, 2020

ATYR PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37378**	**20-3435077**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3545 John Hopkins Court, Suite #250 **San Diego** **(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 8.01. Other Events.

On April 21, 2020, aTyr Pharma, Inc. (the "Company") announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application to evaluate its lead candidate, ATYR1923, in a Phase 2 study in COVID-19 patients with severe respiratory complications. The Phase 2 clinical trial will be a randomized, double blind, placebo-controlled study with ATYR1923 in 30 confirmed COVID-19 positive patients at up to 10 centers in the United States. Patients enrolled in the trial will be assigned to one of three cohorts of 10 patients each. Patients will receive a single intravenous (IV) dose of either 1.0 or 3.0 mg/kg ATYR1923 or placebo.

A press release announcing the Phase 2 study and the FDA's acceptance of the IND is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release of aTyr Pharma, Inc. dated April 21, 2020.

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: April 21, 2020

IMMEDIATE RELEASE
Contact:
Joyce Allaire
Managing Director, LifeSci Advisors, LLC
jallaire@lifesciadvisors.com

aTyr Pharma Announces Phase 2 Study of ATYR1923 in COVID-19 Patients with Severe Respiratory Complications Following FDA Acceptance of IND Application

SAN DIEGO – April 21, 2020 – aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel immunological pathways, today announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application to evaluate its lead therapeutic candidate, ATYR1923, in a Phase 2 study in COVID-19 patients with severe respiratory complications.

“Many COVID-19 patients with severe disease experience serious, sometimes fatal, respiratory complications caused by an excessive inflammatory response in the lung, primarily driven by T-cells,” said Dr. Sanjay Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “The inflammatory lung injury related to COVID-19 may be similar to that of interstitial lung diseases, or ILDs, for which ATYR1923 is currently being investigated.”

ATYR1923 has been shown pre-clinically to downregulate T-cell responses, thereby dampening the inflammatory cytokine and chemokine signaling, that has been implicated in these severe COVID-19 cases. ATYR1923 has also been shown to improve lung function, as well as to reduce inflammation and fibrosis, in multiple animal models of immune-mediated acute lung injury.

“We believe there is strong scientific rationale for the development of ATYR1923 to treat COVID-19 patients,” said Dr. Shukla. “By targeting aberrant immune responses, we believe that ATYR1923’s mechanism of action has substantial overlap with this disease pathology and presents a compelling opportunity to potentially treat this subset of COVID-19 patients for which there are no approved therapies. We look forward to urgently implementing and advancing this important study as we seek to play a significant role in the global battle against COVID-19.”

The Phase 2 clinical trial will be a randomized, double blind, placebo-controlled study with ATYR1923 in 30 confirmed COVID-19 positive patients at up to 10 centers in the United States. Patients enrolled in the trial will be assigned to one of three cohorts of 10 patients each. Patients will receive a single intravenous (IV) dose of either 1.0 or 3.0 mg/kg ATYR1923 or placebo. The study will look to demonstrate safety and preliminary efficacy of ATYR1923 in COVID-19 patients with severe respiratory complications.

Interim safety data results from a Phase 1b/2a study of ATYR1923 in patients with pulmonary sarcoidosis were announced in December 2019. Study drug (ATYR1923 or placebo) was observed to be generally safe and well tolerated with no drug-related serious adverse events, consistent with Phase 1 study results in healthy volunteers.

About ATYR1923

aTyr is developing ATYR1923 as a potential therapeutic for patients with interstitial lung diseases. ATYR1923, a fusion protein comprised of the immuno-modulatory domain of histidyl tRNA synthetase fused to the FC region of a human antibody, is a selective modulator of neuropilin-2 that downregulates the innate and adaptive immune response in inflammatory disease states. aTyr is currently enrolling a proof-of-concept Phase 1b/2a trial evaluating ATYR1923 in patients with pulmonary sarcoidosis. This Phase 1b/2a study is a multi-ascending dose, placebo-controlled, first-in-patient study of ATYR1923 that has been designed to evaluate the safety, tolerability, steroid sparing effect, immunogenicity and pharmacokinetics profile of multiple doses of ATYR1923.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel immunological pathways. 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 ATYR1923, a clinical-stage product candidate which binds to the neuropilin-2 receptor and is designed to down-regulate immune engagement in interstitial lung diseases. 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 Litigation Reform Act. Forward-looking statements are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "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 potential therapeutic benefits and applications of our product candidates; our ability to successfully advance our product candidates, undertake certain development activities (such as the initiation of clinical trials, clinical trial enrollment, the conduct of clinical trials and the announcement of top-line results) and accomplish certain development goals, and the timing of such events; and the scope and strength of our intellectual property portfolio. 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, risks associated with the discovery, development and regulation of our product candidates, 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 (including difficulties or delays in patient enrollment in planned clinical trials), the possibility of unexpected expenses or other demands on our cash resources, 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.