

August 9, 2018



# Aurinia Reports Second Quarter Financial Results and Operational Highlights

**AURORA Phase III Trial in lupus nephritis anticipated to complete enrollment ahead of schedule**

**Trials in FSGS and Dry Eye initiated**

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH / TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the second quarter ended June 30, 2018. Amounts, unless specified otherwise, are expressed in U.S. dollars.

"We are excited to announce that the AURORA Phase III trial in lupus nephritis is running ahead of schedule and we now anticipate completing enrollment in early Q4 2018. We are extremely pleased with the trial's progress thus far and having patients roll over into the AURORA 2 extension study reinforces our confidence in the program", said Richard Glickman, Aurinia's CEO and Chairman of the Board. "Our clinical team continues to deliver on our important milestones with the Phase II trials in FSGS and Dry Eye now initiated. We are well-capitalized into 2020 and look forward to an eventful second half of the year."

## Highlights

- Our Phase III clinical trial ("AURORA") to evaluate voclosporin for the treatment of lupus nephritis ("LN"), which we initiated in May of 2017, is now expected to complete enrollment in early Q4 2018. We have over 225 clinical trial sites activated and able to enroll patients in 29 countries around the globe.
- The first patients have rolled over into the AURORA 2 blinded extension study from the AURORA Phase III clinical trial. The purpose of AURORA 2 is to assess the long-term safety and tolerability of voclosporin in patients with LN; however, this study is not a requirement for potential regulatory approval for voclosporin.
- We initiated a Phase II proof-of-concept study in focal segmental glomerulosclerosis ("FSGS") in June 2018. This is an open-label study of 20 treatment naïve patients. We submitted our Investigational New Drug application ("IND") to the FDA in Q1 2018 and received agreement from the FDA with regards to the guidance we provided on this study.
- We also initiated a Phase II head-to-head tolerability study of voclosporin ophthalmic solution ("VOS") versus Restasis® (cyclosporine ophthalmic emulsion) 0.05% for the treatment of Dry Eye Syndrome ("DES") in July 2018. Depending on the pace of recruitment, data could be available as early as the end of this year or early 2019. This four-week study of approximately 90 patients is expected to be completed by the end of 2018. We believe calcineurin inhibitors ("CNIs") are a mainstay of treatment for DES,

and the goal of this program is to develop a best-in-class treatment option, and upon completion, we will look to evaluate strategic alternatives for this asset.

### **Financial Liquidity at June 30, 2018**

At June 30, 2018, we had cash, cash equivalents and short term investments of \$150.2 million compared to \$159.1 million at March 31, 2018 and \$173.5 million at December 31, 2017. Net cash used in operating activities was \$12.3 million for the second quarter ended June 30, 2018 compared to \$14.0 million for the second quarter ended June 30, 2017.

We believe, based on our current plans, that we have sufficient financial resources to fund our existing LN program, including the AURORA trial and the NDA submission to the FDA, conduct the Phase II trials for FSGS and DES, and fund operations into 2020.

### **Financial Results for the Three and Six Months Ended June 30, 2018**

We reported a consolidated net loss of \$15.7 million or \$0.19 per common share for the three months ended June 30, 2018, as compared to a consolidated net loss of \$2.4 million or \$0.03 per common share for the three months ended June 30, 2017.

The increase in the loss for the three months ended June 30, 2018 compared to the same period in 2017 was primarily due to the non-cash change in the estimated fair value of derivative warrant liabilities of \$9.4 million. The three months ended June 30, 2018 reflected a \$1.9 million increase in the estimated fair value of derivative warrant liabilities compared to a reduction of \$7.5 million in the estimated fair value of derivative warrant liabilities for the three months ended June 30, 2017. The change in the revaluation of the derivative warrant liabilities is primarily driven by the change in our share price at each period end. An increase in our share price results in an increase in the estimated fair value of derivative warrant liabilities and vice versa. The derivative warrant liabilities will ultimately be eliminated on the exercise or forfeiture of the warrants and will not result in any cash outlay by the Company.

The net loss before the non-cash change in estimated fair value of derivative warrant liabilities was \$13.8 million for the three months ended June 30, 2018 compared to \$9.9 million for the same period in 2017 with the increased loss amount primarily reflecting higher research and development expenses.

For the six months ended June 30, 2018, the consolidated net loss was \$31.2 million or \$0.37 per common share compared to a consolidated net loss of \$54.3 million or \$0.78 per common share for the comparable period in 2017. For the six months ended June 30, 2018 we recorded an increase of \$4.6 million in the estimated fair value of derivative warrant liabilities compared to \$33.3 million for the comparable period in 2017.

The net loss before the non-cash change in estimated fair value of derivative warrant liabilities was \$26.6 million for the six months ended June 30, 2018 compared to \$21.1 million for the same period in 2017. The increased loss reflected higher research and development expenses.

Research and development expenses increased to \$10.5 million for the three months ended June 30, 2018, compared to \$7.1 million for the three months ended June 30, 2017. We incurred research and development expenses of \$19.4 million for the six months ended June

30, 2018, as compared to \$14.4 million for the same period in 2017. The increased research and development expenses reflected higher AURORA clinical and drug supply costs as well as startup costs for the AURORA 2 extension study, and the FSGS and DES studies.

Corporate, administration and business development expenses increased to \$3.5 million for the three months ended June 30, 2018, compared to \$2.9 million for the same period in 2017. We incurred corporate, administration and business development expenses of \$7.3 million for the six months ended June 30, 2018 compared to \$6.3 million for the comparable period in 2017. The increase was primarily due to higher non-cash stock compensation expense in 2018 compared to the same periods in 2017.

## **About Aurinia**

Aurinia Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. The company is currently developing *voclosporin*, an investigational drug, for the potential treatment of lupus nephritis, focal segmental glomerulosclerosis, and Dry Eye Syndrome. The company is headquartered in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at [www.auriniapharma.com](http://www.auriniapharma.com).

## **About Voclosporin**

Voclosporin, an investigational drug, is a novel and potentially best-in-class CNI with clinical data in over 2,400 patients across indications. Voclosporin is an immunosuppressant, with a synergistic and dual mechanism of action. By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses, and stabilizes the podocyte in the kidney. It has been shown to have a more predictable pharmacokinetic and pharmacodynamic relationship (potentially requires no therapeutic drug monitoring), an increase in potency (vs cyclosporin), and an improved metabolic profile compared to legacy CNIs. Aurinia anticipates that upon regulatory approval, patent protection for voclosporin will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027 under the Hatch-Waxman Act and comparable laws in other countries and until April 2028 with anticipated pediatric extension.

## **About VOS**

VOS (voclosporin ophthalmic solution) is an aqueous, preservative free nanomicellar solution containing 0.2% voclosporin intended for use in the treatment of DES. Studies have been completed in rabbit and dog models, and a single Phase I has also been completed in healthy volunteers and patients with DES. VOS has IP protection until 2031.

## **About Lupus Nephritis (LN)**

LN is an inflammation of the kidney caused by Systemic Lupus Erythematosus (“SLE”) and represents a serious progression of SLE. SLE is a chronic, complex and often disabling disorder. The disease is highly heterogeneous, affecting a wide range of organs & tissue systems. Unlike SLE, LN has straightforward disease outcomes (measuring proteinuria) where an early response correlates with long-term outcomes. In patients with LN, renal damage results in proteinuria and/or hematuria and a decrease in renal function as

evidenced by reduced estimated glomerular filtration rate (“eGFR”), and increased serum creatinine levels. LN is debilitating and costly and if poorly controlled, LN can lead to permanent and irreversible tissue damage within the kidney, resulting in end-stage renal disease (“ESRD”), thus making LN a serious and potentially life-threatening condition.

### **About FSGS**

FSGS is a rare disease that attacks the kidney’s filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and even renal failure. FSGS is one of the leading causes of Nephrotic Syndrome (NS) and is identified by biopsy and proteinuria. NS is a collection of signs and symptoms that indicate kidney damage, including: large amounts of protein in urine; low levels of albumin and higher than normal fat and cholesterol levels in the blood, and edema. Similar to LN, early clinical response (measured by reduction of proteinuria) is thought to be critical to long-term kidney health in patients with FSGS. Currently, there are no approved therapies for FSGS in the United States and the European Union.

### **About Dry Eye Syndrome (DES)**

Dry eye syndrome (DES) is characterized by irritation and inflammation that occurs when the eye’s tear film is compromised by reduced tear production, imbalanced tear composition, or excessive tear evaporation. The impact of DES ranges from subtle, yet constant eye irritation to significant inflammation and scarring of the eye’s surface. Discomfort and pain resulting from DES can reduce quality of life and cause difficulty reading, driving, using computers and performing daily activities. DES is a chronic disease. There are currently two FDA approved therapies for the treatment of dry eye; however, there is opportunity for improvement in the effectiveness by enhancing tolerability and onset of action and alleviating the need for repetitive dosing.

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

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include, but are not limited to statements or information with respect to: AURORA completing enrollment in early Q4, 2018, the timing voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; the timing of completion of the Phase II tolerability study of VOS; and that Aurinia has sufficient financial resources to fund the existing LN program, including the AURORA trial, and the NDA submission to the FDA, conduct the Phase II trials for FSGS and DES and fund operations into 2020. It is possible that such results or conclusions may change based on further analyses of these data. Words such as “anticipate”, “will”, “believe”, “estimate”, “expect”, “intend”, “target”, “plan”, “goals”, “objectives”, “may” and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the market value for the LN program; that another company will not create a substantial competitive product for Aurinia’s LN business without violating Aurinia’s intellectual property rights; the burn rate of Aurinia’s cash for operations; the costs and expenses associated with Aurinia’s clinical trials; the planned studies achieving positive results; Aurinia being able to extend its patents on terms acceptable to Aurinia; and the size

of the LN market. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: difficulties, delays, or failures we may experience in the conduct of our AURORA clinical trial; difficulties we may experience in completing the development and commercialization of voclosporin; the market for the LN business may not be as estimated; Aurinia may have to pay unanticipated expenses; estimated costs for clinical trials may be underestimated, resulting in Aurinia having to make additional expenditures to achieve its current goals; Aurinia not being able to extend its patent portfolio for voclosporin; and competitors may arise with similar products. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

Except as required by law, Aurinia will not update forward-looking information. All forward-looking information contained in this press release is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business can be found in Aurinia's most recent Annual Information Form available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at [www.sedar.com](http://www.sedar.com) or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at [www.sec.gov/edgar](http://www.sec.gov/edgar).

*We seek Safe Harbor.*

**Aurinia Pharmaceuticals Inc.**  
**Interim Condensed Consolidated Statements of Financial Position**  
**(unaudited – amounts in thousands of U.S. dollars)**

	June 30, 2018	December 31, 2017
	\$	\$
<b>Assets</b>		
Cash and cash equivalents	132,302	165,629
Short term investments	17,899	7,833

Other current assets	3,598	1,790
Total current assets	153,799	175,252
Acquired intellectual property and other intangible assets	13,354	14,116
Other non-current assets	702	479
Total assets	167,855	189,847
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	4,886	7,959
Other current liabilities	190	191
Total current liabilities	5,076	8,150
Derivative warrant liabilities	16,357	11,793
Other non-current liabilities	4,252	4,161
Total liabilities	25,685	24,104
Shareholders' equity	142,170	165,743
Total liabilities and shareholders' equity	167,855	189,847

**Aurinia Pharmaceuticals Inc.**

**Interim Condensed Consolidated Statements of Operations and Comprehensive Loss  
(unaudited – amounts in thousands of U.S. dollars, except per share data)**

	Three Months Ended		Six months Ended	
	June 30, 2018	June 30, 2017	June 30, 2018	June 30, 2017
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing revenue	29	329	59	359
<b>Expenses</b>				
Research and development	10,504	7,107	19,391	14,432
Corporate, administration and business development	3,462	2,901	7,253	6,328
Amortization of acquired intellectual property and other intangible assets	397	364	793	721
Amortization of property and equipment	6	6	9	12
Other (income) expense	(566)	(152)	(766)	(77)
	13,803	10,226	26,680	21,416

<b>Net loss before change in estimated fair value of derivative warrant liabilities</b>	(13,774)	(9,897)	(26,621)	(21,057)
<b>Change in estimated fair value of derivative warrant liabilities</b>	<u>(1,933)</u>	<u>7,498</u>	<u>(4,564)</u>	<u>(33,283)</u>
<b>Net loss and comprehensive loss for the period</b>	<u>(15,707)</u>	<u>(2,399)</u>	<u>(31,185)</u>	<u>(54,340)</u>
<b>Net loss per common share (expressed in \$ per share)</b>				
Basic and diluted loss per common share	<u>(0.19)</u>	<u>(0.03)</u>	<u>(0.37)</u>	<u>(0.78)</u>
<b>Weighted average number of common shares outstanding (in thousands)</b>	<u>84,350</u>	<u>82,973</u>	<u>84,833</u>	<u>69,899</u>

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Source: Aurinia Pharmaceuticals Inc.