

November 8, 2018



# Aurinia Reports Third Quarter Financial Results, Clinical Highlights and Corporate Development

- *AURORA Phase III Trial in lupus nephritis completes enrollment ahead of schedule*
- *Phase II data for the treatment of dry eye expected in January 2019*
- *Phase II FSGS Trial ongoing*
- *Richard M. Glickman announces his intention to retire as CEO next year, upon identification and appointment of an appropriate successor*

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, 2018. Amounts, unless specified otherwise, are expressed in U.S. dollars.

"We achieved a significant milestone in September with the completion of enrollment for the AURORA Phase III trial ahead of schedule. Our target enrollment of 324 patients was surpassed due to high patient demand with 358 LN patients randomized in sites across 27 countries." said Richard M. Glickman, Aurinia's CEO and Chairman of the Board. "I continue to be impressed by our clinical team which has delivered on our important milestones, and to that end, I am pleased to announce enrollment for the phase II dry eye trial will be completed in the next couple of days, and we expect top-line data in January 2019."

## Clinical Highlights

- Our Phase III clinical trial ("AURORA") to evaluate voclosporin for the treatment of lupus nephritis ("LN"), which we initiated in May of 2017, completed enrollment in September 2018. We expect top-line data to be available in late 2019.
- A significant percentage of patients who have completed the AURORA trial are rolling over into the AURORA 2 blinded extension study ("AURORA 2") from the AURORA Phase III clinical trial. The purpose of AURORA 2 is to assess the long-term benefit/risk of voclosporin in patients with LN; however, this study is not a requirement for potential regulatory approval for voclosporin.
- We 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, and full enrollment is

anticipated imminently. This four-week study of approximately 90 patients is expected to complete by the end of 2018 with data available in January 2019. 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.

- We also initiated a Phase II proof-of-concept study in focal segmental glomerulosclerosis (“FSGS”) in June 2018 and are currently in the process of enrolling patients. This is an open-label study of 20 treatment naïve patients diagnosed with primary FSGS.

## **Corporate Development**

Aurinia also announced today that Richard M. Glickman, the Company’s Chairman and Chief Executive Officer, intends to retire from his position once a suitable replacement is identified and appointed. The Board of Directors will retain a search firm and initiate a search for his successor.

“Richard is a gifted entrepreneur who has established Aurinia as a leading biotech company and shepherded it to its next phase of growth. On behalf of the Board of Directors, I want to thank him for his inspired leadership and significant contribution to both the Company and patient community since Aurinia’s inception in 2012,” said George M. Milne Jr, Ph.D., Independent Director and Chairman of the Governance Committee. “Under his direction, the Company has delivered on all its key milestones and evolved into a patient-centric, late-stage clinical company with investigational drugs addressing multiple indications across the global immunology market.”

“Two years ago - a critical time in the company’s growth - my decision to come out of retirement to join Aurinia as CEO was fueled by my absolute belief in the potential for voclosporin to transform the lupus nephritis treatment landscape,” said Dr. Glickman. “I’m incredibly proud of Aurinia’s progress over the last 21 months, and I know this is the optimal time to bring in a new CEO who will build on our clinical success as we approach commercialization. My commitment to the Company and the patients it serves is steadfast, and I plan to remain a resource to the Board and management team as it enters its next chapter.”

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

At September 30, 2018, we had cash, cash equivalents and short term investments of \$138.9 million compared to \$150.2 million at June 30, 2018 and \$173.5 million at December 31, 2017. Net cash used in operating activities was \$11.3 million for the third quarter ended September 30, 2018 compared to \$8.5 million for the third quarter ended September 30, 2017.

We believe that our cash position is sufficient to fund our existing LN program including the AURORA clinical trial, conduct our current studies in FSGS and DES, complete the work required for the NDA submission to the FDA, and fund operations into 2020.

## **Financial Results for the Three and Nine Months Ended September 30, 2018**

We reported a consolidated net loss of \$18.3 million or \$0.21 per common share for the three months ended September 30, 2018, as compared to a consolidated net loss of \$13.1 million or \$0.16 per common share for the three months ended September 30, 2017.

The increase in the loss for the three months ended September 30, 2018 compared to the same period in 2017 was primarily due to the non-cash change of \$5.2 million in the estimated fair value of derivative warrant liabilities. The three months ended September 30, 2018 reflected a \$4.8 million increase in the estimated fair value of derivative warrant liabilities compared to a reduction of \$355,000 in the estimated fair value of derivative warrant liabilities for the three months ended September 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 \$13.5 million for the three months ended September 30, 2018 compared to \$13.5 million for the same period in 2017.

For the nine months ended September 30, 2018, the consolidated net loss was \$49.5 million or \$0.59 per common share compared to a consolidated net loss of \$67.5 million or \$0.91 per common share for the comparable period in 2017. For the nine months ended September 30, 2018 we recorded an increase of \$9.4 million in the estimated fair value of derivative warrant liabilities compared to \$32.9 million for the comparable period in 2017.

The net loss before the non-cash change in estimated fair value of derivative warrant liabilities was \$40.1 million for the nine months ended September 30, 2018 compared to \$34.5 million for the same period in 2017. The increased loss was primarily due to higher research and development expenses.

Research and development expenses increased to \$11.2 million for the three months ended September 30, 2018, compared to \$10.8 million for the three months ended September 30, 2017. We incurred research and development expenses of \$30.5 million for the nine months ended September 30, 2018, as compared to \$25.2 million for the same period in 2017. The increased research and development expenses reflected costs associated with the commencements of AURORA 2 and the FSGS and DES studies.

Corporate, administration and business development expenses increased to \$2.9 million for the three months ended September 30, 2018, compared to \$2.7 million for the same period in 2017. We incurred corporate, administration and business development expenses of \$10.2 million for the nine months ended September 30, 2018 compared to \$9.0 million for the comparable period in 2017. The increase was due primarily to higher non-cash stock compensation expense in 2018 compared to the same periods in 2017.

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, 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).

Aurinia will host a conference call and webcast to discuss third quarter 2018 financial results today, Thursday, November 8, 2018 at 4:30 p.m. ET. This event can be accessed on the investor section of the Aurinia website at [www.aurinia.com](http://www.aurinia.com).

## **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 potential 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 having data in Q4 2019, completing NDA submissions in a successful and timely manner, 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 current 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 Statement of Financial Position**

**(unaudited – amounts in thousands of U.S. dollars)**

	<b>September 30, 2018 \$</b>	<b>December 31, 2017 \$</b>
<b>Assets</b>		
Cash and cash equivalents	114,898	165,629

Short term investments	23,985	7,833
Other current assets	5,164	1,790
Total current assets	<u>144,047</u>	<u>175,252</u>
Acquired intellectual property and other intangible assets	12,951	14,116
Other non-current assets	697	479
Total assets	<u>157,695</u>	<u>189,847</u>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	6,694	7,959
Other current liabilities	190	191
Total current liabilities	<u>6,884</u>	<u>8,150</u>
Derivative warrant liabilities	21,154	11,793
Other non-current liabilities	4,315	4,161
Total liabilities	<u>32,353</u>	<u>24,104</u>
Shareholders' equity	125,342	165,743
Total liabilities and shareholders' equity	<u>157,695</u>	<u>189,847</u>

#### **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		Nine months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing revenue	30	29	89	388
Contract revenue	345	-	345	-
	<u>375</u>	<u>29</u>	<u>434</u>	<u>388</u>
<b>Expenses</b>				
Research and development	11,152	10,807	30,543	25,239
Corporate, administration and business development	2,923	2,650	10,176	8,978
Amortization of acquired intellectual property and other intangible assets	403	357	1,196	1,078
Amortization of property and equipment	5	5	14	17
Other (income) expense	(563)	(315)	(1,329)	(392)
	<u>(563)</u>	<u>(315)</u>	<u>(1,329)</u>	<u>(392)</u>

	13,920	13,504	40,600	34,920
<b>Net loss before change in estimated fair value of derivative warrant liabilities</b>	(13,545)	(13,475)	(40,166)	(34,532)
<b>Change in estimated fair value of derivative warrant liabilities</b>	(4,797)	355	(9,361)	(32,928)
<b>Net loss for the period</b>	(18,342)	(13,120)	(49,527)	(67,460)
<b>Other comprehensive income (loss)</b>				
Net change in fair value of short term investments	-	(89)	-	(89)
<b>Net comprehensive loss for the period</b>	(18,342)	(13,209)	(49,527)	(67,549)
<b>Net loss per common share</b> (expressed in \$ per common share)				
Basic and diluted loss per common share	(0.21)	(0.16)	(0.59)	(0.91)
<b>Weighted average number of common shares outstanding (in thousands)</b>	84,321	83,608	84,579	74,519

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Source: Aurinia Pharmaceuticals Inc.