# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 6-K
REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13A-16 OR 15D-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934
Dated October 31, 2019
Commission File Number 001-36421
AURINIA PHARMACEUTICALS INC. (Exact name of Registrant as specified in its charter)
N/A (Translation of Registrant's Name)
#1203-4464 Markham Street Victoria, British Columbia V8Z7X8 (250) 708-4272 (Address and telephone number of registrant's principal executive offices)
Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F □ Form 40-F ⊠
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): □
Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission sursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.
Yes ⊠ No □
This Form 6-K is hereby filed and incorporated by reference in the registrant's Registration Statement on Form F-10 (File No. 333-222413).

## **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, thereunto duly authorized.

Dated: October 31, 2019

## Aurinia Pharmaceuticals Inc.

By: /s/ Peter S. Greenleaf

Name: Peter S. Greenleaf Title: Chief Executive Officer

### EXHIBIT INDEX

# Exhibit Description of Exhibit 99.1 News Release - AURINIA ANNOUNCES INITIATION OF PATIENT DOSING IN PHASE 2/3 AUDREY™ CLINICAL TRIAL FOR DRY EYE SYNDROME

Exhibit 99.1 included with this report on Form 6-K is hereby incorporated by reference as exhibits to the Registration Statement on Form F-10 of Aurinia Pharmaceuticals Inc. (File No. 333-222413), as amended or supplemented.

# Aurinia Announces Initiation of Patient Dosing in Phase 2/3 AUDREY<sup>TM</sup> Clinical Trial for Dry Eye Syndrome

- Voclosporin ophthalmic solution (VOS) AUDREY trial results anticipated in the second half of 2020 -

VICTORIA, British Columbia--(BUSINESS WIRE)--October 31, 2019--Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX:AUP) ("Aurinia" or the "Company"), a late-stage clinical biopharmaceutical company focused on advancing voclosporin across multiple inflammatory and autoimmune conditions, today announced the initiation of patient dosing in the Phase 2/3 AUDREY<sup>TM</sup> clinical trial evaluating voclosporin ophthalmic solution ("VOS") for the potential treatment of dry eye syndrome ("DES").

"Based upon the impressive results seen with VOS in the head-to-head exploratory Phase 2a study against cyclosporin A, we are focused on rapidly advancing this promising treatment for those who suffer from dry eye syndrome," commented Peter Greenleaf, President and Chief Executive Officer of Aurinia. "Through the Phase 2/3 AUDREY trial, we will generate important dose-ranging and clinical data aimed at bringing VOS towards registration and commercialization."

The AUDREY trial is a randomized, double-masked, vehicle-controlled, dose-ranging study evaluating the efficacy and safety of VOS in subjects with DES. A total of approximately 480 subjects are expected to be enrolled. The study will consist of four arms with a 1:1:1:1 randomization schedule, in which patients will receive either 0.2% VOS, 0.1% VOS, 0.05% VOS or vehicle, dosed twice daily for 12 weeks. The primary outcome measure for the trial is the proportion of subjects with a 10mm improvement in Schirmer Tear Test ("STT") at four weeks. Secondary outcome measures will include STT at other time points, Fluorescein Corneal Staining ("FCS") at multiple time points, change in eye dryness, burning/stinging, itching, photophobia, eye pain and foreign body sensation at multiple time points, and additional safety endpoints. Top-line results from the AUDREY clinical study are anticipated during the second half of 2020.

"Despite available therapies, DES continues to have a significant impact on individuals affected. We are encouraged by the efficacy data we saw in our exploratory study which demonstrated rapid and statistical superiority versus the current standard of care on objective signs of DES," stated Neil Solomons, M.D., Chief Medical Officer at Aurinia. "Based on these data, the Company has gained confidence that VOS represents a potential best-in-class calcineurin inhibitor for DES."

In January of 2019, Aurinia reported Phase 2 results demonstrating that VOS (voclosporin 0.2%) administered twice daily was superior to cyclosporin A 0.05% (Restasis®) administered twice daily across all objective endpoints including FCS and STT. This statistical superiority was observed after two weeks of dosing. The exploratory study also showed no statistically significant nor clinically meaningful difference in drop discomfort, as measured by drop discomfort scores at one and five minutes after first application, between VOS 0.2% and cyclosporin A 0.05%.

Joseph Tauber, M.D., practicing ophthalmologist and founder of the Tauber Eye Center, Kansas City, MO, commented, "To the best of my knowledge, the Phase 2 results reported by Aurinia earlier this year represent the first double-masked, randomized, head-to-head study to show objective superiority over an active comparator for DES."

#### **About Aurinia**

Aurinia Pharmaceuticals is a late clinical-stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company is currently developing the investigational drug, voclosporin, for the treatment of lupus nephritis ("LN"), focal segmental glomerulosclerosis ("FSGS"), and DES. The Company's head office is in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at www.auriniapharma.com.

#### About Voclosporin

Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor ("CNI") with clinical data in over 2,600 patients across indications. Voclosporin is an immunosuppressant, with a synergistic and dual mechanism of action. By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses and stabilizes the podocyte in the kidney. It has been shown to have a more predictable pharmacokinetic and pharmacodynamic relationship (potentially requires no therapeutic drug monitoring), an increase in potency (vs cyclosporin), and an improved metabolic profile compared to legacy CNIs. Aurinia anticipates that upon regulatory approval, patent protection for voclosporin will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027 under the *Hatch-Waxman Act* and comparable laws in other countries and until April 2028 with anticipated pediatric extension. Further, the new Notice of Allowance is expected to result in the issuance of a U.S. patent with a term extending to December 2037. If the FDA approves the use of voclosporin for LN and the label for such use follows the dosing protocol under the Notice of Allowance, the issuance of this patent will expand the scope of intellectual property protection for voclosporin to December 2037.

#### About Voclosporin ophthalmic solution (VOS)

Voclosporin ophthalmic solution ("VOS") is an aqueous, preservative free nanomicellar solution intended for use in the treatment of DES. A Phase 2a study was recently completed with results released in January of 2019. Previously, a Phase 1 study with healthy volunteers and patients with DES was also completed as were studies in rabbit and dog models. VOS has IP protection until 2031.

#### About DES

Dry eye syndrome ("DES") is characterized by irritation and inflammation that occurs when the eye's tear film is compromised by reduced tear production, imbalanced tear composition, or excessive tear evaporation. The impact of DES ranges from subtle, yet constant eye irritation to significant inflammation and scarring of the eye's surface. Discomfort and pain resulting from DES can reduce quality of life and cause difficulty reading, driving, using computers and performing daily activities. DES is a chronic disease estimated to affect more than 16 million people in the United States. There are multiple FDA approved therapies for the treatment of dry eye; however, there is opportunity for potential improvements in the effectiveness, tolerability, and onset of action.

#### Forward-Looking Statements

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: the ability to fully-enroll and report top-line results from the AUDREY clinical trial during the second half of 2020, and the number of subjects expected to be enrolled; voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity and that Aurinia has sufficient financial resources to fund existing DES programs, including AUDREY. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "anticipate", "will", "believe", "estimate", "expect", "intend", "target", "plan", "goals", "objectives", "may" and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the market value for the DES program; that another company will not create a substantial competitive product for Aurinia's DES business without violating Aurinia's intellectual property rights; the burn rate of Aurinia's cash for operations; the costs and expenses associated with Aurinia's clinical trials; the planned studies achieving positive results; Aurinia being able to extend and protect its patents on terms acceptable to Aurinia; and the size of the DES market. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: difficulties, delays, or failures we may experience in the conduct of our clinical trial; difficulties we may experience in completing the development and commercialization of voclosporii; the market for the DES business may not be as estimated; Aurinia may have to pay unanticipated expenses; estimated costs for clinical trials may be underestimated, resulting in Aurinia having to make additional expenditures to achieve its current goals; Aurinia not being able to extend or fully protect its patent portfolio for voclosporin and voclosporin ophthalmic solution; and competitors may arise with similar products. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

Except as required by law, Aurinia will not update forward-looking information. All forward-looking information contained in this press release is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business can be found in Aurinia's most recent Annual Information Form available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar.

We seek Safe Harbor.

# **Contacts**

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