

March 5, 2020



# Aurinia Reports Fourth Quarter and Full Year 2019 Financial Results and Operational Highlights

- *Cash and cash equivalents totaled approximately \$306 million at December 31, 2019 -*
- *Positive AURORA Phase 3 results with voclosporin enabling an NDA submission for the treatment of lupus nephritis (“LN”) by the end of the second quarter 2020 -*
- *Continued build out of a top-tier commercial team, highlighted by the appointment of Max Colao, Chief Commercial Officer, focused on launch activities -*
- *AUDREY Phase 2/3 Dry Eye Study remains on-track with results anticipated during the second half of 2020 -*

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH / TSX: AUP) (“Aurinia” or the “Company”) today issued its financial results for the fourth quarter and year ended December 31, 2019. Amounts, unless specified otherwise, are expressed in U.S. dollars.

“2019 was a truly transformational year for Aurinia, highlighted by the positive results achieved with voclosporin in the Phase 3 AURORA clinical trial for the treatment of LN. As the team works diligently to prepare and file a New Drug Application to the U.S. FDA next quarter, we continue to build out an incredibly talented and experienced commercial team that will be led by Max Colao, Aurinia’s newly appointed Chief Commercial Officer,” commented Peter Greenleaf, President and Chief Executive Officer of Aurinia.

“Beyond the impact voclosporin could bring to those living with LN, we continue to evaluate voclosporin in additional indications, including the rare kidney disease, FSGS, as well as for the potential management of dry eye syndrome. During the second half of 2020, we anticipate reporting new data from both of these development programs, consisting of interim data from the exploratory Phase 2 FSGS study and results from the Phase 2/3 AUDREY DES trial evaluating 3 concentrations of VOS compared to vehicle alone,” said Neil Solomons, Chief Medical Officer of Aurinia.

## Recent Operational Highlights

### Pre-NDA Meeting with the U.S. Food & Drug Administration (“FDA”)

Aurinia held a positive and successful Pre-NDA meeting with the FDA Division of Pulmonary, Allergy and Rheumatology Products on February 25, 2020. The Company presented information about the safety and efficacy data to be included in the filing, reviewed the format and content of the planned application, and gained agreement on the rolling review

plans for filing modules of the NDA. No obstacles were raised by FDA that would prevent submission of the complete NDA by the end of the second quarter as planned.

**Appointment of Max Colao as Chief Commercial Officer and build out of commercial team**

On February 25, 2020, Aurinia announced the appointment of Max Colao to the newly created position of Chief Commercial Officer. In addition, Aurinia has recruited an experienced team of leaders across key commercial functions including sales, marketing, market access, and commercial operations.

## **AURORA Phase 3 LN Trial**

On December 4, 2019, Aurinia announced positive efficacy and safety results from its pivotal AURORA Phase 3 trial of voclosporin, in combination with mycophenolate (“MMF”) and low-dose corticosteroids, in the treatment of LN. The global study in which 357 patients with active LN were enrolled, met its primary endpoint of Renal Response rates of 40.8% for voclosporin vs. 22.5% for the control (OR 2.65;  $p < 0.001$ ). Additionally, all pre-specified hierarchical secondary endpoints achieved statistical significance in favor of voclosporin, which included Renal Response at 24 weeks, Partial Renal Response at 24 and 52 weeks, time to achieve urinary protein-to-creatinine ratio (“UPCR”)  $\leq 0.5$ , and time to 50% reduction in UPCR. The robustness of the data was also supported by all pre-specified subgroup analyses (age, sex, race, biopsy class, region, and prior MMF use) favoring voclosporin.

Voclosporin was well tolerated with no unexpected safety signals. Serious adverse events (“SAEs”) were reported in 20.8% of voclosporin patients vs. 21.3% in the control arm. Infection was the most commonly reported SAE with 10.1% of voclosporin patients versus 11.2% of patients in the control arm. Overall mortality in the trial was low, with six deaths observed; one in the voclosporin arm and five in the control group. Additionally, the voclosporin arm showed no significant decrease at week 52 in estimated glomerular filtration rate (“eGFR”) or increase in blood pressure, lipids or glucose, which are common adverse events associated with legacy calcineurin inhibitors (“CNIs”).

The AURORA Phase 3 clinical trial was initiated in May of 2017 and completed enrollment in September 2018.

## **AURORA 2 Extension Trial**

Eligible patients completing the AURORA trial had the option to roll over into a 104-week blinded extension study (the “AURORA 2 extension study”). A total of 216 patients enrolled into the AURORA 2 extension study. The data from the AURORA 2 extension study will allow the Company to assess the long-term benefit/risk of voclosporin in LN patients, however, this study is not a requirement for potential regulatory approval for voclosporin. Data from the AURORA 2 extension study assessing long-term outcomes in LN patients should be valuable in a post-marketing setting and for future interactions with regulatory authorities.

## **Voclosporin Drug-Drug Interaction (“DDI”) Study**

On November 7, 2019, Aurinia announced the completion of a FDA-requested clinical DDI study in patients with lupus that investigated the potential effect of voclosporin on blood levels of mycophenolate acid (“MPA”), the active metabolite of MMF. MMF, also known as CellCept®, is considered by treating physicians to be part of the current standard of care for lupus nephritis (“LN”) in the United States.

This FDA-requested clinical DDI study aimed to measure, and potentially quantify, the impact voclosporin may have on MPA blood levels when given concomitantly with MMF in patients with lupus. The study results indicate that the coadministration of voclosporin with MMF had no clinically significant impact on MPA blood concentrations. In past studies, it was reported that the legacy calcineurin inhibitors (“CNIs”) inhibit the multidrug-resistance-associated protein 2 (MRP-2) transporter in the biliary tract thereby preventing the excretion

of mycophenolic acid glucuronide (MPAG) into the bile leading to the enterohepatic recirculation of MPA1. This adverse impact of cyclosporine on MPA pharmacokinetics has resulted in a 30 – 50% reduction in MPA exposure when used in combination.<sup>1</sup>

### **Voclosporin '036 Method-of-Use Patent for Proteinuric Kidney Diseases**

On May 14, 2019, Aurinia was granted U.S. Patent 10,286,036 entitled 'PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS") with a term potentially extending to December 2037, for claims directed at our novel voclosporin dosing protocol for LN. 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 study and our 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.

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 until December 2037, supplementing an already robust manufacturing, formulation, synthesis and composition of matter patents.

### **AUDREY™ Phase 2/3 Trial for Dry Eye Syndrome (“DES”)**

In October 2019, Aurinia announced the initiation of patient dosing in the Phase 2/3 AUDREY™ clinical trial evaluating voclosporin ophthalmic solution (“VOS”) for the potential treatment of DES. The AUDREY trial is a randomized, double-masked, vehicle-controlled, dose-ranging study evaluating the efficacy and safety of VOS in subjects with DES. A total of approximately 480 subjects are expected to be enrolled. The study will consist of four arms with a 1:1:1:1 randomization schedule, in which patients will receive either 0.2% VOS, 0.1% VOS, 0.05% VOS or vehicle, dosed twice daily for 12 weeks. The primary outcome measure for the trial is the proportion of subjects with a 10mm improvement in Schirmer Tear Test (“STT”) at four weeks. Secondary outcome measures will include STT at other time points, Fluorescein Corneal Staining (“FCS”) at multiple time points, change in eye dryness, burning/stinging, itching, photophobia, eye pain and foreign body sensation at multiple time points, and additional safety endpoints. Top-line results from the AUDREY clinical study are anticipated during the second half of 2020.

In January of 2019, Aurinia reported Phase 2 results demonstrating that VOS (voclosporin 0.2%) administered twice daily was superior to cyclosporin A 0.05% (Restasis®) administered twice daily across all objective endpoints including FCS and STT. This statistical superiority was observed after two weeks of dosing. The exploratory study also showed no statistically significant nor clinically meaningful difference in drop discomfort, as measured by drop discomfort scores at one and five minutes after first application, between VOS 0.2% and cyclosporin A 0.05%.

### **Financial Liquidity at December 31, 2019**

At December 31, 2019, Aurinia had cash and cash equivalents of \$306 million at December 31, 2019, compared to \$125.9 million of cash and short-term investments at December 31, 2018. Net cash used in operating activities was \$63.5 million for the year ended December 31, 2019, compared to \$51.6 million for the year ended December 31, 2018.

The Company received net proceeds of \$179.9 million pursuant to its December 12, 2019, public offering.

The Company believes that it has sufficient financial resources to fund its current plans, which include conducting its ongoing research and development (“R&D”) programs, completing the NDA submission to the FDA, conducting pre-commercial and launch activities, manufacturing and packaging commercial drug supply required for launch, and fund its supporting corporate and working capital needs through 2021.

### **Financial Results for the Year Ended December 31, 2019**

For the year ended December 31, 2019, Aurinia recorded a consolidated net loss of \$123.8 million or \$1.33 per common share, which included a non-cash increase of \$41.1 million related to the estimated fair value adjustment of derivative warrant liabilities during 2019 and

at December 31, 2019.

The net loss before the change in estimated fair value of derivative warrant liabilities and income taxes was \$82.6 million or \$0.89 per common share for the year ended December 31, 2019. This compared to a consolidated net loss of \$64.1 million or \$0.76 per common share in 2018, which included a non-cash increase of \$10 million in the estimated fair value of derivative warrant liabilities for the year ended December 31, 2018. The net loss before the change in estimated fair value of derivative warrant liabilities income taxes was \$54.1 million or \$0.63 per common share for the year ended December 31, 2018.

The change in the revaluation of the derivative warrant liabilities is primarily driven by the change in Aurinia's share price. The Company's share price was significantly higher in December 2019 when 1.83 million derivative warrants were exercised and at December 31, 2019, when the closing share price was \$20.26, compared to the Company's share price of \$6.82 at December 31, 2018. This increase in share price resulted in a large increase in the estimated fair value of the derivative warrants for 2019. The derivative warrant liabilities will ultimately be eliminated on the exercise of the warrants and will not result in any cash outlay by Aurinia. In fiscal year 2019, 3.6 million derivative warrants were exercised with 1.7 million derivative warrants outstanding as of December 31, 2019.

Aurinia incurred R&D expenses of \$52.9 million for the year ended December 31, 2019, as compared to \$41.4 million for the year ended December 31, 2018. The increase in R&D expenses in 2019 included \$6.6 million to manufacture voclosporin for potential future commercial use and higher costs related to the AURORA 2 extension trial, the DDI study and ongoing dry eye studies, partially offset by a decrease in AURORA trial costs.

Aurinia incurred corporate, administration and business development expenses of \$22.2 million for the year ended December 31, 2019, as compared with \$13.7 million for the same period in fiscal 2018. The increase in these expenses reflected higher corporate activity levels including pre-commercial and launch readiness activities, higher professional and recruiting fees, insurance costs and personnel compensation costs.

Non-cash stock compensation expense was \$7.4 million for the year ended December 31, 2019, compared to \$6.9 million for the year ended December 31, 2018, and was included in both R&D and corporate, general and business development expenses.

### **Financial Results for the Fourth Quarter Ended December 31, 2019**

Aurinia reported a consolidated net loss of \$76.5 million or \$0.78 per common share for the fourth quarter ended December 31, 2019, as compared to a consolidated net loss of \$14.6 million, or \$0.17 per common share, for the fourth quarter ended December 31, 2018.

The increase in the loss for the fourth quarter ended December 31, 2019, primarily reflected an increase of \$48.0 million in the estimated fair value of derivative warrant liabilities compared to an increase of \$593,000 in the estimated fair value of derivative warrant liabilities for the fourth quarter ended December 31, 2018. This change in the estimated fair value reflected the significant increase in the Company's share price in December 2019 when 1.83 million derivative warrants were exercised and at December 31, 2019, when the closing share price was \$20.26, compared to the Company's share price of \$6.82 at December 31, 2018.

The net loss before the non-cash change in estimated fair value of derivative warrant liabilities and income taxes was \$28.9 million or \$0.29 per common share for the fourth quarter ended December 31, 2019, compared to \$13.9 million or \$0.17 per common share for the same period in 2018.

R&D expenses increased to \$13.3 million in the fourth quarter of 2019, compared to \$10.8 million in the fourth quarter of 2018. The increase in these expenses reflected costs related to NDA submission preparation costs, higher personnel costs, higher costs incurred for the AURORA 2 extension trial, and the AUDREY DES phase 2/3 study partially offset by lower

## AURORA trial costs.

Corporate, administration and business development expenses increased to \$7.2 million for the fourth quarter of 2019, compared to \$3.5 million for the fourth quarter of 2018, reflecting higher pre-commercial and launch readiness activities, higher consulting and professional fees, insurance costs, and personnel compensation costs as the corporate organization build continued to ramp up during the fourth quarter of 2019.

The audited financial statements and the Management's Discussion and Analysis for the year ended December 31, 2019, 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, 2019, financial results today, Thursday, March 5, 2020, 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 Voclosporin**

Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor (“CNI”) with clinical data in over 2,600 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 (versus cyclosporine A), 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, a U.S. patent has also been issued covering the voclosporin dosing protocol with a term extending to December 2037, if the FDA incorporates the dosing protocol used in both the AURA and AURORA trials into the product label.

## **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 an investigational drug, for the treatment of lupus nephritis, focal segmental glomerulosclerosis and dry eye syndrome. The Company’s head office is in Victoria, British Columbia and focuses its development efforts globally.

## **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: completing NDA priority review submissions in a successful and timely manner including the anticipated NDA filing during the first half of 2020; the potential for commercial launch of voclosporin for use in LN in 2021; voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; Aurinia’s anticipation that upon regulatory approval, patent protection for voclosporin composition of matter 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; a US patent has also been issued covering the voclosporin dosing protocol with a term extending to December 2037, if the FDA incorporates the dosing protocol used in both the AURA and the AURORA studies into the product label; that the results of the AURORA clinical study are pivotal and potentially groundbreaking for LN patients; that voclosporin may be positioned to become the standard of care for people living with LN; that Aurinia will present AURORA study results at a future

scientific conference during 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, DES and FSGS programs; that another company will not create a substantial competitive product for Aurinia’s LN, DES and FSGS 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 and protect its patents on terms acceptable to Aurinia; and the size of the LN, DES or FSGS markets; Aurinia will be able to obtain all necessary regulatory approvals for commercialization of voclosporin for use in LN on terms that are acceptable to it and that are commercially viable; and that Aurinia’s intellectual property rights are valid and do not infringe the intellectual property rights of other parties. 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 clinical trial; difficulties we may experience in completing the development and commercialization of voclosporin; the market for the LN, DES and FSGS 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 or fully protect its patent portfolio for voclosporin; competitors may arise with similar products; Aurinia may not be able to obtain necessary regulatory approvals for commercialization of voclosporin in a timely fashion, or at all; and Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion. 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 harbour.*

**Aurinia Pharmaceuticals Inc.**  
**Condensed Consolidated Statements of Financial Position**  
**(unaudited – amounts in thousands of U.S. dollars)**

	<b>December 31, 2019 \$</b>	<b>December 31, 2018 \$</b>
<b>Assets</b>		
Cash and cash equivalents	306,019	117,967
Short term investments	-	7,889
Accounts receivable and accrued interest receivable	368	217
Prepaid expenses, deposits and other	8,750	6,775
Total current assets	<u>315,137</u>	<u>132,848</u>
Acquired intellectual property and other intangible assets	11,244	12,616
Other non-current assets	302	399
<b>Total assets</b>	<b><u>326,683</u></b>	<b><u>145,863</u></b>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	11,177	7,071
Other current liabilities	118	190
Total current liabilities	<u>11,295</u>	<u>7,261</u>
Derivative warrant liabilities	29,353	21,747
Other non-current liabilities	12,519	4,280
Total liabilities	<u>53,167</u>	<u>33,288</u>
Shareholders' equity	273,516	112,575
<b>Total liabilities and shareholders' equity</b>	<b><u>326,683</u></b>	<b><u>145,863</u></b>

**Aurinia Pharmaceuticals Inc.**  
**Condensed Consolidated Statements of Operations**  
(unaudited – amounts in thousands of U.S. dollars, except per share data)

	<b>Three Months Ended December 31</b>	
	<b>2019</b>	<b>2018</b>
	<b>\$</b>	<b>\$</b>
<b>Revenue</b>		
Licensing revenue	29	29
Contract revenue	-	-
	<u>29</u>	<u>29</u>
<b>Expenses</b>		
Research and development	13,292	10,839
Corporate, administration and business development	7,246	3,498
Amortization of acquired intellectual property and other intangible assets	349	349
Amortization of property and equipment	42	6
Other expenses	7,963	(65)
	<u>28,892</u>	<u>14,627</u>
<b>Loss before interest income, finance costs, change in estimated fair value of derivative warrant liabilities and income tax expense</b>	(28,863)	(14,598)
Interest income	479	671
Finance costs	(9)	-
<b>Loss before change in estimated fair value of derivative warrant liabilities and income tax expense</b>	(28,393)	(13,927)
Change in estimated fair value of derivative warrant liabilities	(47,986)	(593)
<b>Loss before income taxes</b>	(76,379)	(14,520)
Income tax expense	90	73
<b>Net loss and comprehensive loss for the period</b>	<u>(76,469)</u>	<u>(14,593)</u>
<b>Net loss per common share (expressed in \$ per share)</b>		
Basic and diluted loss per common share	<u>(0.78)</u>	<u>(0.17)</u>
Weighted average number of common shares outstanding	<u>97,936</u>	<u>85,384</u>

<sup>1</sup> CellCept® (mycophenolate mofetil) package insert, Genentech USA, Inc., A Member of the

Roche Group, 1 DNA Way, South San Francisco

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Source: Aurinia Pharmaceuticals Inc.