# 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**

**April 24, 2017**
**Date of Report (Date of earliest event reported)**

# 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, California 92121**

**(Address of principal executive offices, including zip code)**

**(858) 731-8389**

**(Registrant's telephone number, including area code)**

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))

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 7.01 Regulation FD Disclosure.**

On April 24, 2017, aTyr Pharma, Inc. (the "Company") announced further detail on the previously announced clinical data from the Company's Phase 1b/2 Trial (004) in adult patients with limb girdle muscular dystrophy type 2B (GLMD2B) and facioscapulohumeral muscular dystrophy (FSHD) to be presented in a poster presentation at the Emerging Platform Session at the American Academy of Neurology 69th Annual Meeting on Tuesday, April 25, 2017. The press release related to this announcement is attached as Exhibit 99.1

The information under this Item 7.01, including Exhibit 99.1 hereto is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities 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 8.01 Other Events**

The poster referenced above is titled "Results of a Phase 1b/2 Study of ATYR1940 in Adult Patients with Limb Girdle Muscular Dystrophy Type 2B (LGMD2B) and Facioscapulohumeral Muscular Dystrophy (FSHD) (ATYR1940-C-004)," and is filed as Exhibit 99.2 and incorporated herein by reference.

The poster presentation provides further detail on the previously announced results from the completed Phase 1b/2 open-label, intra-patient dose escalation 004 trial testing doses of Resolaris (*ATYR1940*) of up to 3.0 mg/kg biweekly in patients with LGMD2B and FSHD. Data from all clinical trials completed to date demonstrate that Resolaris has a favorable safety profile and was generally well-tolerated across all doses tested. There have been no observed signs of general immunosuppression and low-level anti-drug antibody signals did not result in clinical symptoms. 78% of the LGMD2B patients in the trial recorded increases in muscle function at 14 weeks as measured by manual muscle test (MMT) score, a validated assessment tool. 50% of the FSHD patients in the trial recorded increases in muscle function as measured by MMT score. The Company believes these data are supportive of further advancement of Resolaris.

This Current Report on Form 8-K 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, including statements regarding the potential and potential therapeutic benefits of Resolaris™, the ability of the Company to successfully advance its pipeline or product candidates, undertake certain development activities (such as clinical trial enrollment and the conduct of clinical trials) and accomplish certain development goals and the timing of such activities and development goals, the timing of initiation of additional clinical trials and of reporting results from our clinical trials, the scope and strength of our intellectual property portfolio, our ability to receive regulatory approvals for, and commercialize, our product candidates and 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 those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the 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 Physiocrine-based product candidates, as well as those set forth in our most recent Annual Report on Form 10-K for the year ended December 31, 2016 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.

**Item 9.01 Exhibits.**

(d) Exhibits.

| | |
|---|---|
| 99.1 | Press Release of aTyr Pharma, Inc. dated April 24, 2017. |
| 99.2 | Poster presentation titled "Results of a Phase 1b/2 Study of ATYR1940 in Adult Patients with Limb Girdle Muscular Dystrophy Type 2B (LGMD2B) and Facioscapulohumeral Muscular Dystrophy (FSHD) (ATYR1940-C-004)." |

**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/ John D. Mendlein
John D. Mendlein, Ph.D.
Chief Executive Officer

Date: April 24, 2017

**INDEX TO EXHIBITS**

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Exhibit 99.1

**IMMEDIATE RELEASE**

**Contact:**
**Mark Johnson**
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858-223-1163

**aTyr Pharma Presents Analyses of Resolaris Phase 1b/2 Trial in Patients with Limb Girdle Muscular Dystrophy 2B and Facioscapulohumeral Muscular Dystrophy at the American Academy of Neurology 69th Annual Meeting**

*- Resolaris Demonstrated Favorable Safety Profile and Promising Signals of Clinical Activity -*

*- Resolaris has FDA Fast Track and Orphan Drug Designation for Limb Girdle Muscular Dystrophy 2B (LGMD2B) and Facioscapulohumeral Muscular Dystrophy (FSHD) -*

[DRAFT] SAN DIEGO – April 24, 2017 – aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of Physiocrine-based therapeutics to address severe, rare diseases, today announced its participation as part of the Emerging Science Platform Session at the upcoming American Academy of Neurology (AAN) 69th Annual Meeting to be held April 22 – 28, 2017 in Boston, MA.

Details of the session are below:

**Emerging Science Platform Session: Tuesday, April 25, 2017 from 5:45 p.m. – 7:15 p.m. (ET)**

- **Title:** *Results of a Phase 1b/2 Study of ATYR1940 in Adult Patients with Limb Girdle Muscular Dystrophy Type 2B (LGMD2B) and Facioscapulohumeral Muscular Dystrophy (FSHD) (ATYR1940-C-004)*
- **Author and Presenter:** John Vissing, M.D., Ph.D., Professor of Neurology, University of Copenhagen
- **Supporting Authors:** Attarian S., Gidaro T., Mozaffar T., Iyadurai S., Walker G., Shukla, S., Servais, L., Wagner, K.
- **Location:** Boston Convention and Exhibition Center, 415 Summer St., Boston, MA

The poster presentation provides further detail on the previously announced results from the completed Phase 1b/2 open-label, intra-patient dose escalation 004 trial testing doses of Resolaris (*ATYR1940*) of up to 3.0 mg/kg biweekly in patients with LGMD2B and FSHD. Data from all clinical trials completed to date demonstrate that Resolaris has a favorable safety profile and was generally well-tolerated across all doses tested. There have been no observed signs of general immunosuppression and low-level anti-drug antibody signals did not result in clinical symptoms. 78% of the LGMD2B patients in the trial recorded increases in muscle function at 14 weeks as measured by manual muscle test (MMT) score, a validated assessment tool. 50% of the FSHD patients in the trial recorded increases in muscle function as measured by MMT score.

aTyr believes these data are supportive of further advancement of Resolaris.

**About Resolaris™**

aTyr Pharma is developing Resolaris as a potential first-in-class intravenous protein therapeutic candidate for the treatment of rare myopathies with an immune component. Resolaris is derived from a naturally occurring protein released by human skeletal muscle cells. aTyr believes Resolaris has the potential to provide therapeutic benefit to patients with rare myopathies with an immune component characterized by excessive immune cell involvement.

**About aTyr Pharma**

aTyr Pharma is engaged in the discovery and clinical development of innovative medicines for patients suffering from severe, rare diseases using its knowledge of Physiocrine biology, a newly discovered set of physiological pathways. To date, the company has generated three innovative therapeutic candidate programs based on its knowledge of Physiocrine biology in three different therapeutic areas. aTyr has built an intellectual property estate, to protect its pipeline, comprising over 175 issued patents or allowed patent applications that are owned or exclusively licensed, including over 300 potential Physiocrine-based protein compositions. aTyr's key programs are currently focused on severe, rare diseases characterized by immune imbalance for which there are currently limited or no treatment options. 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, including statements regarding the potential and potential therapeutic benefits of Resolaris™, the ability of the Company to successfully advance its pipeline or product candidates, undertake certain development activities (such as clinical trial enrollment and the conduct of clinical trials) and accomplish certain development goals and the timing of such activities and development goals, the timing of initiation of additional clinical trials, the scope and strength of our intellectual property portfolio, our ability to receive regulatory approvals for, and commercialize, our product candidates and of reporting results from our clinical trials 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 those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the 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 Physiocrine-based product candidates, as well as those set forth in our most recent Annual Report on Form 10-K for the year ended December 31, 2016 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.

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# Results of a Phase 1b/2 Study of ATYR1940 in Adult Patients with Limb Girdle Muscular Dystrophy Type 2B (LGMD2B) and Facioscapulohumeral Muscular Dystrophy (FSHD) (ATYR1940-C-004)

**John Vissing,[1] Shahram Attarian,[2] Teresa Gidaro,[3] Tahseen Mozaffar,[4] Stanley Iyadurai,[5] Gennyne Walker,[6] Sanjay Shukla,[6] Laurent Servais,[3] Kathryn Wagner[7]**

[1]Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; [2]Hôpital de La Timone, Marseille, France; [3]Institut de Myologie, Paris, France; [4]University of California Irvine, Irvine, CA, USA; [5]Ohio State University Wexner Medical Center, Columbus, OH, USA; [6]aTyr Pharma, San Diego, CA, USA; [7]Kennedy Krieger Institute, Baltimore, MD, USA

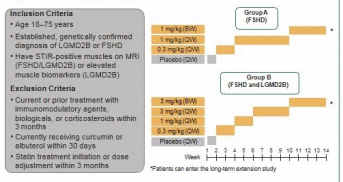
## Introduction

- Limb girdle muscular dystrophy Type 2B (LGMD2B; dysferlinopathy) and facioscapulohumeral muscular dystrophy (FSHD) are rare genetic myopathies characterized by inflammatory cell infiltration into muscle tissue,[1] debilitating skeletal muscle deterioration, and weakness.
- Dysferlinopathies including LGMD2B are recessively inherited dystrophies with 2 distinct clinical phenotypes[2]:
  - LGMD2B: Early weakness and slowly progressing atrophy of the pelvic and shoulder girdle muscles presenting in adolescents or young adults.
  - Miyoshi myopathy: Muscle weakness and atrophy in young adults, especially in the distal parts of the legs.
- FSHD is an autosomal dominant muscular dystrophy that typically affects muscles in the face and shoulder, as well as muscles of the lower extremities.[3]
- There are no targeted pharmacological interventions for the treatment of FSHD or LGMD2B.
- ATYR1940 (Resolaris™) is a Physiocrine protein that is nearly identical to human histidyl tRNA synthetase (HARS):
  - Aside from its established intracellular role in protein synthesis, HARS is believed to have extracellular roles, including modulating immune responses in skeletal muscle.[4]
  - Because the immune component may play a role in FSHD and LGMD2B pathophysiology, ATYR1940, a novel noncorticosteroid immunomodulator, is being investigated as a potential therapy for these diseases.
- In a previous first-in-patient study of ATYR1940 (0.3–3.0 mg/kg) in adults with FSHD (ClinicalTrials.gov; NCT02239224), results demonstrated that ATYR1940 was generally well-tolerated in that patient population.[5]

## Methods

- This Phase 1b/2, multicenter, open-label, intrapatient, dose-escalation study assigned eligible patients to 1 week of placebo, then 12 weeks of ATYR1940 in 2 groups (**Figure 1**):
  - Group A: Patients with FSHD received ATYR1940 titrated up to 1.0 mg/kg twice every week.
  - Group B: Patients with LGMD2B/Miyoshi Myopathy or FSHD received ATYR1940 titrated up to 3.0 mg/kg twice every week.
  - Dose escalation was based on the patient's tolerance of the previous dose and the clinical investigator's judgment.

### Figure 1. Study Design




BW, twice every week; MRI, magnetic resonance imaging; QW, once weekly; STIR, short tau inversion recovery.

## Key Study Endpoints

- Safety and tolerability as assessed by incidence of adverse events (AEs), antidrug antibody titers, and Jo-1 antibody levels:
  - Safety assessments also included laboratory investigations, electrocardiograms, and pulmonary function tests.
- Clinical activity, as assessed by change from baseline in:
  - *Manual Muscle Testing (MMT)*: An assessment of muscle weakness in 14 muscle groups using a modified Medical Research Council Scale.[4]
  - *Individualized Neuromuscular Quality of Life (INQoL) Questionnaire*: A validated, self-administered muscle-disease–specific measure of quality of life. The primary assessment was change from baseline to week 14 of treatment.
- Other endpoints included the evaluation of changes in targeted magnetic resonance imaging (MRI) parameters and muscle biomarkers.

## Results

- All patients completed the study; however, 4 patients did not receive all doses of study drug (Jo-1 levels above 1.5 U/mL, n = 2; infusion-related reaction (IRR), n = 1; withdrawal of consent, n = 1).
- Patient demographics and characteristics are shown in **Table 1**.

### Table 1. Patient Baseline Disease Characteristics

| Characteristic | Group A FSHD (n = 4) | Group B FSHD (n = 4) | Group B LGMD2B* (n = 10) |
|---|---|---|---|
| Mean disease duration, years (SD) | 22.6 (13.6) | 17.3 (3.5) | 19.8 (15.2) |
| Mean age of onset, years (SD) | 22.8 (12.3) | 18.0 (2.7) | 18.5 (4.3) |
| Mean clinical severity score (SD)† | 2.63 (1.1) | 2.88 (0.5) | 5.7 (2.5) |

*50% of patients had LGMD2B phenotype and 50% had Miyoshi Myopathy.
†For patients with FSHD: FSHD-specific Clinical Severity Score; for patients with LGMD2B: modified 10-point Gardner-Medwin and Walton scale.
SD, standard deviation.

## Safety and Tolerability

- All patients experienced at least 1 treatment-emergent AE (TEAE):
  - No serious AEs (SAEs) were reported.
  - All TEAEs were Grades 1 or 2 (mild or moderate in intensity).
  - 1 Patient experienced an IRR event that was of moderate intensity and resolved the same day, following discontinuation of study drug.
  - TEAEs reported for ≥ 2 patients treated with ATYR1940 are shown in **Table 2**.
- No trends in hematology or serum chemistries were observed.
- No signals or trends in electrocardiograms or pulmonary function tests were observed.
- There was no evidence of general immunosuppression by review of hematology parameters and TEAEs (infections).

### Table 2. Treatment-Emergent Adverse Events in ≥ 2 Patients

| Preferred Term n (%) | Group A FSHD (n = 4) | Group B FSHD (n = 4) | Group B LBMD2B (n = 10) | Total (N = 18) |
|---|---|---|---|---|
| Headache | 2 (50) | 2 (50) | 5 (50) | 9 (50) |
| Diarrhea | 2 (50) | 0 | 2 (20) | 4 (22) |
| Fall | 0 | 1 (25) | 3 (30) | 4 (22) |
| Asthenia | 1 (25) | 0 | 2 (20) | 3 (17) |
| Fatigue | 2 (50) | 0 | 1 (10) | 3 (17) |
| Nasopharyngitis | 0 | 1 (25) | 2 (20) | 3 (17) |
| Insomnia | 0 | 1 (25) | 1 (10) | 2 (11) |
| Musculoskeletal pain | 0 | 2 (50) | 0 | 2 (11) |
| Nausea | 0 | 0 | 2 (20) | 2 (11) |
| Oropharyngeal pain | 0 | 1 (25) | 1 (10) | 2 (11) |
| Pain in extremity | 1 (25) | 1 (25) | 0 | 2 (11) |
| Presyncope | 0 | 0 | 2 (20) | 2 (11) |
| Pyrexia | 0 | 1 (25) | 1 (10) | 2 (11) |

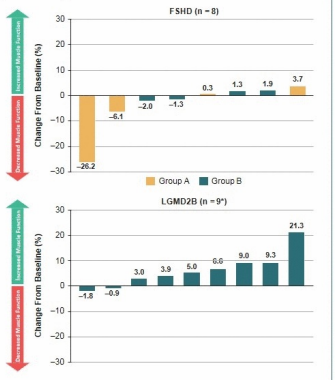
## Immunogenicity

- 11 of the 18 patients treated with ATYR1940 tested positive for anti-ATYR1940 antibody signals; however, no patient had titers high enough to trigger testing in a neutralizing antibody assay.
- No patients had Jo-1 (antisynthetase) antibody levels that were considered positive or equivocal for antisynthetase syndrome:
  - 2 Patients were discontinued from treatment due to elevated Jo-1 antibody levels above the protocol-specified threshold of ≥1.5 U/mL.

## Efficacy

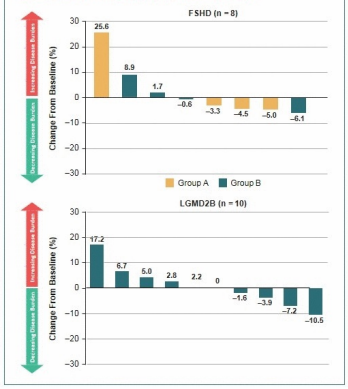
- Patients treated with ATYR1940 generally demonstrated improved muscle function as assessed by MMT (**Figure 2**):
  - In patients with FSHD (Group A and B), mean overall MMT scores did not change markedly from baseline. Equal numbers of patients (4 each) had slight improvements or declines in MMT scores over the 14-week assessment period. Of note, half of patients with FSHD (Group A) received a lower maximum dose (1 mg/kg) compared with patients in Group B (maximum dose, 3 mg/kg)
  - In patients with LGMD2B or Miyoshi Myopathy-type dysferlinopathies (Group B, 7 out of 9 patients showed improvements from baseline (mean overall MMT score increase of 6.2% [range, -1.8% to 21%]).
- No clear trend was seen in INQoL assessments among patients treated with ATYR1940 (**Figure 3**):
  - For both patients with FSHD and LGMD2B, the mean overall scores did not change substantially over the 3-month treatment period
  - There were similar proportions of patients who had small decreases and patients who had small increases in INQoL scores.
- No consistent changes over time were observed for targeted MRI or circulating biomarkers.

### Figure 2. Percentage Change From Baseline in Manual Muscle Testing Composite Summary Scores (at Week 14)




*One patient was excluded because they were wheelchair-bound.

### Figure 3. Percentage Change From Baseline in Overall Individualized Neuromuscular Quality of Life Questionnaire Response (at Week 14)




## Conclusions

- In this exploratory open-label study, ATYR1940 at doses up to 3 mg/kg administered once or twice every week was generally safe and well-tolerated in patients with FSHD and LGMD2B:
  - Most TEAEs were mild or moderate in intensity, and no SAEs occurred.
  - Only 1 patient experienced an IRR event, which was moderate in intensity and resolved upon treatment discontinuation.
- Although this study was not designed or powered to assess efficacy, a mean increase in MMT of 6.2% was observed in patients with LGMD2B after 12 weeks of treatment.
- These results support further investigation of ATYR1940 in patients with LGMD2B or FSHD.

### References

1. Malik A et al. *Front Neurol*. 2015;7:64; 2. Pegoraro E, Hoffman EP. Limb-Girdle Muscular Dystrophy Overview GeneReviews® 2012. https://www.ncbi.nlm.nih.gov/books/NBK1406/. Accessed 20 March 2017; 3. Tawil R et al. *Skeletal Muscle*. 2014;4:12; 4. Zhou JJ et al. *J Biol Chem*. 2014;289:16259–75; 5. Gershman A et al. Poster presented at the 21st International Congress of the World Muscle Society; 4–8 October 2016; Granada, Spain; 6. Personius KE et al. *Phys Ther*. 1994;74:253–63.

### Acknowledgements

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### Disclosures

**JV**, advisory boards: Alexion Pharmaceuticals, Ultragenyx Pharmaceuticals, Genzyme Sanofi, Sarepta, Novo Nordisk, Santhera. **TM**, speaker fees: Genzyme Corporation, Grifols; advisory boards: Amicus, Biomarin, Genzyme, Idera Pharmaceuticals, Ultragenyx; research support: Cytokinetics, Alexion, Amicus, Biomarin, Grifols, GSK, Ultragenyx, Novartis. **SI**, advisory boards: Alnylam, Genzyme. **KW**, advisory boards: Solid Biosciences, Marathon Pharma; research support: Pfizer, aTyr, Akashi, Sarepta. **GW, SS**: aTyr employees. **SA, TG, LS**: report no disclosures.

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Presented at the American Academy of Neurology Annual Meeting; 22–28 April 2017; Boston, MA, USA.