

May 11, 2016



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

***Enrollment completed in Phase 2b clinical trial with data read out in third quarter of 2016***

***FDA Fast Track designation granted to voclosporin for lupus nephritis***

***Early AURION results support the use of voclosporin as a component of multi-targeted therapy in lupus nephritis***

***Company leadership team strengthened with expanded capabilities***

VICTORIA, British Columbia--

Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH)(TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the first quarter ended March 31, 2016. Amounts, unless specified otherwise, are expressed in U.S. dollars.

The first quarter of 2016 was highlighted by the completion of patient enrollment in our Phase 2b (AURA) clinical trial and obtaining fast track designation from the FDA for voclosporin. In addition to these clinical and regulatory successes, the Company received promising data from the open-label AURION study that further supports our hypothesis on the potential for multi-targeted therapy with voclosporin for the treatment of lupus nephritis (LN). The team is focused on preparations for the AURA primary end point data release in the latter half of the third quarter of 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 some 24 and 48 week data points.

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

"While only being in this role a short time, I am both excited and greatly encouraged by the performance and focus of the team. I plan to continue to execute on initiatives to maximize shareholder value and help bring a desperately needed therapy to market for patients suffering from LN." said Charlie Rowland, CEO of Aurinia Pharmaceuticals Inc.

## **Key Developments**

## **AURA Phase 2b Clinical Trial Update – Patient Enrollment Completed**

On January 19, 2016, the Company announced completion of patient enrollment of its AURA clinical trial at 265 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.

## **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.

## **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, of the 10 patients enrolled in the study, that have reached at least eight weeks of therapy in the AURION study, 100% (7/7) achieved at least a 25% reduction in proteinuria compared to study entry. A 25% reduction in proteinuria at eight weeks has been shown to be predictive of a positive clinical response at 24 weeks<sup>1</sup>. Additionally, in the first eight weeks of the open-label AURION study 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 also remained stable. The Company plans to release further AURION data as it becomes available.

## **Strengthening Leadership and Capabilities**

On April 11, 2016 the Company appointed Mr. Charles A. Rowland, Jr., MBA, CPA, as its Chief Executive Officer. Mr. Rowland has more than 30 years of experience in pharmaceutical operations, strategic value creation as well as financial management. He served as the Vice President and Chief Financial Officer of ViroPharma Incorporated, an international biopharmaceutical company, until it was acquired by Shire plc for \$4.2B in January 2014. As a member of the executive team, he was key to developing the global

strategic direction of the company, its international expansion and its strong financial position.

On April 29, 2016 the Company appointed Bradley J. Dickerson as an officer of the Company in the position of General Manager of the Americas and Global Commercial Assessment. Mr. Dickerson has more than 15 years of experience in the healthcare industry with a focus on pharmaceutical market access, distribution and patient services. He served as Vice President, Access and Reimbursement at NPS Pharmaceuticals, until it was acquired by Shire plc. Prior to his role at NPS, Mr. Dickerson was Director of Managed Markets at ViroPharma with responsibility for all market access functions. He also provided leadership for the launch and ongoing commercialization of Cinryze®.

### **Expected Upcoming Milestones and Events**

- AURION 10 patients to 8 weeks – Q2/2016
- AURION 7 patients to 24 weeks – Q2/2016
- AURA-LV 24 week primary end-point data release – Q3/2016
- AURION 10 patients to 24 weeks – Q3/2016
- Filing for Breakthrough Designation – Q3/2016-pending data from AURA trial – 24 week results
- Investor Day-Fall/2016
- End of Phase 2 meeting with FDA – Q4/2016
- Scientific meetings:
  - Abstract presentation – European Renal Association / European Dialysis and Transplantation Meeting (ERA/EDTA) –Q2/2016
  - Poster presentation – European League Against Rheumatism (EULAR) – Q2/2016

### **Financial Results for the First Quarter Ended March 31, 2016**

For the first quarter ended March 31, 2016, the Company reported a consolidated net loss of \$4.3 million or \$0.13 per common share, as compared to a consolidated net loss of \$8.6 million or \$0.27 per common share for the same period in 2015.

The decrease in the net loss was primarily attributable to recording a non-cash gain on revaluation of derivative warrant liability of \$664,000 in 2016 compared to a non-cash loss on revaluation of derivative warrant liability of \$2.9 million for the comparable period in 2015 and a reduction in stock compensation expense of \$955,000 in the first quarter ended March 31, 2016 compared to the corresponding period in 2015.

After adjusting for the non-cash impact of the revaluation of the derivative warrant liability, the net loss from operations for the first quarter ended March 31, 2016 was \$4.9 million compared to \$5.7 million for the corresponding period in 2015.

The Company incurred net research and development expenditures of \$3.3 million for the first quarter ended March 31, 2016, as compared to \$3.3 million for the same period in 2015. Research and development expenditures for both periods related primarily to drug distribution, patient enrollment and treatment activities associated with the AURA trial.

The Company incurred corporate, administration and business development costs of \$1.2 million for the first quarter ended March 31, 2016, as compared with \$1.9 million for the same period in 2015. These costs included a non-cash stock compensation expense of \$261,000 in 2016 compared to \$897,000 in 2015.

The Company had cash, cash equivalents and short term investments of \$10.5 million as at March 31, 2016 compared to \$15.8 million as at December 31, 2015. In order to complete the AURA LN clinical trial and be able to undertake further development of voclosporin, the Company will need to raise additional funds within the next 12 months.

The unaudited interim condensed consolidated financial statements and the MD&A for the first quarter ended March 31, 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).

<sup>1</sup>Dall’Era, M., Stone, D., Levesque, V., Cisternas, M., & Wofsy, D. (2011). *Arthritis Care and Research*, 63(3), 351–357.

#### **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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