

August 5, 2016



# **Aurinia Reports Second Quarter 2016 Financial Results and Operational Highlights**

***Completed private placement for gross proceeds of \$7.08 million***

***AURION results support the use of voclosporin for the treatment of lupus nephritis***

***AURA topline primary endpoint results imminent***

VICTORIA, British Columbia-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH-TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the second quarter ended June 30, 2016. Amounts, unless specified otherwise, are expressed in U.S. dollars.

The Aurinia team is focused on preparations for the AURA primary end point data release expected prior to the end of August, 2016, and initiation of the Phase 3 program in 2017. The Company is making the necessary investments now to ensure the team has the tools to deliver future success. The remainder of the year will also see further data releases from the AURION study including additional 24 week data points.

The Company is also in the process of completing assessments of key markets in the Americas, Europe and Asia. The Company will share more on these developments during future investor presentations.

"We are fast approaching a pivotal event for Aurinia with primary endpoint data from the AURA trial expected very soon. The Aurinia team is excited to have reached this stage in the development of voclosporin for lupus nephritis. We plan to continue to execute on initiatives to maximize shareholder value and help bring a desperately needed therapy to market for patients suffering from this disease," said Charlie Rowland, CEO of Aurinia Pharmaceuticals Inc.

## **Operational and Corporate Developments**

### **AURA Phase 2b Clinical Trial Update**

On January 19, 2016, the Company announced completion of patient enrollment of its AURA Phase 2b clinical trial at 265 patients (the target number of patients was 258).

Un-blinding and disclosure of the primary 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

prior to the end of August, 2016.

### **AURION Study Update**

On June 28, 2016 the Company announced that it completed an analysis of the first 7 patients to complete 24 weeks in its open-label AURION (Aurinia early Urinary protein Reduction Predicts Response) study. At 24 weeks 57% (4/7) of patients continued to be in complete remission as measured by a urinary protein creatinine ratio of  $\leq 0.5\text{mg/mg}$ , eGFR within 20% of baseline and concomitant steroid dose of less than 5mg/day. Among these seven AURION patients there was a 54% mean reduction in proteinuria at 24 weeks compared to pre-treatment levels along with consistent improvements in C3, C4 and anti-DS DNA. Renal function as measured by eGFR remained stable and no new safety signals were observed.

### **Private Placement Financing**

On June 22, 2016 the Company completed a private placement of 3 million units of the Company at US\$2.36 per unit for total gross proceeds of US\$7.08 million. Each unit consisted of one common share of the Company and a 0.35 of one common share purchase warrant exercisable for a period of two years from the date of issuance at an exercise price of US\$2.77.

### **At the Market (ATM) Facility**

On July 22, 2016 the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") pursuant to which the Company may from time to time sell, through at-the-market ("ATM") offerings with Cantor Fitzgerald acting as sales agent, such common shares as would have an aggregate offer price of up to US\$10 million.

### **The Company expects the following milestones and events in the second half of 2016:**

- AURA-LV 24 week primary end point data release – prior to the end of August 2016
- AURION 10 patients to 24 weeks – Q3/2016
- Investor Day – September 2016
- End of Phase 2 meeting with FDA– Q4/2016
- Scientific meetings: ACR & ASN

### **Financial Results for the Second Quarter Ended June 30, 2016**

The Company had cash, cash equivalents and short term investments of \$12.1 million at June 30, 2016 compared to \$10.5 million at March 31, 2016 and \$15.8 million at December 31, 2015. Net cash used in operating activities was \$5.0 million for the second quarter ended June 30, 2016. The Company generated \$6.6 million from financing activities during the quarter as a result of completing the private placement on June 22, 2016.

For the second quarter ended June 30, 2016, the Company reported a consolidated net loss of \$3.3 million or \$0.10 per common share, as compared to a consolidated net loss of \$733,000 or \$0.02 per common share for the same period in 2015. The increase in the reported consolidated net loss was primarily attributable to a reduction in the non-cash gain on the quarterly fair value revaluation of the derivative warrant liability of \$4.0 million offset to a lesser degree by a reduction in research and development expenses of \$1.9 million in the second quarter ended June 30, 2016 compared to the same period in 2015.

For the six months ended June 30, 2016, the consolidated net loss was \$7.5 million or \$0.23 per common share compared to a consolidated net loss of \$9.3 million or \$0.29 per common share for the comparable period in 2015. The lower consolidated net loss reflected a decrease in research and development expenses of \$1.9 million for the 2016 period compared to the same period in 2015.

Research and development expenses decreased to \$2.4 million for the three months ended June 30, 2016, compared to \$4.3 million for the three months ended June 30, 2015 as the costs related to the active treatment phase of the AURA trial have decreased as patients complete the trial. The Company incurred net research and development expenditures of \$5.7 million for the six months ended June 30, 2015, as compared to \$7.6 million for the same period in 2015.

Corporate, administration and business development expenses increased to \$1.8 million for the three months ended June 30, 2016, compared to \$1.4 million for the same period in 2015. The Company incurred corporate, administration and business development expenses of \$3.0 million for the six months ended June 30, 2016 compared to \$3.3 million for the same period in 2015.

The unaudited interim condensed consolidated financial statements and the MD&A for the second quarter ended June 30, 2016 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.

### ***Forward-Looking Statements***

A statement is forward-looking when it uses what the Company knows and expects today to make a statement about the future. Forward-looking statements may include words such as “*anticipate*”, “*believe*”, “*intend*”, “*expect*”, “*goal*”, “*may*”, “*outlook*”, “*plan*”, “*seek*”, “*should*”, “*strive*”, “*target*”, “*could*”, “*continue*”, “*potential*” and “*estimated*”, or the negative of such terms or comparable terminology. You should not place undue reliance on forward-looking statements, particularly those concerning anticipated events relating to the development, clinical trials, regulatory approval, and marketing of the Company’s product and the timing or magnitude of those events, as they are inherently risky and uncertain.

Securities laws encourage companies to disclose forward-looking information so that investors can get a better understanding of the Company’s future prospects and make informed investment decisions. In this press release, these statements may include, without limitation:

- plans to fund the Company’s operations;
- summary statements relating to results of the past voclosporin trials or plans to advance the development of voclosporin;
- the timing of the release of the primary end-point results of AURA ;
- the timing of the analysis and review of the AURA data with the FDA;
- the timing of commencement and completion of clinical trials;
- voclosporin being a best-in-class calcineurin inhibitor;
- the Company’s anticipated future financial position, future revenues and projected costs;
- the Company’s intention to raise additional funds in the next 12 months;

- the timing of the Company's anticipated milestones for 2016; and
- plans and objectives of management.

Such statements reflect the Company's current views with respect to future events and are subject to risks and uncertainties and are necessarily based on a number of estimates and assumptions that, while considered reasonable by the Company, as at the date of such statements, are inherently subject to significant business, economic, competitive, political, scientific and social uncertainties and contingencies, many of which, with respect to future events, are subject to change. The factors and assumptions used by the Company to develop such forward-looking statements include, but are not limited to: the assumption that the Company will be able to reach agreements with regulatory agencies on executable development programs; the assumption that recruitment to clinical trials will occur as projected; the assumption that the Company will successfully complete its clinical programs on a timely basis, including the AURA clinical trial currently in progress, to enable the Company to proceed to conduct future required LN clinical trials and meet regulatory requirements for approval of marketing authorization applications and new drug approvals; the assumption the regulatory requirements will be maintained; the assumption that the Company will be able to manufacture and secure a sufficient supply of voclosporin on a timely basis to successfully complete the development and commercialization of voclosporin; the assumption that market data and reports reviewed by the Company are accurate; the assumptions relating to the availability of capital on terms that are favourable to the Company; the assumption that the Company will be able to attract and retain skilled staff; the assumption that general business and economic conditions will be maintained, and the assumptions relating to the feasibility of future clinical trials.

It is important to know that:

- Actual results could be materially different from what the Company expects if known or unknown risks affect its business, or if the Company's estimates or assumptions turn out to be inaccurate. As a result, the Company cannot guarantee that any forward-looking statement will materialize and, accordingly, you are cautioned not to place undue reliance on these forward-looking statements.
- Forward-looking statements do not take into account the effect that transactions or non-recurring or other special items announced or occurring after the statements are made may have on the Company's business. For example, they do not include the effect of mergers, acquisitions, other business combinations or transactions, dispositions, sales of assets, asset write-downs or other charges announced or occurring after the forward-looking statements are made. The financial impact of such transactions and non-recurring and other special items can be complex and necessarily depends on the facts particular to each of them. Accordingly, the expected impact cannot be meaningfully described in the abstract or presented in the same manner as known risks affecting the Company's business.
- The Company disclaims any intention and assumes no obligation to update any forward-looking statements even if new information becomes available, as a result of future events, new information, or for any other reason except as required by law.

Such forward-looking statements involve known and unknown risks, uncertainties, and

other factors that may cause the Company's actual results, performance, or achievements to differ materially from any further results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause such differences include, among other things, the following:

- the need for additional capital to fund the Company's development programs and the effect of capital market conditions and other factors on capital availability;
- difficulties, delays, or failures the Company may experience in the conduct of and reporting of results of its clinical trials for voclosporin, and in particular its current AURA clinical trial;
- difficulties, delays or failures in obtaining regulatory approvals for the initiation of clinical trials;
- difficulties the Company may experience in completing the development and commercialization of voclosporin;

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance or achievements. These forward-looking statements are made as of the date hereof.

*We seek Safe Harbor.*

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