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): January 4, 2021

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 January 4, 2021, aTyr Pharma, Inc. (the "Company") announced positive topline results from its Phase 2 double-blind, placebo-controlled clinical trial of its lead therapeutic candidate, ATYR1923, in hospitalized COVID-19 patients with severe respiratory complications who do not require mechanical ventilation. The trial met its primary endpoint of safety, demonstrating that a single, intravenous (IV) dose of ATYR1923 was generally safe and well-tolerated in both the 1.0 and 3.0 mg/kg treatment groups, with no drug-related serious adverse events.

The study demonstrated a preliminary signal of activity through clinical improvement in the high dose cohort with the assessment of time to recovery, defined as either achieving a WHO ordinal scale score of ≤3 or hospital discharge with no requirement of supplemental oxygen. Patients who received the 3.0 mg/kg dose of ATYR1923 experienced a median time to recovery of 5.5 days compared to 6 days in the placebo group. In addition, 83% of patients receiving the high dose of ATYR1923 achieved recovery by day 6, compared to 56% in the placebo arm. Patients in the 1.0 mg/kg treatment arm experienced a median time to recovery of 7 days. All patients in the study received standard of care treatment at the time of enrollment, which included remdesivir and/or dexamethasone.

Adverse events were mostly mild or moderate in severity and generally assessed as unrelated to the study drug. This is in line with previous safety assessments of ATYR1923, including an interim safety analysis from an ongoing Phase 1b/2a trial in patients with pulmonary sarcoidosis, a chronic form of interstitial lung disease. There were two deaths observed in the study, both in the 1.0 mg/kg treatment arm, which were deemed not related to ATYR1923 by an independent data safety monitoring board.

The Phase 2 clinical trial was a randomized, double blind, placebo-controlled study of ATYR1923 in 32 hospitalized COVID-19 patients with severe respiratory complications, who did not require mechanical ventilation, at hospitals in the U.S. and Puerto Rico. Patients enrolled in the trial were randomized 1:1:1 to a single IV dose of either 1.0 or 3.0 mg/kg of ATYR1923 or placebo. Patients were followed for 60 days post treatment. The study was not powered for statistical significance and was designed to evaluate safety and identify preliminary signs of activity of ATYR1923 as compared to placebo.

Following the topline results, the Company will be reviewing the full data set from the study, which will include clinical biomarker data and 60 day follow up. The clinical biomarker data collected during the study, when patients' lungs are inflamed, may provide additional insight into the COVID-19 disease pathology and the effects of 1923 on key inflammatory cytokines. Of note, the vast majority of patients in the trial received concomitant dexamethasone as part of standard of care. The overwhelming use of dexamethasone in the study may also impact the biomarker analysis.

The Company believes that even with the availability of vaccines and the current standard of care, additional treatments will be needed for patients who develop severe disease and require hospitalization. The Company will continue to assess the opportunity and need for effective therapies, and assess the evolving standard of care, including additional data expected on the use of dexamethasone, and continue to monitor the status of vaccine administration. The Company has observed in other trials where background Dexamethasone has been used as standard of care—patients tended to recover in 7-10 days. This data continues to rapidly evolve and the severity of those patients does vary. The Company will be reviewing not only the additional insights from the full data set but also monitoring the evolving standard of care treatment landscape for COVID-19 patients in the near term to best inform the Company's next step planning.

A press release announcing the topline results is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of aTyr Pharma, Inc. dated January 4, 2021

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: January 4, 2021

IMMEDIATE RELEASE

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

aTyr Pharma Announces Positive Topline Results from Phase 2 Clinical Trial of ATYR1923 in COVID-19 Patients with Severe Respiratory Complications

Study met primary safety endpoint in moderate to severe hospitalized COVID-19 patients.

A single dose of 3.0 mg/kg of ATYR1923 resulted in a median time to recovery of 5.5 days.

83% of patients receiving 3.0 mg/kg dose of ATYR1923 achieved recovery in less than a week.

Management to host conference call and webcast today, January 4, at 5:00pm ET/2:00pm PT.

SAN DIEGO – January 4, 2021 – aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel biological pathways, today announced positive topline results from its Phase 2 double-blind, placebo-controlled clinical trial of its lead therapeutic candidate, ATYR1923, in hospitalized COVID-19 patients with severe respiratory complications who do not require mechanical ventilation. The trial met its primary endpoint of safety, demonstrating that a single, intravenous (IV) dose of ATYR1923 was generally safe and well-tolerated in both the 1.0 and 3.0 mg/kg treatment groups, with no drug-related serious adverse events.

“We are pleased with the results of this study which continue to demonstrate ATYR1923’s favorable safety profile in inflammatory lung conditions,” said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “We are very encouraged by the signal of clinical activity seen in the 3.0 mg/kg cohort of ATYR1923. The relatively faster time to recovery seen by adding a single dose of ATYR1923 to standard of care treatment and the greater proportion of patients recovering within a week compared to placebo give us further confidence in this signal.”

The study demonstrated a preliminary signal of activity through clinical improvement in the high dose cohort with the assessment of time to recovery, defined as either achieving a WHO ordinal scale score of ≤3 or hospital discharge with no requirement of supplemental oxygen. Patients who received the 3.0 mg/kg dose of ATYR1923 experienced a median time to recovery of 5.5 days compared to 6 days in the placebo group. In addition, 83% of patients receiving the high dose of ATYR1923 achieved recovery by day 6, compared to 56% in the placebo arm. Patients in the 1.0 mg/kg treatment arm experienced a median time to recovery of 7 days. All patients in the study received standard of care treatment at the time of enrollment, which included remdesivir and/or dexamethasone.

Adverse events were mostly mild or moderate in severity and generally assessed as unrelated to the study drug. This is in line with previous safety assessments of ATYR1923, including an interim safety analysis from an ongoing Phase 1b/2a trial in patients with pulmonary sarcoidosis, a chronic form of interstitial lung disease. There were two deaths observed in the study, both in the 1.0 mg/kg treatment arm, which were deemed not related to ATYR1923 by an independent data safety monitoring board.

The Phase 2 clinical trial was a randomized, double blind, placebo-controlled study of ATYR1923 in 32 hospitalized COVID-19 patients with severe respiratory complications, who did not require mechanical ventilation, at hospitals in the U.S. and Puerto Rico. Patients enrolled in the trial were randomized 1:1:1 to a single IV dose of either 1.0 or 3.0 mg/kg of ATYR1923 or placebo. Patients were followed for 60 days post treatment. The study was not powered for statistical significance and was designed to evaluate safety and identify preliminary signs of activity of ATYR1923 as compared to placebo.

“Against the backdrop of the rapidly evolving standard of care for COVID-19 patients, we have reaffirmed the positive safety profile of ATYR1923 observed in our ongoing trial in patients with pulmonary sarcoidosis, a chronic form of inflammatory lung disease. We have also elucidated a signal of drug activity from a single 3.0 mg/kg dose of ATYR9123 in this small trial. I would like to thank the clinical sites, investigators and patients that contributed to these important findings,” said Dr. Shukla.

aTyr Pharma will host a conference call and webcast to discuss the results today, January 4, at 5:00pm ET/2:00pm PT. Interested parties may access the call by dialing toll-free 844-358-9116 from the US, or 209-905-5951 internationally and using conference ID 8045947. 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 ATYR1923

aTyr is developing ATYR1923 as a potential therapeutic for patients with inflammatory 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 recently completed enrollment in 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 pharmacokinetic profile of multiple doses of ATYR1923. In response to the COVID-19 pandemic, aTyr completed a Phase 2 clinical trial with ATYR1923 in COVID-19 patients with severe respiratory complications. This Phase 2 study was a randomized, double blind, placebo-controlled study that was designed to evaluate the safety and preliminary efficacy of a single dose of ATYR1923.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel biological 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 inflammatory 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 Securities Litigation Reform Act of 1995. 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 potential therapeutic benefits and applications of ATYR1923; timelines and plans with respect to certain development activities (such as the timing of data from clinical trials); and certain 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, uncertainty regarding the COVID-19 pandemic, risks associated with the discovery, development and regulation of our product candidates, the risk that we or our partners 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 that existing collaborations could be terminated early, 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.