

March 19, 2019



# Aurinia Reports Fourth Quarter and Full Year 2018 Financial Results and Operational Highlights

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

## 2018 and Recent Highlights

- *Notice of Allowance from the United States Patent and Trademark Office ("USPTO") for claims which have the potential to cover voclosporin's method of use and dosing protocol for lupus nephritis ("LN") until December 2037.*
- *Phase 2a Dry Eye Study results released in January 2019 demonstrating statistically superior efficacy of voclosporin ophthalmic solution ("VOS") versus Restasis®.*
- *AURORA Phase 3 trial in LN completed patient enrollment, ahead of schedule, in September 2018 - on track for top-line data in late 2019.*
- *Phase 2 FSGS study with voclosporin initiated in June 2018 with patient recruitment ongoing.*
- *Cash, cash equivalents, and short-term investments of \$125.9 million as of December 31, 2018.*
- *Balance sheet strengthened with additional \$30 million raised through ATM facility during Q1 2019.*

"The team at Aurinia has made extraordinary progress throughout 2018 by achieving a number of significant clinical milestones with voclosporin, and we are excited for what lies ahead in 2019. In addition to completing enrollment in the AURORA Phase 3 trial ahead of schedule last September, we also released Phase 2a dry eye study results with VOS that we believe further demonstrate the potential of voclosporin", commented Richard M. Glickman, Chief Executive Officer and Chairman of the Board of Aurinia Pharmaceuticals."

Dr. Glickman further commented, "With the recent Notice of Allowance we received from the USPTO for claims covering voclosporin's method of use and dosing protocol for the treatment of proteinuric kidney diseases including LN, we are very pleased with the additional exclusivity that could extend to December 2037 which I believe provides additional value creating opportunities for our shareholders."

## Highlights

## USPTO Notice of Allowance

On February 25, 2019, Aurinia announced that it received a Notice of Allowance from the USPTO for claims directed at its novel voclosporin dosing protocol for LN (U.S. patent application 15/835,219, entitled “PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS”).

The allowed claims broadly cover the novel voclosporin *individualized flat-dosed pharmacodynamic treatment protocol* adhered to and required in both the previously reported Phase 2 AURA-LV trial and the Company’s ongoing Phase 3 confirmatory AURORA trial. Notably, the allowed claims cover a method of modifying the dose of voclosporin in patients with LN based on patient specific pharmacodynamic parameters.

This Notice of Allowance concludes a substantive examination of the patent application at the USPTO, and after administrative processes are completed and fees are paid, is expected to result in the issuance of a U.S. patent with a term extending to December 2037. If the FDA approves the use of voclosporin for LN and the label for such use follows the dosing protocol under the Notice of Allowance, the issuance of this patent will expand the scope of intellectual property protection for voclosporin, which already includes robust manufacturing, formulation, synthesis and composition of matter patents.

## AURORA LN Clinical Trials

Aurinia’s Phase 3 clinical trial (“AURORA”) is evaluating voclosporin for the treatment of LN, which was initiated in May of 2017, completed enrollment in September 2018. The target enrolment of 324 patients was surpassed due to high patient and investigator demand with 358 LN patients randomized in sites across 27 countries. Top-line data is expected to be available in Q4 2019.

A significant percentage of patients who have completed the AURORA trial are rolling over into the AURORA blinded extension trial (“AURORA 2”). The purpose of AURORA 2 is to assess the long-term benefit/risk of voclosporin in patients with LN; this trial is not a requirement for potential regulatory approval of voclosporin.

## Dry Eye Syndrome (“DES”)

In July 2018, Aurinia initiated a Phase 2a head-to-head study of voclosporin ophthalmic solution (“VOS”) versus Restasis® (cyclosporine ophthalmic emulsion) 0.05% for the treatment of moderate to severe DES. This four-week study enrolled a total of 100 patients.

In January 2019 the Company announced results from this study. The study evaluated efficacy, safety and tolerability head to head with Restasis®.

- *VOS showed statistical superiority to Restasis® on FDA-accepted objective signs of DES*
- *42.9% of VOS subjects vs 18.4% of Restasis® subjects ( $p=0.0055$ ) demonstrated  $\geq 10$ mm improvement in Schirmer Tear Test (“STT”) at Week 4*
- *VOS showed statistical superiority to Restasis in Fluorescein Corneal Staining (“FCS”) ( $p=0.0003$ )*

- *The primary endpoint of drop discomfort at 1-minute on the first day of therapy showed no statistical difference between the treatment groups, as both groups exhibited low drop discomfort scores*

With respect to the primary endpoint of drop discomfort, VOS did not meet the primary endpoint as both drugs were well tolerated and demonstrated less than anticipated drop discomfort. However, secondary outcome measures on efficacy, namely the STT and FCS, demonstrated statistically superior results over Restasis®.

### **Focal Segmental Glomerulosclerosis (“FSGS”)**

Aurinia initiated a Phase 2 proof-of-concept study for FSGS in June 2018 and is currently in the process of enrolling patients with this disease. This proof-of-concept Phase 2 open-label study aims to enroll approximately 20 treatment-naïve patients diagnosed with primary FSGS.

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

At December 31, 2018, Aurinia had cash, cash equivalents and short-term investments of \$125.9 million compared to \$173.5 million of cash and short-term investments at December 31, 2017. Net cash used in operating activities was \$51.6 million for the year ended December 31, 2018, compared to \$41.2 million for the year ended December 31, 2017.

### **At-The-Market (“ATM”) Facility**

On November 30, 2018, Aurinia entered into an open market sale agreement with Jefferies LLC pursuant to which the Company could from time to time sell, through ATM offerings, common shares that would have an aggregate offering amount of up to \$30 million. Subsequent to year-end, the ATM was fully utilized. Aurinia received gross proceeds of \$30 million and issued 4.6 million common shares. The Company incurred share issue costs of \$1.2 million including a 3% commission and professional and filing fees related to the ATM offering.

### **February 14, 2014 Warrant Exercises**

The derivative warrants outstanding related to the February 14, 2014 private placement offering were exercised subsequent to December 31, 2018. Certain holders of these warrants elected the cashless exercise option and the Company issued 687,000 common shares on the cashless exercise of 1.3 million warrants. Three holders of 464,000 warrants exercised these warrants for cash, at a price of \$3.2204. We received cash proceeds of \$1.5 million and issued 464,000 common shares.

The Company believes, based on its current plans that Aurinia has sufficient financial resources to fund the existing LN program, including the AURORA trial and the AURORA 2 extension trial, complete the NDA submission to the FDA, conduct the ongoing Phase 2 study for FSGS, commence additional DES studies and fund operations into mid-2020.

### **Financial Results for the Fourth Quarter Ended December 31, 2018**

The Company reported a consolidated net loss of \$14.6 million or \$0.17 per common share for the fourth quarter ended December 31, 2018, as compared to a consolidated net loss of

\$3.3 million or \$0.04 per common share for the fourth quarter ended December 31, 2017.

The loss for the fourth quarter ended December 31, 2018 reflected an increase of \$593,000 in the estimated fair value of derivative warrant liabilities compared to a reduction of \$9.0 million in the estimated fair value of derivative warrant liabilities for the fourth quarter ended December 31, 2017.

The net loss before this non-cash change in estimated fair value of derivative warrant liabilities was \$13.9 million for the fourth quarter ended December 31, 2018 compared to \$12.3 million for the same period in 2017.

Research and development ("R&D") expenses increased to \$10.8 million in the fourth quarter of 2018, compared to \$8.7 million in the fourth quarter of 2017. The increase in these expenses primarily reflected costs incurred for the AURORA 2 extension trial, the DDI study and the FSGS and DES Phase 2 studies which were newly enrolled studies in 2018.

Corporate, administration and business development expenses increased to \$3.5 million for the fourth quarter of 2018, compared to \$3.1 million for the fourth quarter of 2017, reflecting higher professional fees incurred during the fourth quarter of 2018.

### **Financial Results for the Year Ended December 31, 2018**

For the year ended December 31, 2018, Aurinia recorded a consolidated net loss of \$64.1 million or \$0.76 per common share, which included a non-cash increase of \$10.0 million related to the estimated fair value annual adjustment of derivative warrant liabilities at December 31, 2018. After adjusting for this non-cash impact, the net loss before this change in estimated fair value of derivative warrant liabilities was \$54.1 million.

This compared to a consolidated net loss of \$70.8 million or \$0.92 per common share in 2017, which included a non-cash increase of \$23.9 million in the estimated fair value of derivative warrant liabilities for the year ended December 31, 2017. After adjusting for this non-cash impact for 2017, the net loss before this change in estimated fair value of derivative warrant liabilities was \$46.9 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 \$6.82 was significantly higher at December 31, 2018, compared to our share price of \$4.53 at December 31, 2017. This increase in our share price resulted in large increases in the estimated fair value of derivative warrant liabilities for each of 2018 and 2017. 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 Aurinia.

We incurred R&D expenses of \$41.4 million for the year ended December 31, 2018, as compared to \$33.9 million for the year ended December 31, 2017. The increase in R&D expenses in 2018 primarily reflected costs related to the AURORA 2 extension trial, the DDI study and the FSGS and DES Phase 2 studies.

We incurred corporate, administration and business development expenses of \$13.7 million for the year ended December 31, 2018, as compared with \$12.1 million for the same period in fiscal 2017. The increase in these expenses reflected higher corporate activity levels

overall, and higher personnel compensation costs which included a non-cash stock compensation expense of \$4.2 million for the year ended December 31, 2018, compared to \$3.2 million for the year ended December 31, 2017.

The audited financial statements and the Management's Discussion and Analysis for the year ended December 31, 2018, 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 the fourth quarter and year ended December 31, 2018 financial results today, Tuesday, March 19, 2019 at 4:30 p.m. ET. This event can be accessed on the investor section of the Aurinia website at [www.auriniapharma.com](http://www.auriniapharma.com).

### **About Aurinia**

Aurinia Pharmaceuticals is a late clinical-stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are impacted by 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, 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 Calcineurin inhibitors ("CNIs") 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. Further, the new Notice of Allowance is expected to result in the issuance of a U.S. patent with a term extending to December 2037. If the FDA approves the use of voclosporin for LN and the label for such use follows the dosing protocol under the Notice of Allowance, the issuance of this patent will expand the scope of intellectual property protection for voclosporin to December 2037.

### **About VOS**

Voclosporin ophthalmic solution ("VOS") is an aqueous, preservative free nanomicellar solution intended for use in the treatment of DES. Studies have been completed in rabbit and dog models, and a single Phase 1 has also been completed in healthy volunteers and patients with DES. VOS has IP protection until 2031.

### **About LN**

Lupus Nephritis (“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 and 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**

Focal segmental glomerulosclerosis (“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 the 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 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 around the end of this year, completing NDA submissions in a successful and timely manner, voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; 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 2a study for FSGS, commence additional studies for DES and fund operations into mid-2020 and that the efficacy endpoint clearly signals that VOS has the potential to have a more rapid onset than Restasis® as measured by signs of the disease. 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.**

**Condensed Consolidated Statements of Financial Position**

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

	December 31, 2018 \$	December 31, 2017 \$
<b>Assets</b>		
Cash and cash equivalents	117,967	165,629
Short term investments	7,889	7,833
Accounts receivable and accrued interest receivable	217	109
Prepaid expenses, deposits and other	6,775	1,681
Total current assets	<u>132,848</u>	<u>175,252</u>
<b>Acquired intellectual property and other intangible assets</b>	12,616	14,116
<b>Other non-current assets</b>	399	479
<b>Total assets</b>	<u><u>145,863</u></u>	<u><u>189,847</u></u>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	7,071	7,959
Other current liabilities	190	191
Total current liabilities	<u>7,261</u>	<u>8,150</u>
Derivative warrant liabilities	21,747	11,793
<b>Other non-current liabilities</b>	4,280	4,161
<b>Total liabilities</b>	<u>33,288</u>	<u>24,104</u>
Shareholders' equity	112,575	165,743
<b>Total liabilities and shareholders' equity</b>	<u><u>145,863</u></u>	<u><u>189,847</u></u>

**Aurinia Pharmaceuticals Inc.**

**Condensed Consolidated Statements of Operations and Comprehensive Loss**

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

	Three Months Ended		Year Ended	
	December 31 2018	December 31 2017	December 31 2018	December 31 2017
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing revenue	29	30	118	418
Contract revenue	-	-	345	-
	<u>29</u>	<u>30</u>	<u>463</u>	<u>418</u>



**Expenses**

Research and development	10,839	8,691	41,382	33,930
Corporate, administration and business development	3,498	3,118	13,674	12,096
Amortization of acquired intellectual property and other intangible assets	349	356	1,545	1,434
Amortization of property and equipment	6	5	20	22
Other expense (income)	(736)	196	(2,065)	(196)
	<u>13,956</u>	<u>12,366</u>	<u>54,556</u>	<u>47,286</u>

**Net loss before change in estimated fair value of derivative warrant liabilities**

(13,927) (12,336) (54,093) (46,868)

**Change in estimated fair value of derivative warrant liabilities**

(593) 9,004 (9,954) (23,924)

**Loss before income taxes**

(14,520) (3,332) (64,047) (70,792)

**Income tax expense**

73 - 73 -

**Net loss for the period**

(14,593) (3,332) (64,120) (70,792)

**Other comprehensive loss**

Item that may be reclassified subsequently to loss

Net change in fair value of short term investments - 11 - (78)

**Net comprehensive loss for the period**

(14,593) (3,321) (64,120) (70,870)

**Net loss per common share (in \$ per share)**

Basic and diluted loss per common share (0.17) (0.04) (0.76) (0.92)

**Weighted average number of common shares outstanding**

85,384 84,038 84,782 76,918

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Source: Aurinia Pharmaceuticals Inc.