

March 18, 2016



# Aurinia Reports Fourth Quarter and Full Year 2015 Financial Results and Recent Operational Highlights

VICTORIA, British Columbia-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH)(TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the fourth quarter and year ended December 31, 2015. Amounts, unless specified otherwise, are expressed in U.S. dollars.

## Recent operational highlights

### **Aura-LV (AURA) Phase 2b clinical trial update- Patient enrollment completed**

On January 19, 2016, the Company announced completion of patient enrollment of its AURA (**A**urinia **U**rinary protein **R**eduction in **A**ctive lupus nephritis or AURA) clinical trial at 265 patients (target 258 patients). This Phase 2b trial, is a randomized, controlled, double-blind study comparing the efficacy of voclosporin as a component of multi-targeted therapy against placebo in achieving remission in patients with active lupus nephritis (LN). AURA is one of the largest prospective registration-quality studies ever conducted within this specific disease area.

The AURA trial has been designed to demonstrate that voclosporin can induce a rapid and sustained reduction of proteinuria with extremely low steroid exposure. The placebo-controlled trial assesses two doses of voclosporin, with all patients receiving background therapy of mycophenolate mofetil (MMF) coupled with an aggressive oral corticosteroid taper. There will be a primary analysis to determine complete remission at week 24 (confirmed at 26 weeks) and various secondary analyses at both 24 and 48 weeks which include biomarkers and markers of non-renal lupus. This disease has shown to be particularly difficult to treat with fewer than 20% of patients achieving clinical remission at six months on existing regimens which often require unacceptably high steroid exposure in this predominantly young, female population.

### **AURION study update**

On February 8, 2016 the Company announced that it had completed a preliminary analysis of its AURION (Aurinia early Urinary protein Reduction Predicts Response) study. In the first seven patients that have reached at least eight weeks of therapy in the AURION study, 100% (7/7) have achieved at least a 25% reduction in proteinuria compared to study entry. A 25% reduction in proteinuria has been shown to be predictive of a positive clinical response at 24 weeks. All of the other pre-specified eight week biomarkers of

active lupus nephritis (LN) have also improved and are trending towards normalization. These biomarkers have also been shown to be predictive of positive clinical response rates at 24 weeks.

In the first eight weeks of a 48 week regimen of multi-target therapy including voclosporin in AURION, an overall mean reduction of proteinuria of 72% compared to pre-treatment levels was observed, and 57% (4/7) of these patients achieved complete remission as defined by a urinary protein creatinine ratio of  $\leq 0.5\text{mg/mg}$ . Overall renal function as measured by eGFR in these patients has remained stable.

The AURION study is an open label, single arm, exploratory study assessing the ability of biomarkers at 8 weeks to predict clinical response rates at 24 and 48 weeks in subjects taking voclosporin 23.7mg twice daily in combination with standard of care, mycophenolate mofetil and corticosteroids, in patients with active LN. It is the first ever trial with voclosporin in this patient population and supports the Company's hypothesis that utilizing a multi-targeted approach with voclosporin may help LN patients.

### **FDA Fast Track**

On March 2, 2016 the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for *voclosporin*, the Company's next generation calcineurin inhibitor, for the treatment of LN.

The Fast Track program was created by the FDA to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address significant unmet medical needs. Compounds that receive this FDA designation benefit from more frequent meetings and communications with the FDA to review the drug's development plan including the design of clinical trials and the use of biomarkers to support approval. Additionally, Fast Track designation allows the Company to submit parts of the New Drug Application (NDA) on a rolling basis for review as data becomes available. The Company expects to analyse and review the AURA data with the FDA later in 2016 in order to determine the appropriate next steps.

### **Looking forward – Expected upcoming milestone**

Un-blinding and disclosure of the primary AURA trial data is scheduled within approximately one month of the last enrolled patient completing 24 weeks of active treatment. Therefore, the Company expects that the primary end-point results of the AURA trial will be released in the third quarter ended September 30, 2016.

### **Financial results for the year ended December 31, 2015**

The Company made significant progress with its ongoing AURA trial in 2015 with patient enrollment completed early in 2016. Activities focused on the recruitment, enrollment and treatment of patients with lupus nephritis (LN). Over 90 sites are set up in 20 countries worldwide. The Company also made progress with its AURION study in Malaysia with eight week data released on the first seven patients as noted above.

For the year ended December 31, 2015, the Company recorded a consolidated net loss of \$18.6 million or \$0.58 per common share, as compared to a consolidated net loss of \$19.4 million or \$0.67 per common share in 2014.

The change was primarily attributable to an increase of \$6.9 million in research and development costs offset by a change of \$7.9 million in the derivative warrant liability to a gain of \$5.1 million for the year ended December 31, 2015 compared to a loss of \$2.8 million in 2014. In addition the 2014 comparative figure reflected a gain on extinguishment/re-measurement of warrant liability of \$2.8 million. There was no similar item in 2015.

After adjusting for the non-cash impact of the revaluation of the derivative warrant liability, the net loss from operations for the year ended December 31, 2015 was \$23.7 million compared to \$16.6 million for the corresponding period in 2014.

The Company incurred net research and development expenditures of \$16.0 million for the year ended December 31, 2015, as compared to \$9.1 million for the same period in 2014. Research and development expenditures increased year over year as the number of patients enrolled in the trial increased substantially in 2015. Research and development expenditures in 2015 reflected higher costs related primarily to drug distribution, patient recruitment, enrollment and treatment activities associated with the AURA trial compared to the same period in 2014. AURA trial costs are forecast to decrease in 2016 as patients complete the trial.

The Company incurred corporate, administration and business development expenditures of \$6.3 million for the year ended December 31, 2015, as compared with \$6.9 million for the same period in fiscal 2014. Corporate, administration and business development expense in 2015 included \$2.4 million of non-cash stock option compensation expense related to the issuance of stock options compared to \$1.9 million of non-cash stock option compensation expense in 2014.

Other expense (income) reflected expense of \$128,000 for the year ended December 31, 2015 compared to other income of \$1.7 million for 2014. The change was primarily due to the Company recording in 2014 a non-cash gain of \$2.8 million on extinguishment and re-measurement of warrant liability initially recorded upon the completion of the private placement on February 14, 2014. There was no similar item in 2015. The Company also recorded as other expense, a revaluation adjustment on contingent consideration to ILJIN Life Science Co., Ltd. in the amount of \$337,000 in 2015 compared to \$848,000 in 2014.

### **Financial results for the fourth quarter ended December 31, 2015**

The Company reported a consolidated net loss of \$4.1 million or \$0.13 per common share for the three months ended December 31, 2015, as compared to a consolidated net loss of \$6.4 million or \$0.20 per common share for the three months ended December 31, 2014.

The decrease in the consolidated net loss was primarily attributable to recording a fair value adjustment gain on derivative warrant liability of \$1.5 million in the fourth quarter of 2015 versus of loss of \$1.4 million in the comparable period in 2014.

Research and development expenditures increased to \$3.7 million in the fourth quarter of 2015, compared to \$3.1 million in the fourth quarter of 2014 resulting from the progression of the AURA trial and the AURION study during 2015.

Corporate and administration expenses were \$1.6 million for the fourth quarter of 2015, compared to \$1.4 million for the fourth quarter of 2014.

## **Financial Liquidity**

The Company had cash, cash equivalents and short term investments of \$15.8 million as at December 31, 2015. Aurinia believes its financial resources should be sufficient to finance the AURA trial, the AURION study and corporate costs until approximately December 31, 2016. However, future cash requirements could vary from current estimates due to a number of factors including the costs associated with its AURA trial.

The audited financial statements and the Management's Discussion and Analysis for the year ended December 31, 2015, are accessible on Aurinia's website at [www.auriniapharma.com](http://www.auriniapharma.com) or on SEDAR at [www.sedar.com](http://www.sedar.com) or on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

## **About Aurinia**

Aurinia is a clinical stage pharmaceutical company focused on the global nephrology market. The fully-enrolled AURA clinical trial is evaluating the efficacy of its lead drug, voclosporin, as a treatment for active LN. LN is an inflammation of the kidneys, that if inadequately treated can lead to end-stage renal disease, making LN a serious and potentially life-threatening condition.

Voclosporin is a novel and potentially best-in-class calcineurin inhibitor ("CNI") with extensive clinical data in over 2,000 patients in other indications. Voclosporin is made by a modification of a single amino acid of the cyclosporine molecule (a CNI approved for use in transplant patients since 1983). This modification results in a more predictable pharmacokinetic and pharmacodynamic relationship, an increase in potency vs. cyclosporine, an altered metabolic profile, and potential for flat dosing.

## **About AURA:**

The AURA trial is an adequate and well-controlled clinical trial that enrolled 265 patients and is being conducted in over 20 countries worldwide. This trial will compare the efficacy of voclosporin against placebo in achieving remission in patients with active lupus nephritis. The AURA trial designed to demonstrate that voclosporin can induce a rapid and sustained reduction of proteinuria in the presence of extremely low steroid exposure. It will compare two dosage groups of voclosporin (23.7mg and 39.5mg) compared to placebo, with all patients receiving mycophenolate mofetil (MMF) and oral corticosteroids as background therapy. There will be a primary analysis to determine complete remission at week 24 (confirmed at 26 weeks) and various secondary analyses at week 48 which include biomarkers and markers of non-renal SLE.

## **About AURION:**

The AURION study is an open label, exploratory study being conducted at two sites in Malaysia to assess the short term predictors of response using voclosporin (23.7mg) in combination with mycophenolate mofetil and oral corticosteroids in patients with active lupus nephritis. This study will examine biomarkers of disease activity at 8 weeks and their ability to predict response at 24 and 48 weeks.

*We seek Safe Harbor.*

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Aurinia Pharmaceuticals Inc.

Mr. Michael Martin, 250-708-4272

Chief Operating Officer

Fax: 250-744-2498

[mmartin@auriniapharma.com](mailto:mmartin@auriniapharma.com)

or

Mr. Dennis Bourgeault, 780-643-2260

Chief Financial Officer

Fax: 780-484-4105

[dbourgeault@auriniapharma.com](mailto:dbourgeault@auriniapharma.com)

Source: Aurinia Pharmaceuticals Inc.