

May 10, 2018



# Aurinia Reports First Quarter Financial Results and Operational Highlights

**AURORA Phase III Trial in lupus nephritis remains on track**

**Trials in FSGS and Dry Eye expected to begin in June 2018**

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH / TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the first quarter ended March 31, 2018. Amounts, unless specified otherwise, are expressed in U.S. dollars.

"Our first quarter has been characterized by diligently executing our clinical programs. We remain on track to complete recruitment for our Phase III trial in lupus nephritis later this year and are pleased with the trial's progress. Start-up activities are underway for our FSGS and Dry Eye programs, and we expect to commence these in June. We continue to be well-capitalized into 2020 and look forward to a productive 2018," said Richard Glickman, Aurinia CEO and Chairman of the Board.

## 2018 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 on track to complete enrollment in Q4 2018. We have 212 clinical trial sites activated and able to enroll patients around the globe.
- A Phase II proof-of-concept study in focal segmental glomerulosclerosis ("FSGS") is expected to initiate in June 2018. This will be an open-label study of 20 treatment naïve patients. We submitted our Investigational New Drug application ("IND") to the FDA in Q1 2018. We received agreement from the FDA with regards to the guidance we provided on this study, and the IND is now active.
- We also expect to initiate a Phase IIa 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 June 2018, with data expected to be available by the end of 2018. This will be a four-week study of approximately 90 patients. Upon productive meetings with the FDA, we re-activated our existing IND and are aligned to proceed. 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.
- We strengthened the breadth and scope of our Board of Directors with the additions of Dr. Michael Hayden and Joseph Hagan in February of 2018.

## **Financial Liquidity at March 31, 2018**

At March 31, 2018, we had cash, cash equivalents and short term investments of \$159.1 million and working capital of \$156.7 million compared to \$173.5 million of cash, cash equivalents and short term investments and \$167.1 million of working capital at December 31, 2017. Net cash used in operating activities was \$14.4 million for the first quarter ended March 31, 2018 compared to \$9.7 million for the first quarter ended March 31, 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 planned Phase II trials for FSGS and DES, and fund operations into 2020.

## **Financial Results for the First Quarter ended March 31, 2018**

We reported a consolidated net loss of \$15.5 million or \$0.18 per common share for the first quarter ended March 31, 2018, as compared to a consolidated net loss of \$51.9 million or \$0.92 per common share for the first quarter ended March 31, 2017.

The loss for the first quarter ended March 31, 2018 reflected a \$2.6 million increase in the estimated fair value of derivative warrant liabilities compared to an increase of \$40.8 million in the estimated fair value of derivative warrant liabilities for the first quarter ended March 31, 2017. An increase in estimated fair value of derivative warrant liabilities increases the loss recorded for the period.

The increases in the estimated fair value of derivative warrant liabilities were primarily the result of increases in our share prices at March 31, 2018 and March 31, 2017 compared to December 31, 2017 and December 31, 2016 respectively.

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 these non-cash changes in estimated fair value of derivative warrant liabilities was \$12.8 million for the first quarter ended March 31, 2018 compared to \$11.2 million for the same period in 2017.

Research and development ("R&D") expenses increased to \$8.9 million in the first quarter of 2018, compared to \$7.3 million in the first quarter of 2017. The increase in these expenses resulted from higher clinical patient enrollment and treatment costs for our AURORA trial and costs associated with the planning and start-up phase for the FSGS and DES Phase II trials, and the LN continuation study. R&D expenses for the first quarter ended March 31, 2017 included costs related to the AURORA planning phase and completion costs for the Phase II AURA trial.

Corporate, administration and business development expense also increased to \$3.8 million for the first quarter ended March 31, 2018, compared to \$3.4 million for the first quarter ended March 31, 2017, primarily reflecting increased personnel costs due to the expansion of our activities.

This press release should be read in conjunction with our unaudited interim condensed consolidated financial statements and the Management's Discussion and Analysis for the first quarter ended March 31, 2018 which 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).

### **About Aurinia**

Aurinia 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 LN, FSGS and DES. The Company is headquartered in Victoria, BC and focuses its development efforts globally.

### **About 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 lesion characterized by persistent scarring identified by biopsy and proteinuria. FSGS is a cause of Nephrotic Syndrome (“NS”) and is characterized by high morbidity. NS is a collection of 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 and reduction of proteinuria is thought to be critical to long-term kidney health. Currently, there are no approved therapies for FSGS in the United States and the European Union.

### **About DES**

DES, or keratoconjunctivitis sicca, is a chronic, multifactorial, heterogeneous disease in which a lack of moisture and lubrication on the eye’s surface results in irritation and inflammation of the eye.

### **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, an increase in potency, an altered metabolic profile and potential for flat dosing 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 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.

### ***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 being on track to complete enrollment in the second half of 2018, the timing voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; the timing for Aurinia initiating a Phase II clinical trial for voclosporin in FSGS patients; the timing for interim data readouts for the Phase II clinical trial for FSGS patients; the timing for commencement of a Phase IIa tolerability study of VOS; the timing for data availability for the Phase IIa tolerability study; the anticipated commercial potential of voclosporin for the treatment of LN, FSGS, DES and other autoimmune diseases; that the expansion of the renal franchise could create significant value for shareholders and that Aurinia has sufficient financial resources to fund the existing LN program, including the AURORA trial, conduct work on the new indications 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 planned 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)**

	<b>March 31, 2018 \$</b>	<b>December 31, 2017 \$</b>
<b>Assets</b>		
Cash and cash equivalents	131,227	165,629
Short term investments	27,905	7,833
Other current assets	2,850	1,790
Total current assets	<u>161,982</u>	<u>175,252</u>
Acquired intellectual property and other intangible assets	13,720	14,116
Other non-current assets	708	479
Total assets	<u>176,410</u>	<u>189,847</u>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	5,121	7,959
Other current liabilities	190	191
Total current liabilities	<u>5,311</u>	<u>8,150</u>
Derivative warrant liabilities	14,424	11,793
Other non-current liabilities	4,221	4,161

Total liabilities	23,956	24,104
Shareholders' equity	152,454	165,743
Total liabilities and shareholders' equity	176,410	189,847

**Aurinia Pharmaceuticals Inc.**

**Interim Condensed Consolidated Statements of Operations**

(unaudited – amounts in thousands of U.S. dollars, except per share data)

	Three months ended March 31, 2018	Three months ended March 31, 2017
	\$	\$
<b>Revenue</b>		
Licensing revenue	30	30
<b>Expenses</b>		
Research and development	8,887	7,325
Corporate, administration and business development	3,791	3,427
Amortization of acquired intellectual property and other intangible assets	396	357
Amortization of property and equipment	3	6
Other (income) expense	(200)	75
	12,877	11,190
<b>Net loss before change in estimated fair value of derivative warrant liabilities</b>	(12,847)	(11,160)
Change in estimated fair value of derivative warrant liabilities	(2,631)	(40,781)
<b>Net loss and comprehensive loss for the period</b>	(15,478)	(51,941)
<b>Net loss per common share (expressed in \$ per share)</b>		
Basic and diluted loss per common share	(0.18)	(0.92)
<b>Weighted average common share outstanding (in thousands)</b>	84,052	56,680

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**Aurinia Pharmaceuticals Inc.**

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Source: Aurinia Pharmaceuticals Inc.