# 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): March 30, 2016

# 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 (I.R.S. Employer Identification No.)

3545 John Hopkins Court, Suite #250 San Diego, CA 92121

#### (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 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))

## Item 2.02. Results of Operations and Financial Condition.

On March 30, 2016, the Company announced financial results for the quarter and year ended December 31, 2015 in the earnings release attached hereto as Exhibit 99.1.

The information under this Item 2.02 and 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 (the "Securities Act") or the Exchange Act, except as expressly set forth by specific reference in such filing.

## Item 8.01 Other Events.

On March 30, 2016, the Company announced results from a Phase 1b/2 clinical trial evaluating Resolaris in adult FSHD (facioscapulohumeral muscular dystrophy) patients. The Company is developing Resolaris, a potential first-in-class protein therapeutic, for the treatment of rare myopathies with an immune component (RMICs). The Phase 1b/2 study was designed to evaluate the safety, tolerability, immunogenicity and pharmacokinetic (PK) profile of Resolaris in adult FSHD patients, the Company's first treated RMIC population. In addition, the study also evaluated the utility of exploratory pharmacodynamic (PD) markers (including MRI measurements to quantitate areas of potential muscle inflammation) and clinical assessments (including patient reported outcomes).

In this randomized, double-blind, placebo-controlled trial, Resolaris was studied in three dose escalation cohorts (0.3, 1.0, and 3.0 mg/kg) across four sites and 20 patients. In each cohort, patients were randomized at a ratio of 3:1 to receive Resolaris or placebo. Patients in the first two dose cohorts were dosed weekly over a period of one month, and patients in the third cohort were dosed weekly over a period of three months. As planned, the Company enrolled a total of four patients in the first cohort and eight patients in each of the second and third cohorts. For the second and third cohorts, inclusion criteria included the presence of at least one skeletal muscle in the legs identified by a non-quantitative MRI technique, which is thought to indicate inflammation. The analysis is based on data available through early March 2016.

A number of exploratory PD markers and clinical assessments were conducted to better understand their utility in FSHD. The study was not powered to demonstrate statistically significant evidence of therapeutic utility or a specific activity endpoint. As part of clinical assessments, a validated patient reported outcome measure designed specifically for neuromuscular diseases, the individualized neuromuscular quality of life (INQoL) questionnaire, was utilized in the study. The Company believes that data from this patient reported outcome measure suggest potential improvement at three months of weekly dosing at 3.0 mg/kg in this relatively small clinical trial of FSHD patients.

Results of the INQoL Overall Score are set forth in the table below:

## INQoL Overall Score <sup>1</sup> (Negative values represent improvement or less disease burden/impact on a patient)

	Change from Baseline (%) ITT Population (n=20)						
Treatment Duration Group	Placebo	0.3 mg/kg	1.0 mg/kg	3.0 mg/kg			
1 Month	4.12 (n=5) <sup>2</sup>	2.77 (n=3)	-1.22 (n=4) <sup>3</sup>	-3.78 (n=6)			
3 Months	15.55 (n=2)	NA <sup>4</sup>	NA <sup>4</sup>	-9.90 <sup>5</sup> (n=6)			

 The INQoL Overall Score is comprised of a scoring of five Life domains: Activities, Independence, Social Relationships, Emotions and Body Image. Changes were primarily observed in the categories of patient Activities, Independence and Emotions.

2) Placebo for 1 month data includes patients from all 3 dose cohorts per the aforementioned eligibility criteria.

3) INQoL Overall Score could not be calculated for two patients in the 1.0 mg/kg cohort due to unreported values.

- 4) NA is not applicable; only 1 month of dosing.
- 5) The relative improvement between placebo and the 3.0 mg/kg cohort at three months is 25.5% (p=0.03).

The proportion of patients with improved INQoL Overall Scores is set forth in the table below:

	Proportion of Patients with Improved INQoL Overall Scores						
Treatment Duration Group	Placebo	0.3 mg/kg	1.0 mg/kg	3.0 mg/kg			
1 Month	2/5	1/3	2/4	4/6			
3 Months	0/2	NA <sup>1</sup>	NA <sup>1</sup>	5/6			

1) NA is not applicable; only 1 month of dosing.

Manual muscle testing (MMT), which measures muscle strength, was performed across 15 selected muscle groups. The composite MMT score showed approximately 0.5% improvement with Resolaris compared to a 1% decline in the placebo treated patients, indicating no reportable disease progression by this technique in either placebo and test article groups after three months of weekly treatment. An exploratory MRI technique, to quantitate inflammation in a targeted lower limb muscle, did not record differences between placebo and test article groups after three months of weekly treatment. No substantial differences between the placebo and test article groups were observed after three months of weekly treatment in certain exploratory circulating PD markers, however only 2/20 patients had elevated levels above the normal range at screening.

Across all dose groups (0.3, 1.0 and 3.0 mg/kg), the Company believes the safety, tolerability, immunogenicity and PK profile of Resolaris supports advancement of Resolaris in FSHD and potentially other rare diseases. No serious adverse events were reported by study investigators. Mild to moderate adverse events were observed in both the test article and placebo treated patients. One moderate adverse event in a test article treated patient (a reversible generalized, infusion related reaction in the third cohort), which was reported by a study investigator, was reclassified to a serious adverse event by aTyr. This patient was discontinued from dosing at week 11 of the 12 weeks of treatment, but completed the study visits. The PK of Resolaris was generally well behaved across all dose cohorts and throughout the study. Anti-drug antibodies (ADAs) were confirmed in approximately 40% of the dosed patients. ADAs were of low titer and had no significant effect on PK.

aTyr intends to expand its experience with Resolaris in RMIC patients as follows:

- In adult FSHD patients by additional enrollment of patients in a new or existing clinical trial setting at a dose of 3.0mg/kg building on the data from these first three cohorts and integrating data in the fourth quarter of this year from the Company's ongoing RMIC trials.
- Continuing efforts in 2016 in the Company's ongoing trials comprising:
  - adult LGMD2B patients (the Company's first LGMD2B trial) evaluating the safety, tolerability, immunogenicity, PK, exploratory PD markers and clinical assessments of a different dosing paradigm from the study reported today;
  - adult FSHD patients (as a subset of the ongoing LGMD2B trial) evaluating the safety, tolerability, immunogenicity, PK, exploratory PD markers and clinical assessments of a different dosing paradigm from the study reported today;
  - early onset FSHD patients (potentially the most severe form of FSHD) evaluating the safety, tolerability, immunogenicity, exploratory PD markers and clinical assessments; and
  - adult FSHD patients rolled over from the study reported today in a long-term safety extension study.

### **Forward-Looking Statements**

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. 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, including statements regarding the potential of Resolaris, the ability of the Company to undertake certain development activities (such as clinical trial enrollment and the conduct of clinical trials) and accomplish certain development goals, and the timing of initiation of additional clinical trials and of reporting results from its clinical trials reflect the Company's current views about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Although the Company believes that its plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, the Company 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 the Company's control including, without limitation, risks associated with the discovery, development and regulation of the Company's Physiocrine-based product candidates, including with respect to observed results not being replicated in subsequent studies or clinical trials or such product candidates not producing therapeutic benefit or causing other unanticipated side effects, as well as those risks set forth in the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2015 and in our 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.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits	
Exhibit No.	Description
99.1	Earnings Press Release of aTyr Pharma, Inc. dated March 30, 2016

# SIGNATURES

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.

Date: March 30, 2016

# aTyr Pharma, Inc.

By: /s/ John D. Mendlein John D. Mendlein, Ph.D. Chief Executive Officer

Exhibit No.	Description
99.1	Earnings Press Release of aTyr Pharma, Inc. dated March 30, 2016



IMMEDIATE RELEASE

Contact:

Sanuj K. Ravindran, MD and Chief Business Officer sravindran@atyrpharma.com 858-223-1163

Jessica Rowlands Feinstein Kean Healthcare jessica.rowlands@fkhealth.com 202-729-4089

#### aTyr Pharma Announces Fourth Quarter 2015 Operating Results

#### Company Continues Expansion of Resolaris™ Program

SAN DIEGO – March 30, 2016 – 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 operating results for the fourth quarter and year ended December 31, 2015.

#### Fourth Quarter Results

Research and development expenses were \$12.7 million and \$4.3 million for the quarters ended December 31, 2015 and 2014, respectively. The increase of \$8.4 million was primarily due to an additional \$6.5 million related to manufacturing costs and clinical development incurred in support of various activities for Resolaris<sup>TM</sup> and a \$1.6 million increase related to compensation expenses resulting from increased headcount in research and development functions, including \$1.0 million in non-cash stock-based compensation.

The Company expects its research and development expense to continue to increase with its Resolaris franchise expansion activities, including the expanding manufacturing and clinical development of Resolaris, the first protein therapeutic development candidate from the Resokine Pathway; advancements in the development of a second program leveraging the Resokine pathway using an iMod.Fc protein therapeutic, as well as other therapeutic modalities to harness the power of the pathway in muscle or lung disease; and continued engagement in additional research and development activities relating to the therapeutic applications of Physiocrines beyond the Resokine pathway.

General and administrative expenses were \$3.8 million and \$1.7 million for the quarters ended December 31, 2015 and 2014, respectively. The increase was of \$2.1 million was due primarily to a \$1.9 million increase in personnel costs resulting from increased headcount, including \$0.3 million in non-cash stock-based compensation.

The Company expects general and administrative expenses to increase substantially to support the continued development of its product candidates and the costs associated with operating as a public company, which include supporting regulatory and listing requirements, insurance and investor relations. These increases will also include the cost of additional personnel and fees to outside consultants, among other expenses.

1

#### **Full Year Results**

Research and development expenses for the year ended December 31, 2015 and 2014 were \$34.5 million and \$16.8 million, respectively. The increase of \$17.7 million was due primarily to a \$11.4 million increase related to manufacturing costs and clinical development incurred in support of various activities for Resolaris; a \$4.1 million increase related to compensation expenses, including \$2.0 million of non-cash stock-based compensation expense; and a one-time \$1.4 million non-cash expense for the assignment of certain intellectual property rights.

General and administrative expenses were \$13.1 million and \$6.8 million for the year ended December 31, 2015 and 2014, respectively. The increase of \$6.3 million was due primarily to a \$3.8 million increase in personnel costs resulting from increased headcount, including \$1.1 million in stock-based compensation; a \$1.7 million increase in public company costs and a \$0.3 million increase in intellectual property-related projects.

Net loss for the year ended December 31, 2015 was \$48.0 million, as compared to \$24.4 million for the same period in 2014.

As of December 31, 2015, the number of shares outstanding was 23.7 million and the Company had cash, cash equivalents and investments totaling \$125.3 million.

#### 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 modulators. The Company's lead candidate, Resolaris<sup>TM</sup>, is a potential first-in-class intravenous protein therapeutic for the treatment of rare myopathies with an immune component. Resolaris is currently in a Phase 1b/2 clinical trial in adult patients with facioscapulohumeral muscular dystrophy (FSHD); a Phase 1b/2 trial in adult patients with limb-girdle muscular dystrophy 2B (LGMD2B or dysferlinopathy) or FSHD; and a Phase 1b/2 trial in patients with an early onset form of FSHD. To protect this pipeline, aTyr built an intellectual property estate comprising over 70 issued or allowed patents and over 240 pending patent applications that are solely owned or exclusively licensed by aTyr. aTyr's key programs are currently focused on severe, rare diseases characterized by immune dysregulation 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 of Resolaris or iMod.Fc, the ability of the Company to undertake certain development activities (such as clinical trial enrollment and the conduct of clinical trials) and accomplish certain development goals, and the timing of initiation of additional clinical trials 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, 2015 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, fu

3

# ATYR PHARMA INC. Condensed Consolidated Statements of Operations (in thousands, except share and per share data)

	Three Months Ended December 31,		Years Ended December 31,					
		2015		2014		2015		2014
Operating expenses:								
Research and development	\$	12,670	\$	4,341	\$	34,504	\$	16,777
General and administrative		3,813		1,689		13,112		6,777
Total operating expenses		16,483		6,030		47,616		23,554
Loss from operations		(16,483)		(6,030)		(47,616)		(23,554)
Other income (expenses), net		(10)		(8)		(357)		(796)
Net loss		(16,493)		(6,038)		(47,973)		(24,350)
Accretion to redemption value of redeemable convertible preferred stock		<u> </u>	_	<u> </u>		(15)		(416)
Net loss attributable to common stockholders	\$	(16,493)	\$	(6,038)	\$	(47,988)	\$	(24,766)
Net loss per share attributable to common stockholders, basic and diluted	\$	(0.70)	\$	(7.04)	\$	(3.03)	\$	(29.69)
Weighted average shares outstanding, basic and diluted		23,603,661		857,269		15,838,353		834,221

# ATYR PHARMA INC. Condensed Consolidated Balance Sheets

(in thousands)

	De	ecember 31, 2015	December 31, 2014	
Cash, cash equivalents and investments	\$	125,349	\$	15,853
Other assets		2,533		1,925
Property and equipment, net		1,793		2,866
Total assets	\$	129,675	\$	20,644
Accounts payable, accrued expenses and other liabilities	\$	9,483	\$	5,759
Current portion of commercial bank debt		3,366		3,134
Convertible promissory note				2,000
Commercial bank debt, net of current portion		1,776		5,142
Redeemable convertible preferred stock				95,619
Stockholders'equity (deficit)		115,050		(91,010)
Total liabilities and stockholders' equity (deficit)	\$	129,675	\$	20,644

