# 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 August 22, 2016

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 [ X ]
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 pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes [ X ] No [ ]

This Form 6-K is hereby filed and incorporated by reference in the Registrant's Registration Statement on Form F-10 (File No. 333-206994).

# **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: August 22, 2016.

# Aurinia Pharmaceuticals Inc.

By: <u>/s/ Michael R. Martin</u>
Name: Michael R. Martin
Title: Chief Operating Officer

# **EXHIBIT INDEX**

# **Exhibit Description of Exhibit**

99.1 Material Change Report dated August 22, 2016

Exhibit 99.1 included with this report on Form 6-K is hereby incorporated by reference as an exhibit to the Registrant's Registration Statement on Form F-10 (File No. 333-206994), as amended or supplemented.

# FORM 51-102F3 Material Change Report

# Item 1 Name and Address of Company

Aurinia Pharmaceuticals Inc. (the "Company") #1203-4464 Markham Street Victoria, BC A1 V8Z 7X8

# Item 2 Date of Material Change

August 15, 2016

#### **Item 3 News Release**

A news release was issued and disseminated by the Company through Business Wire on August 15, 2016.

# **Item 4 Summary of Material Change**

The Company announced positive top-line results from the Phase 2b AURA-LV ("AURA") clinical study in patients with active lupus nephritis ("LN"). The trial achieved its primary endpoint, demonstrating statistically significantly greater complete remission ("CR") (as defined by confirmed urinary protein/creatinine ratio of ≤0.5 mg/mg at 24 weeks and confirmed at 26 weeks) in patients treated with 23.7 mg of voclosporin twice daily (p=0.045). Both treatment arms, 23.7 mg and 39.5 mg twice daily also showed a statistically significant improvement in the rate of achieving partial remission ("PR") at 24 weeks (p=0.007; p=0.024). Each arm of the study included the current standard of care of mycophenolate mofetil ("MMF") as background therapy and a forced steroid taper to 5 mg/day by week 8 and 2.5 mg by week 16. No unexpected safety signals were observed and voclosporin was shown to be well tolerated.

#### Item 5 Full Description of Material Change

The Company announced positive top-line results from the AURA clinical study in patients with active LN. The trial achieved its primary endpoint, demonstrating statistically significantly greater CR (as defined by confirmed urinary protein/creatinine ratio of  $\leq$ 0.5 mg/mg at 24 weeks and confirmed at 26 weeks) in patients treated with 23.7 mg of voclosporin twice daily (p=0.045). Both treatment arms, 23.7 mg and 39.5 mg twice daily also showed a statistically significant improvement in the rate of achieving PR at 24 weeks (p=0.007; p=0.024). Each arm of the study included the current standard of care of MMF as background therapy and a forced steroid taper to 5 mg/day by week 8 and 2.5 mg by week 16. No unexpected safety signals were observed and voclosporin was shown to be well tolerated.

Based on the results of the 24-week analysis, Aurinia plans to meet with the U.S. Food and Drug Administration in the fourth quarter of 2016 to discuss these data and the drug's subsequent clinical development and path to registration in LN. Further analyses of the data will also be conducted and will be released later this year. Additionally, the

Company plans to submit the results for presentation at a major medical meeting in the near future. The study will continue through 48 weeks, and these data will be available for release in early 2017.

#### AURA-LV Trial Design

The AURA-LV study or "Aurinia Urine Protein Reduction in Active Lupus Nephritis Study" compared the efficacy of voclosporin added to current standard of care of mycophenolate mofetil (MMF, also known as CellCept®) against standard of care with placebo in achieving CR in patients with active LN. It enrolled 265 patients at centers in over 20 countries worldwide. On entry to the study, patients were required to have a diagnosis of LN according to established diagnostic criteria (American College of Rheumatology) and clinical and biopsy features indicative of highly active nephritis.

Patients were randomized to one of two dosage groups of voclosporin (23.7 mg BID and 39.5 mg BID) or placebo, with all patients also receiving mycophenolate mofetil and oral corticosteroids as background therapy. All patients had an initial IV dose of steroids (500-1000 mg) and then were started on 20-25 mg/daily, which was tapered down to a low dose of 5 mg daily by week 8 and 2.5 mg daily by week 16.

The primary endpoint was a measure of the number of patients who achieved CR at 24 weeks (confirmed at 26 weeks); CR was defined as a protein/creatinine ratio of  $\leq 0.5$  mg/mg as well as normal stable renal function (eGFR  $\geq 60$  mL/min/1.73m2 or no confirmed decrease from baseline in eGFR of  $\geq 20\%$ .).

Secondary endpoints included durability of remission, CR as per the primary analysis at 48-weeks and extra-renal lupus activity (SLEDAI), which will be evaluated and reported at a later date.

#### Summary of Results

The groups were generally well-balanced for age, gender and race, however when considered together, the proteinuria and GFR data suggest that disease severity was greater for the low-dose voclosporin group.

#### **Efficacy**

- The primary endpoint of CR was met for the low-dose voclosporin group in the ITT analysis (p=0.045). 32.6% of patients on low dose achieved CR, compared to 27.3% on high dose and 19.3% in the control arm.
  - o The odds ratio indicates that patients were twice as likely to achieve CR at 24 weeks compared to the control arm (OR=2.03).
  - o The primary endpoint was re-analyzed using the 24-hour urine data in place of First Morning Void collections, confirming the finding that patients were twice as likely to achieve CR at 24 weeks compared to the control arm (p=0.047; OR=2.12).
- Both voclosporin groups had a significantly faster time to CR (UPCR ≤ 0.5 mg/mg) than the control arm. Results of time to CR for co-variate analyses were broadly consistent with overall efficacy rates in those sub-groups.

- The secondary endpoint of PR (50% reduction in UPCR over baseline) was met for both voclosporin groups in the ITT analysis with 69.7% of patients on low dose achieving PR (p=0.007) and 65.9% in the high dose group (p=0.024). 49.4% of patients in the control arm achieved PR.
- Time to PR was similar (4 weeks) in the two voclosporin groups and was shorter than what was observed in the control group (6.6 weeks).

#### Safety

- The overall rate of adverse events ("AEs") was similar across all groups.
- The overall rate of serious adverse events ("SAEs") was higher in both voclosporin groups but the nature of SAEs is consistent with highly active LN.
- The overall pattern of AEs and SAEs was consistent with that observed in other LN studies.

  There were 13 deaths across the trial: (2) in the high-dose voclosporin arm; (10) in the low-dose voclosporin arm; and (1)
- in the control arm, with the majority of overall deaths (11/13) occurring in Asia. All deaths were assessed by the Investigator as being unrelated to study treatment. No dose relationship was observed for the deaths.

# **Item 5.2 Disclosure of Restructuring Transactions**

Not applicable.

# Item 6 Reliance on subsection 7.1(2) of National Instrument 51-102

Not applicable.

# **Item 7 Omitted Information**

No significant facts remain confidential in, and no information has been omitted from, this report.

#### **Item 8 Executive Officer**

For further information, please contact:

Mr. Michael R. Martin, Chief Operating Officer 250-415-9713 mmartin@auriniapharma.com

# **Item 9 Date of Report**

August 22, 2016

#### Forward-looking Statements

This material change report contains forward-looking statements, including statements related to the Company's regulatory strategy (including plans to meet with the U.S. Food and Drug Administration to discuss these data and the voclosporin's subsequent clinical development and path to registration in LN), the Company's analysis, assessment and conclusions of the results of the AURA-LV clinical study, and the efficacy and commercial potential of voclosporin. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "plans," "intends," "may," "will," "believe," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company's current expectations. Forwardlooking statements involve risks and uncertainties, the Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risk that the Company's analyses, assessment and conclusions of the results of the AURA-LV clinical study set forth in this release may change based on further analyses of such data, and the risk that the Company's clinical studies for voclosporin may not lead to regulatory approval. These and other risk factors are discussed under "Risk Factors" and elsewhere in the Company's Annual Information Form for the year ended December 31, 2015 filed with Canadian securities authorities and available at www.sedar.com and on Form 40-F with the U.S. Securities Exchange Commission and available at www.sec.gov, each as updated by subsequent filings, including filings on Form 6-K. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.