

March 9, 2017



# Aurinia Reports Fourth Quarter and Full Year 2016 Financial Results and Recent Operational Highlights

**AURA-LV Phase IIb Study Meets 48-Week Remission Endpoints, Achieving Highest Complete Remission Rate of Any Global Lupus Nephritis Study**

**48-Week AURA-LV Data to be presented in Late Breaker Presentation at National Kidney Foundation 2017 Scientific Clinical Meetings**

**AURORA Phase III Trial with Voclosporin on Track to Commence Q2 2017**

VICTORIA, British Columbia--(BUSINESS WIRE)-- 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, 2016. Amounts, unless specified otherwise, are expressed in U.S. dollars.

Aurinia plans to initiate a single, Phase III clinical trial ("AURORA") whose design is consistent with that of the ongoing AURA-LV ("AURA") clinical trial. The totality of data from both the AURORA and AURA trials will serve as the basis for a New Drug Application (NDA) submission following completion of the Phase III trial. The Company continues to focus its efforts on finalizing the study protocol and regulatory submissions in parallel with site selection, making the necessary investments now to ensure the team has the tools to execute a successful clinical trial.

"I am proud of the important milestones our team has reached over the past several months, including our most recent and significant achievement to date, the promising 48-week results from our AURA study of voclosporin, demonstrating significantly improved long-term outcomes for patients suffering from lupus nephritis," said Richard Glickman, Aurinia CEO and Chairman of the Board. "The recent news that our late-breaking abstract for voclosporin has been accepted for oral presentation at the National Kidney Foundation 2017 Scientific Clinical Meetings underscores the importance of this compelling dataset. We remain committed to advancing voclosporin with the end goal of improving the lives of patients impacted by this devastating disease, and potentially altering the treatment paradigm of lupus nephritis."

## **Recent operational highlights**

### **AURA 48-Week Results**

On March 1, 2017, the Company announced top-line results from its AURA study in lupus nephritis (LN). At 48 weeks, the trial met the complete and partial remission ("CR"/"PR") endpoints, demonstrating statistically significant greater CR and PR in patients in both low

dose (23.7mg of voclosporin twice daily ( $p < .001$ )) and high dose (39.5mg twice daily ( $p = .026$ )) cohorts versus the control group. Each arm of the study included the current standard of care of mycophenolate mofetil (MMF) as background therapy and a forced steroid taper to 5mg/day by week 8 and 2.5mg by week 16. No unexpected safety signals were observed and there were no additional deaths in the voclosporin treated patients; however, there were three deaths and one malignancy reported in the control arm after completion of the study treatment period. Additional data analyses for the AURA study at 48 weeks will be released at future corporate, medical and scientific meetings, including in a late breaker presentation at the National Kidney Foundation 2017 Scientific Clinical Meetings April 18-22, 2017 in Orlando, FL.

The 24 and 48-week top-line efficacy results are summarized below:

Endpoint	Treatment	24 weeks	Odds ratio	P-value*	48 weeks	Odds Ratio	P-value*
Complete Remission	23.7mg VCS BID	32.6%	2.03	$p = .045$	49.4%	3.21	$p < .001$
	39.5mg VCS BID	27.3%	1.59	$p = .204$	39.8%	2.10	$p = .026$
	Control Arm	19.3%	NA	NA	23.9%	NA	NA
Partial Remission	23.7mg VCS BID	69.7%	2.33	$p = .007$	68.4%	2.34	$p = .007$
	39.5mg VCS BID	65.9%	2.03	$p = .024$	71.6%	2.68	$p = .002$
	Control Arm	49.4%	NA	NA	48.3%	NA	NA

*\*All p-values are vs control*

### Japanese Phase I Ethnic Bridging Study for Voclosporin

On February 14, 2017, the Company announced results of a supportive Phase I safety, pharmacokinetic (PK) and pharmacodynamics (PD) study in healthy Japanese patients, which supports further development of voclosporin in this patient population. Based on evaluations comparing the Japanese ethno-bridging data vs. previous PK and PD studies in non-Japanese patients, voclosporin demonstrated no statistically significant differences in exposure with respect to Area Under the Curve (AUC) measurements. Furthermore, the PK parameters in Japanese patients were generally consistent with previously evaluated PK parameters in non-Japanese volunteers. There were no unusual or unexpected safety signals in the study. The Company plans to share its findings with the Japanese Pharmaceuticals and Medical Devices Agency (“PMDA”) in Q2 2017 and determine a path forward for regulatory submission in Japan.

### Long-Term Manufacturing Agreement with Lonza

In Q4 2016, Aurinia announced a long-term agreement with Lonza for the manufacture of voclosporin active pharmaceutical ingredient (API). The agreement followed a successful multi-year clinical manufacturing relationship where the companies had refined the process and analytical methods to produce clinical and commercial supplies of voclosporin. Under the terms of the agreement, Lonza agreed to produce cGMP-grade voclosporin drug

substance for use in the AURORA trial and for future commercial use. The agreement also provides an option to have Lonza exclusively supply API for up to 20 years.

**The Company expects the following additional milestones and events in the first half of 2017:**

- Late breaking presentation of AURA 48-week results at the National Kidney Foundation 2017 Scientific Clinical Meetings;
- Outcome of European Medicines Agency (EMA) and PMDA discussions
- AURION open label study 48-week results;
- Initiation of Phase III AURORA trial.

**Financial results for the year ended December 31, 2016**

For the year ended December 31, 2016, the Company recorded a consolidated net loss of \$23.3 million or \$0.66 per common share, as compared to a consolidated net loss of \$18.6 million or \$0.58 per common share in 2015.

The increase in the reported consolidated net loss was primarily attributable to recording a non-cash gain of \$1.7 million in 2016 on the fair value revaluation of the derivative warrant liability compared to a gain of \$5.1 million in the same 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 year ended December 31, 2016 was \$25.0 million compared to \$23.7 million for the corresponding period in 2015.

The Company incurred net research and development expenditures of \$14.5 million for the year ended December 31, 2016, as compared to \$16.0 million for the same period in 2015. Research and development expenditures included planning, regulatory, site selection costs and drug manufacturing related to the planned Phase III LN clinical trial, clinical costs related to completing the AURA trial and costs related to conducting the Japanese PK study. Research and development expenditures in 2015 reflected higher costs incurred for the AURA trial including drug distribution, patient recruitment, enrollment and treatment activities.

The Company incurred corporate, administration and business development expenditures of \$7.0 million for the year ended December 31, 2016, as compared with \$6.3 million for the same period in fiscal 2015.

Other expense (income) reflected a net expense of \$2.2 million for the year ended December 31, 2016 compared to a net expense of \$128,000 for 2015. The Company recorded as other expense, a revaluation adjustment on contingent consideration to ILJIN Life Science Co., Ltd. in the amount of \$1.6 million in 2016 compared to \$337,000 in 2015. The Company also recorded an expense of \$655,000 in other expense (income) related to share issue costs allocated to derivative warrants incurred to complete the December 28, 2016 bought deal public offering.

**Financial results for the fourth quarter ended December 31, 2016**

The Company reported a consolidated net loss of \$8.3 million or \$0.21 per common share for the three months ended December 31, 2016, as compared to a consolidated net loss of \$4.1 million or \$0.13 per common share for the three months ended December 31, 2015. The increased loss was attributable to increased expenditures for both research and development and corporate activities as we were finishing the AURA trial while also commencing set up activities for the AURORA trial including drug manufacturing, CRO, and country and site selections.

The increase in the consolidated net loss also reflected a reduction in the fair value adjustment gain on derivative warrant liabilities to \$658,000 in the fourth quarter of 2016 from a gain of \$1.5 million in the comparable period in 2015 and the \$655,000 in share issue costs discussed above.

Research and development expenses increased to \$5.5 million in the fourth quarter of 2016, compared to \$3.7 million in the fourth quarter of 2015 as the Company ramped up activities required for commencing the planned AURORA clinical trial in the second quarter of 2017.

Corporate and administration expenses also increased to \$2.2 million for the fourth quarter of 2016, compared to \$1.6 million for the fourth quarter of 2015, reflecting increased activities related to investor relations, patient advocacy and market research.

## **Financial Liquidity**

In 2016, the Company raised net proceeds of \$40.6 million from equity financings and received \$2.0 million from the exercise of warrants and options. As a result, at December 31, 2016 the Company had cash of \$39.6 million and working capital of \$33.5 million.

The audited financial statements and the Management's Discussion and Analysis for the year ended December 31, 2016, are accessible on Aurinia's website at [www.auriniapharma.com](http://www.auriniapharma.com), on SEDAR at [www.sedar.com](http://www.sedar.com) or on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

## **Forward-Looking Statements**

This press release contains forward-looking statements, including statements around Aurinia's analysis, assessment and conclusions around the future development and commercial potential of voclosporin; the benefits of FDA fast track designation and the timing of future clinical trials; summary statements relating to results of the past voclosporin trials; the timing of commencement and completion of clinical trials; the timing of the Company's anticipated milestones for 2017; and plans and objectives of management.

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 Aurinia's current expectations. Forward-looking statements involve risks and uncertainties. Aurinia'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 Aurinia's analyses, assessment and conclusions of the results of the future development and commercial potential of voclosporin set forth in this release may change based on further analyses of such data, and

the risk that Aurinia's clinical studies for voclosporin may not lead to regulatory approval. These and other risk factors are discussed under "Risk Factors" and elsewhere in Aurinia's Annual Information Form for the year ended December 31, 2016 filed with Canadian securities authorities and available at [www.sedar.com](http://www.sedar.com) and on Form 40-F with the U.S. Securities Exchange Commission and available at [www.sec.gov](http://www.sec.gov), each as updated by subsequent filings, including filings on Form 6-K. Aurinia 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 Aurinia's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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 its planned AURORA 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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