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

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# 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): December 9, 2021**

# Aurinia Pharmaceuticals Inc.

**(Exact name of registrant as specified in its charter)**

| **Canada** | **001-36421** | **46-4129078** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File No.)** | **(IRS Employer Identification No.)** |

**#1203-4464 Markham Street**
**Victoria, British Columbia**
**V8Z 7X8**
**(250) 708-4272**
**(Address and telephone number of registrant's principal executive offices)**

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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))

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 Shares, without par value | AUPH | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 December 9, 2021, Aurinia Pharmaceuticals Inc. announced positive topline results from the AURORA 2 continuation study evaluating the long-term safety and tolerability of LUPKYNIS™ (voclosporin) for the treatment of adults with active lupus nephritis (LN), a serious complication in patients with systemic lupus erythematosus (SLE). In combination with background immunosuppressive therapy, LUPKYNIS is the first and only FDA-approved medicine with three years of pivotal trial results, including long-term safety data, within LN.

**Highlights of topline results from AURORA 2:**

- In the 116 subjects in the voclosporin-treated group who enrolled in AURORA 2, mean estimated glomerular filtration rate (eGFR) was stable over 36 months.
  - Compared to the active control group, the voclosporin-treated group showed an increase from baseline eGFR at the end of the studies of +2.7 mL/min.
- The drug was well tolerated with no unexpected safety signals observed. There were comparable serious adverse events (SAEs) rates in both arms (19% voclosporin vs. 24% control).
- The active control group had a higher percentage of withdrawals compared to the voclosporin-treated group, 15.0% vs. 12.9% respectively.
- There were 4 deaths during AURORA 2 in the active control group, none in the voclosporin-treated group.
- The mean Urine Protein Creatinine Ratio (UPCR) was lower in the voclosporin-treated groups at all time points during the three years.

**AURORA 2 Study Design**
AURORA 2 (NCT03597464) is a Phase 3 randomized, double-blind, placebo-controlled clinical trial to assess the long-term safety and tolerability of voclosporin, in addition to MMF/steroids. Patients who completed 12 months of treatment in the Phase 3 AURORA 1 study were eligible to enroll in the AURORA 2 continuation study with the same randomized treatment of voclosporin at 23.7 mg twice daily or placebo, in combination with MMF at 1 g twice daily with low-dose oral steroids, for up to an additional 24 months. A total of 216 LN patients out of 357 who were enrolled in the AURORA 1 study continued into AURORA 2, with 116 patients in the voclosporin group and 100 patients in the control group. 90 and 78 patients, respectively, received 36 months of total treatment at the completion of the study. Results from the completed Phase 3 randomized, double-blind, placebo-controlled, multicenter AURORA 1 study (NCT03021499) were recently published in *The Lancet.*

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached 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, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

The information contained in Exhibit 99.1 is summary information that is intended to be considered in the context of our Securities and Exchange Commission filings and other public announcements that we may make, by press release or otherwise, from time to time. We undertake no duty or obligation to publicly update or revise such information, except as required by law.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Aurinia Investor Presentation dated December 9, 2021 |
| 104 | Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document) |

**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: December 9, 2021

**AURINIA PHARMACEUTICALS INC.**

By: /s/ *Stephen P. Robertson*
Name: Stephen P. Robertson
Title: EVP, General Counsel, Corporate Secretary and Chief Compliance Officer

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# CLINICAL PROGRAM UPDATE

AURORA 2 / voclosporin

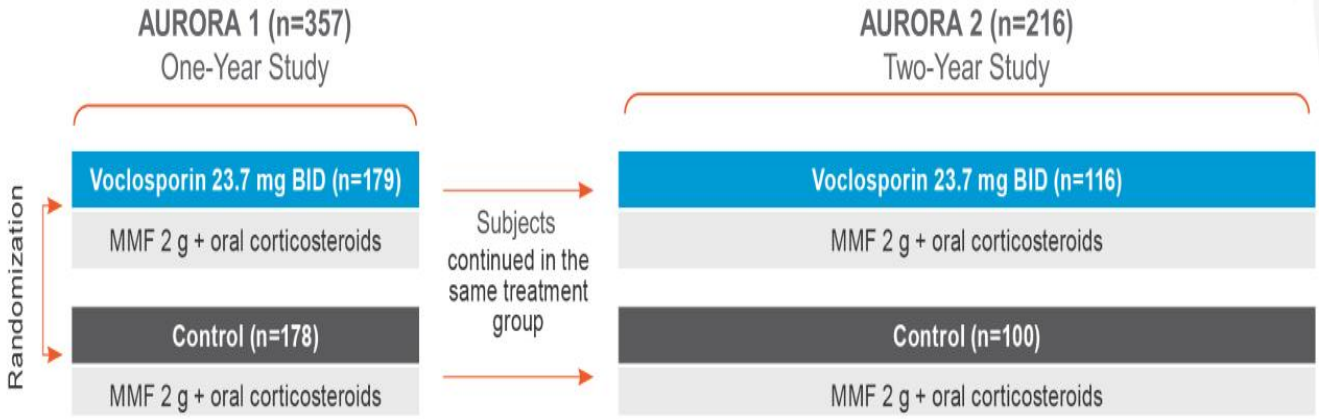
December 9, 2021

# AURORA 2 Readout Results

**AURORA 2 demonstrated a favorable risk/benefit profile over a three-year period, with safety comparable to AURORA 1, and sustained efficacy**

# AURORA 2 Study Design

- AURORA 2 is a Phase 3, global, double-blind, two-year continuation study of AURORA 1 evaluating voclosporin compared to placebo, in combination with MMF and low-dose steroids, in subjects with lupus nephritis
- This final analysis of AURORA 2 subjects includes integrated data from AURORA 1 and AURORA 2 with up to 36 months of total exposure



# AURORA 2 Demographics

| | Placebo n=% (n=100) | Voclosporin n=% (n=116) |
|---|---|---|
| **Age, years** | | |
| Mean (SD) | 11.64 (35.4) | 10.31 (32.3) |
| **Sex, n (%)** | | |
| Female | 88.0 (88) | 90.5 (105) |
| Male | 12.0 (12) | 9.5 (11) |
| **Race, n (%)** | | |
| White | 40.0 (40) | 37.9 (44) |
| Asian | 30.0 (30) | 25.9 (30) |
| Black | 7.0 (7) | 15.5 (18) |
| Other | 23.0 (23) | 20.7 (24) |
| **Biopsy class, n (%)** | | |
| Pure Class III or IV | 58.0 (58) | 67.2 (78) |
| Pure Class V | 14.0 (14) | 14.7 (17) |
| Mixed Class V | 28.0 (28) | 18.1 (21) |
| **Region, n (%)** | | |
| North and Latin America | 36.0 (36) | 42.2 (49) |
| Europe and South Africa | 37.0 (37) | 32.8 (38) |
| Asia | 27.0 (27) | 25.0 (29) |

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AURORA 2 subject characteristics at pre-treatment baseline of AURORA 1.

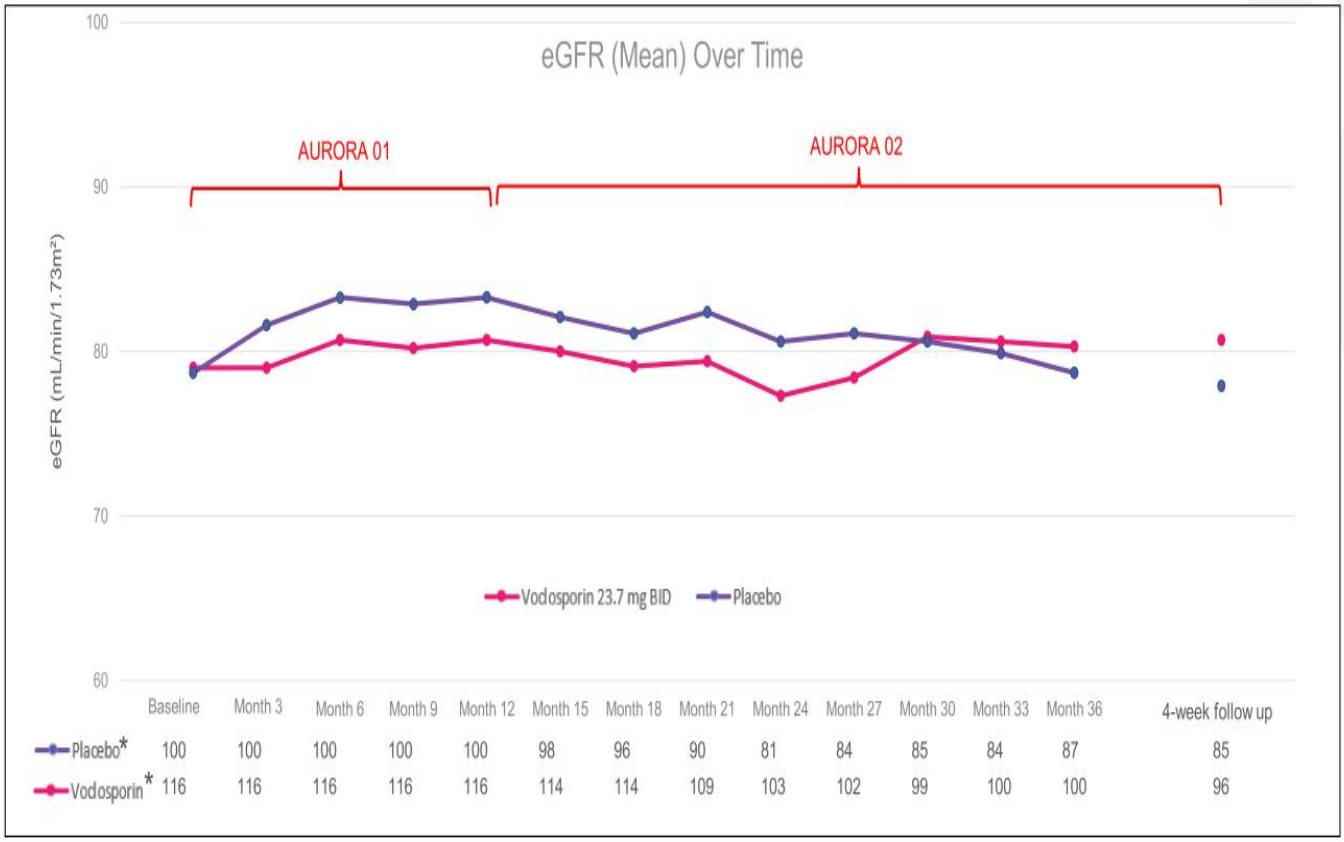
# AURORA 2 Clinical Characteristics

| | Placebo n=% (n=100) | Voclosporin n=% (n=116) |
|---|---|---|
| **Corrected* eGFR, mL/min/1.73 $m^2$, mean (SD)** | | |
| AURORA 1 Baseline | 16.58 (78.7) | 15.05 (79.0) |
| AURORA 2 Baseline (Month 12) | 12.61 (83.3) | 13.53 (80.7) |
| **UPCR, mg/mg, mean (SD)** | | |
| AURORA 1 Baseline | 2.4764 (3.868) | 2.5766 (3.941) |
| AURORA 2 Baseline (Month 12) | 1.640 (1.47) | 1.363 (0.86) |
| **AURORA 2 Baseline (Month 12) oral steroid dose** | | |
| Mean (SD), mg/day | 4.1104 (3.395) | 3.3456 (2.942) |
| ≤2.5 mg/day, n (%) | 85.0 (85) | 87.9 (102) |

AURORA 2 subject characteristics at pre-treatment baseline of AURORA 1 and baseline of AURORA 2.

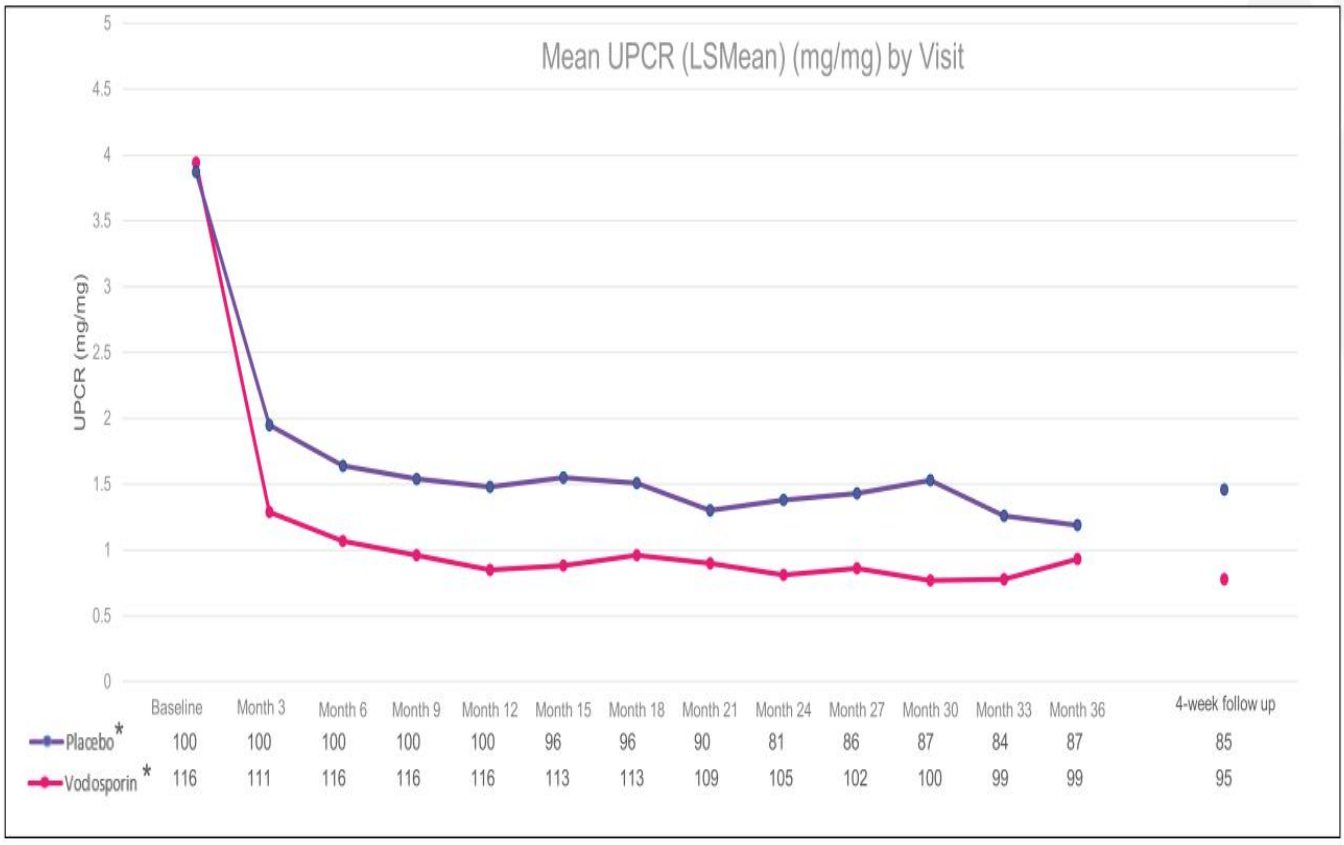
*Renal function assessed with corrected eGFR (Chronic Kidney Disease Epidemiology Collaboration equation) using a prespecified ceiling of 90 mL/min/1.73 $m^2$.

# Corrected eGFR (mL/min/1.73m², mean) Over Time




* Number of patients in study arm

# Mean UPCR by visit




* Number of patients in study arm

# Summary of AURORA 2 Adverse Events (AEs)

| | Placebo (N = 100) | Voclosporin (N = 116) |
|---|---|---|
| | % (n) | % (n) |
| | | |
| Any AE | 83.0 (83) | 88.8 (103) |
| Treatment-Related AE | 25.0 (25) | 27.6 (32) |
| Serious AE | 24.0 (24) | 19.0 (22) |
| Treatment-Related Serious AE | 2.0 (2) | 0.9 (1) |
| AE Leading to voclosporin/Placebo Discontinuation | 18.0 (18) | 10.3 (12) |
| Deaths | 4.0 (4) | 0 |
| Disease-Related AE | 43.0 (43) | 51.7 (60) |
| Disease-Related Serious AE | 13.0 (13) | 6.9 (8) |

# AURORA 2 Readout Results

**AURORA 2 demonstrated a favorable risk/benefit profile over a three-year period, with safety comparable to AURORA 1, and sustained efficacy**

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# Thank you