

November 14, 2017



# **Aurinia Reports Third Quarter 2017 Financial Results and Provides Operational Highlights**

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

**Trials in FSGS, MCD and Dry Eye to begin in the first half of 2018**

**Cash of \$182.4 million as of September 30, 2017**

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH) (TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the third quarter ended September 30, 2017. Amounts, unless specified otherwise, are expressed in U.S. dollars.

## **Operational highlights**

On October 20, 2017 we announced plans to expand our renal franchise by investigating voclosporin in focal segmental glomerulosclerosis (FSGS) and minimal change disease (MCD). Additionally, we announced plans to evaluate our proprietary nanomicellar voclosporin ophthalmic solution (VOS) for the treatment of keratoconjunctivitis sicca or dry eye syndrome (DES). The advancement of these new indications, in addition to lupus nephritis (LN), represents an expansion of the company's strategy, pipeline and commercial opportunities.

A Phase II proof of concept clinical trial for voclosporin in FSGS and MCD patients will be initiated in the first half of 2018. FSGS and MCD affect nearly 150,000 patients globally, accounting for almost 50% of patients with Nephrotic Syndrome (NS). The prevalence of FSGS and MCD is increasing through improved diagnosis, and it has been shown that the control of proteinuria is important for long-term survival of these patients. Interim data readouts are anticipated in the second half of 2018.

We also plan to begin a Phase IIa tolerability study of VOS versus the standard of care for the treatment of DES by the second quarter of 2018, with data available in the second half of 2018. Calcineurin inhibitors (CNIs) are a mainstay in the treatment for DES, and the goal of this program is to develop a best-in-class treatment option.

Our Phase III clinical trial (AURORA) for the treatment of LN is on track to complete enrollment in the second half of 2018, with 138 clinical trial sites active around the globe. Additionally, under voclosporin's fast-track designation, we intend to utilize a rolling New Drug Application (NDA) process, with the first module being submitted in the second half

of 2018.

“With the AURORA trial in LN on track to complete enrollment in the second half of 2018, we’re thrilled to enter this exciting next phase of development for Aurinia,” said Richard Glickman, L.L.D., CEO and Chairman of Aurinia Pharmaceuticals. “By expanding our renal franchise and launching a development program in dry eye, we have the potential to create significant value for shareholders.”

### **Financial Results for the Third Quarter Ended September 30, 2017**

Cash, cash equivalents and short term investments were \$182.4 million as at September 30, 2017 compared to \$189.8 million as of June 30, 2017, and \$39.6 million as at December 31, 2016. We believe, based on our current plans, that we have sufficient financial resources to fund our existing LN program, including the AURORA trial, conduct work on the new indications and fund operations into 2020.

For the three months ended September 30, 2017, we reported a consolidated net loss of \$13.1 million or \$0.16 per common share compared to a consolidated net loss of \$7.4 million or \$0.21 per common share for the three months ended September 30, 2016.

We incurred research and development expenses of \$10.8 million for the three months ended September 30, 2017, as compared to \$3.3 million for the same period in 2016. The increase in research and development expenses for the three months ended September 30, 2017 reflected AURORA clinical expenses such as contract research organization (CRO) service fees and pass thru costs for activities including site activations, regulatory submissions, patient treatment and drug costs for manufacture of voclosporin drug product, and drug encapsulation, packaging and distribution for the trial.

We incurred corporate, administration and business development costs of \$2.6 million for the three months ended September 30, 2017, as compared with \$1.7 million for the same period in 2016. These costs included a non-cash stock compensation expense of \$795,000 for the three months ended September 30, 2017 compared to \$469,000 for the three months ended September 30, 2016.

This press release should be read in conjunction with our unaudited interim condensed consolidated financial statements and the MD&A for the third quarter ended September 30, 2017 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 treatment of LN, FSGS, MCD and DES. The company is headquartered in Victoria, BC and focuses its development efforts globally.

### **About FSGS, MCD and NS**

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. Aurinia is focused specifically on FSGS, a lesion characterized by persistent scarring identified by biopsy and proteinuria and on MCD, a kidney disease in which large amounts of protein are lost in the urine. FSGS and MCD both are causes of NS and characterized by high morbidity. Currently, there are no approved therapies for FSGS and MCD in the United States and the European Union.

### **About DES**

DES, or keratoconjunctivitis sicca, is a chronic disease in which a lack of moisture and lubrication on the eye's surface results in irritation and inflammation of the eye. DES is a multifactorial, heterogeneous disease estimated to affect greater than 20 million people in the United States.

### **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 and affects more than 500,000 people in the United States (mostly women). The disease is highly heterogeneous, affecting a wide range of organs & tissue systems. It is estimated that as many as 60 percent of all SLE patients will develop clinical LN requiring treatment. 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 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. In April 2017, Aurinia announced an agreement granting Merck Animal Health (MAH) worldwide rights to develop and commercialize (VOS) for the treatment of DES in dogs. MAH previously conducted proof of concept research in dogs suffering from DES, which affects one out of every 22 dogs.

### ***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 and MCD patients; the timing for interim data readouts for the Phase II clinical trial for FSGS and MCD 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, NS, 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 Balance Sheet (*Unaudited*)

(*Expressed in thousands of U.S. dollars, except per share data*)

	<b>September 30,</b>	<b>December 31,</b>
	<b>2017</b>	<b>2016</b>
	<b>\$</b>	<b>\$</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	87,546	39,649
Short term investments	94,860	-
Accrued interest and other receivables	415	86
Prepaid expenses, deposits and other	2,064	1,683
	<hr/> 184,885	<hr/> 41,418
<b>Clinical trial contract deposits</b>	448	-
<b>Property and equipment</b>	27	29
<b>Acquired intellectual property and other intangible assets</b>	14,472	15,550
	<hr/> 199,832	<hr/> 56,997

## Liabilities

### Current liabilities

Accounts payable and accrued liabilities	6,665	5,791
Current portion of deferred revenue	118	118
<b>Contingent consideration</b>	72	2,021
	<u>6,855</u>	<u>7,930</u>

<b>Deferred revenue</b>	472	560
<b>Contingent consideration</b>	3,654	3,419
<b>Derivative warrant liabilities</b>	21,207	9,138
	<u>32,188</u>	<u>21,047</u>

### Shareholders' equity

#### Share capital

Common shares	498,698	299,815
Warrants	906	971

<b>Contributed surplus</b>	17,442	17,017
<b>Accumulated other comprehensive loss</b>	(894)	(805)
<b>Deficit</b>	<u>(348,508)</u>	<u>(281,048)</u>

167,644                      35,950

199,832                      56,997

## Aurinia Pharmaceuticals Inc.

Interim Condensed Statements of Operations and Comprehensive Loss (*Unaudited*)  
(Expressed in thousands of U.S. dollars, except per share data)

**Three months ended**  
**September 30, September 30,**  
**2017                      2016**  
**\$                              \$**

### Revenue

Licensing revenue	29	29
Contract services	-	2
	<u>-</u>	<u>2</u>

	29	31
<b>Expenses</b>		
Research and development	10,807	3,342
Corporate, administration and business development	2,650	1,716
Amortization of acquired intellectual property and other intangible assets	357	357
Amortization of property and equipment	5	5
Contract services	-	1
Other expense (income)	(315)	1,078
	<u>13,504</u>	<u>6,499</u>
<b>Net loss before change in estimated fair value of derivative warrant liabilities</b>	(13,475)	(6,468)
Change in estimated fair value of derivative warrant liabilities	355	(951)
	<u>(13,120)</u>	<u>(7,419)</u>
<b>Net loss for the period</b>		
<b>Other comprehensive income (loss)</b>		
Item that may be reclassified subsequently to income (loss)		
Net change in fair value of short term investments	(89)	-
	<u>(13,209)</u>	<u>(7,419)</u>
<b>Net comprehensive loss for the period</b>		
<b>Net loss per common share</b> (expressed in \$ per share)		
Basic and diluted loss per common share	(0.16)	(0.21)

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<http://www.businesswire.com/news/home/20171114006358/en/>

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