

March 15, 2018



# Aurinia Reports Fourth Quarter and Full Year 2017 Financial Results and Operational Highlights

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

**Trials in FSGS and Dry Eye to begin in Q2 2018**

**Cash of \$173.5 million as of December 31, 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, 2017. Amounts, unless specified otherwise, are expressed in U.S. dollars.

"Aurinia gained remarkable momentum in 2017, as demonstrated by the achievement of all of our important milestones—strong Phase II results for voclosporin in LN, initiation of our Phase III AURORA trial for LN, and the announcement of two exciting new clinical programs," said Richard Glickman, Aurinia CEO and Chairman of the Board. "We are well-capitalized into 2020 and positioned for a prolific 2018 as the team continues to execute on the plans we've outlined for 2018. We intend to submit the first module of a rolling NDA later this year for our lead LN program and complete enrollment of our Phase III AURORA trial. In addition, our team is working diligently to initiate Phase II trials for FSGS and dry eye syndrome in Q2."

## **2017 and other recent highlights**

- We strengthened the breadth and scope of our Board of Directors with the recent additions of Michael Hayden and Joseph Hagan in February of 2018 and George Milne in May of 2017.

On October 20, 2017, we announced our plans to pursue additional indications for voclosporin, representing an expansion of the Company's strategy, pipeline and commercial opportunities.

- A Phase II proof-of-concept trial in focal segmental glomerulosclerosis ("FSGS") will begin in Q2 2018. A pre-IND meeting was completed in February 2018.
- A Phase IIa tolerability study of voclosporin ophthalmic solution ("VOS") versus the standard of care for the treatment of dry eye syndrome ("DES") will begin in Q2 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.

- In May 2017, we initiated our Phase III clinical trial (“AURORA”) to evaluate voclosporin for the treatment of lupus nephritis (“LN”). The AURORA trial is on track to complete enrollment in Q4 2018. We currently have 201 clinical trial sites activated and able to enroll patients 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.
- On March 20, 2017, we completed a public offering for net proceeds of \$162.3 million, strengthening the Company’s balance sheet and extending our cash runway into 2020.
- On March 1, 2017, we released positive 48-week results from our Phase II AURA clinical trial for the treatment of LN. Additional data were released on April 20, 2017.

### **Financial Liquidity at December 31, 2017**

In 2017, we raised net proceeds of \$162.3 million from the March 20, 2017 public offering and received \$12.8 million from the exercise of warrants and options. As a result, at December 31, 2017, we had cash, cash equivalents and short term investments of \$173.5 million and working capital of \$167.1 million compared to \$39.6 million of cash and \$33.5 million of working capital at December 31, 2016. Net cash used in operating activities was \$41.2 million for the year ended December 31, 2017, compared to \$18.7 million for the year ended 2016.

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 fourth quarter ended December 31, 2017**

We reported a consolidated net loss of \$3.3 million or \$0.04 per common share for the fourth quarter ended December 31, 2017, as compared to a consolidated net loss of \$8.3 million or \$0.21 per common share for the fourth quarter ended December 31, 2016.

The loss for the fourth quarter ended December 31, 2017 reflected a \$9.0 million reduction in the estimated fair value of derivative warrant liabilities compared to a reduction of \$658,000 in the estimated fair value of derivative warrant liabilities for the fourth quarter ended December 31, 2016.

The net loss before this non-cash change in estimated fair value of derivative warrant liabilities was \$12.4 million for the fourth quarter ended December 31, 2017 compared to \$9.0 million for the same period in 2016.

Research and development (“R&D”) expenses increased to \$8.7 million in the fourth quarter of 2017, compared to \$5.5 million in the fourth quarter of 2016 primarily due to increased AURORA trial costs related to patient enrollment and treatment costs.

Corporate, administration and business development expense also increased to \$3.1

million for the fourth quarter of 2017, compared to \$2.2 million for the fourth quarter of 2016, reflecting increased personnel and level of activities. In addition, these expenses reflected an increase in non-cash stock compensation expense to \$653,000 for the fourth quarter ended December 31, 2017 compared to \$314,000 for the same period in 2016.

### **Financial Results for the year ended December 31, 2017**

For the year ended December 31, 2017, the Company recorded a consolidated net loss of \$70.9 million or \$0.92 per common share, which included a non-cash increase of \$23.9 million related to the estimated fair value annual adjustment of derivative warrant liabilities at December 31, 2017. After adjusting for this non-cash impact, the net loss before this change in estimated fair value of derivative warrant liabilities was \$47.0 million.

This compared to a consolidated net loss of \$23.3 million or \$0.66 per common share in 2016 which included a non-cash reduction of \$1.7 million in the estimated fair value of derivative warrant liabilities for the year ended December 31, 2016. After adjusting for the non-cash impact for 2016, the net loss before this change in estimated fair value of derivative warrant liabilities was \$25.0 million.

The change in the revaluation of the derivative warrant liabilities is primarily driven by the change in our share price. Our share price of \$4.53 was significantly higher at December 31, 2017 compared to our share price of \$2.10 at December 31, 2016. This increase in price resulted in large increases in the estimated fair value of derivative warrant liabilities. 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.

We incurred net R&D expenses of \$33.9 million for the year ended December 31, 2017, as compared to \$14.5 million for the year ended December 31, 2016. The increase in these expenses resulted primarily from the clinical and drug supply expenses associated with our AURORA trial which commenced active patient enrollment and treatment in May of 2017. R&D expenses for 2016 included costs related to the AURORA planning phase and completion costs for the Phase II AURA trial.

We incurred corporate, administration and business development expenses of \$12.1 million for the year ended December 31, 2017, as compared with \$7.0 million for the same period in fiscal 2016. The increase in these expenses reflected overall higher activity levels, higher consulting fees, sponsorships and tradeshow expenses related to greater investor and public affairs activities and higher personnel compensation costs which included non-cash stock compensation expense of \$3.2 million for the year ended December 31, 2017 compared to \$1.0 million for the year ended December 31, 2016.

The audited financial statements and the Management's Discussion and Analysis for the year ended December 31, 2017, 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 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 of 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.**  
**Condensed Consolidated Statements of Financial Position**  
**(unaudited – amounts in thousands of U.S. dollars)**

	<b>December 31, 2017 \$</b>	<b>December 31, 2016 \$</b>
<b>Assets</b>		
Cash and cash equivalents	165,629	39,649
Short term investments	7,833	-
Other current assets	1,790	1,769
Total current assets	<u>175,252</u>	<u>41,418</u>
Acquired intellectual property and other intangible assets	14,116	15,550
Other non-current assets	<u>479</u>	<u>29</u>
Total assets	<u>189,847</u>	<u>56,997</u>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	7,959	5,791
Other current liabilities	191	2,139
Total current liabilities	<u>8,150</u>	<u>7,930</u>
Derivative warrant liabilities	11,793	9,138
Other non-current liabilities	<u>4,161</u>	<u>3,979</u>
Total liabilities	<u>24,104</u>	<u>21,047</u>

Shareholders' equity	165,743	35,950
Total liabilities and shareholders' equity	<u>189,847</u>	<u>56,997</u>

**Aurinia Pharmaceuticals Inc.**

**Condensed Consolidated Statements of Operations**

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

	<b>Three Months</b>		<b>Year Ended</b>	
	<b>Ended</b>		<b>December 31</b>	
	<b>December 31</b>	<b>December 31</b>	<b>December 31</b>	<b>December 31</b>
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Revenue</b>				
Licensing revenue	30	30	418	118
Research and development revenue	-	-	-	50
Contract services	1	-	2	5
	<u>31</u>	<u>30</u>	<u>420</u>	<u>173</u>
<b>Expenses</b>				
Research and development	8,691	5,462	33,930	14,534
Corporate, administration and business development	3,118	2,227	12,096	6,970
Amortization of acquired intellectual property and other intangible assets	361	365	1,434	1,457
Amortization of property and equipment	-	-	22	22
Contract services	-	1	1	4
Other expense (income)	197	966	(195)	2,213
	<u>12,367</u>	<u>9,021</u>	<u>47,288</u>	<u>25,200</u>
<b>Net loss before change in estimated fair value of</b>				
<b>derivative warrant liabilities</b>	(12,336)	(8,991)	(46,868)	(25,027)
Change in estimated fair value of derivative warrant liabilities	9,004	658	(23,924)	1,732
	<u>(3,332)</u>	<u>(8,333)</u>	<u>(70,792)</u>	<u>(23,295)</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	11	-	(78)	-
<b>Net comprehensive loss for the period</b>	<u>(3,321)</u>	<u>(8,333)</u>	<u>(70,870)</u>	<u>(23,295)</u>
<b>Net loss per common share (expressed in \$ per share)</b>				
Basic and diluted loss per common share	<u>(0.04)</u>	<u>(0.21)</u>	<u>(0.92)</u>	<u>(0.66)</u>

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<http://www.businesswire.com/news/home/20180315006132/en/>

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Source: Aurinia Pharmaceuticals Inc.