

August 11, 2020



# Aurinia Reports Second Quarter 2020 Financial Results and Recent Operational Highlights

- *U.S. Food & Drug Administration grants Priority Review for voclosporin and sets PDUFA date of January 22, 2021 -*
- *Cash, cash equivalents and short term investments totaled approximately \$442.06 million at July 31, 2020 -*
- *Conference call and webcast to be hosted today at 4:30pm EDT -*

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX:AUP) (Aurinia or the Company) today reported financial results for the second quarter ended June 30, 2020 and provided an update on recent operational highlights.

“The acceptance of the voclosporin NDA is a significant step towards our goal of delivering the first FDA-approved therapy specifically for people living with lupus nephritis,” commented Peter Greenleaf, President and Chief Executive Officer of Aurinia. “These people suffer from a debilitating, progressive condition that, if not adequately or quickly controlled, leads to life-threatening end-stage renal disease. Despite its high healthcare burden, lupus nephritis has no approved treatments in the United States which we believe has contributed to low awareness of this condition. Aurinia feels the urgency of its mission to change the course of lupus nephritis for this community in need, by combining deep engagement and advocacy efforts with truly innovative medical science.”

In addition to preparing for the launch of voclosporin for use as a potential treatment for lupus nephritis (LN), Aurinia continues to explore voclosporin in other proteinuric kidney indications and expects to provide an update on a planned clinical development program later this year. The Company’s development of voclosporin ophthalmic solution (VOS) for dry eye syndrome (DES) remains on track to report topline results from its Phase 2/3 AUDREY™ dose-ranging trial during the fourth quarter of 2020.

Max Colao, Chief Commercial Officer of Aurinia, commented, “As we make progress on our regulatory submission, we’re rapidly building a world class commercial team that is fully resourced and committed to engaging the lupus nephritis community and healthcare professionals. Our strategy for a successful U.S. launch will be executed by deeply experienced Aurinia specialists and led by a proven leadership team. We are driven to make a difference in the lives of the lupus nephritis patients and our team will be launch ready in advance of our PDUFA date of January 22, 2021.”

## **Second Quarter 2020 Highlights**

## **New Drug Application for voclosporin granted Priority Review and January 22, 2021 PDUFA date**

In July 2020 the Company announced that the U.S. Food & Drug Administration (FDA) has accepted the filing of its New Drug Application (NDA) for voclosporin, as a potential treatment for LN. The FDA has granted Priority Review for the NDA, which provides an expedited six-month review, and has assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021. The FDA has also informed the Company that they are not currently planning to hold an advisory committee meeting to discuss the application. The FDA has the option to change this decision based on review of the pending NDA. There are currently no FDA-approved treatments for LN.

## **Further supportive data from AURORA pivotal study presented at scientific conferences**

The Company presented additional safety data and subgroup analyses from the completed AURORA pivotal trial of voclosporin at two scientific meetings during the quarter: the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) 2020 Virtual Congress and the European League Against Rheumatism (EULAR) 2020 E-Congress. The data further supported the safety profile of voclosporin on an additional measure of kidney function and its clinically meaningful benefits for trial participants across ethnicities and self-reported race. These data were notable for further adding to the evidence supporting voclosporin's benefit over the standard-of-care with no apparent safety penalty, and its potential to deliver equal clinical benefits for patients of ethnicities or self-reported races disproportionately affected by lupus nephritis.

## **Phase 2/3 AUDREY™ Phase 2/3 Clinical Trial of VOS**

In June 2020, Aurinia announced it had completed enrollment for the Phase 2/3 AUDREY™ clinical trial evaluating voclosporin ophthalmic solution (VOS) for the potential treatment of DES, a chronic disease estimated to affect more than 16 million people in the United States.

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 509 subjects have been enrolled and randomized into one of four arms with a 1:1:1:1 randomization schedule, in which patients receive either VOS 0.2%, VOS 0.1%, VOS 0.05% or vehicle, dosed twice daily for 12 weeks. The primary outcome measure for the trial is the proportion of subjects with a 10mm or greater improvement in the 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. AUDREY™ builds on positive exploratory Phase 2 results demonstrating that 0.2% VOS administered twice daily was superior to cyclosporin A 0.05% (Restasis®) administered twice daily across all objective endpoints. Top-line results from the AUDREY™ clinical study are anticipated during the fourth quarter of 2020.

## **Recent Director and Officer Appointments**

### **Appointment of Timothy P. Walbert to the Board**

On April 20, 2020, Aurinia announced the appointment of Mr. Walbert to the Board of Directors. Mr. Walbert has nearly 30 years of experience commercializing pharmaceutical products. Mr. Walbert is currently Chairman, President and Chief Executive Officer of Horizon Therapeutics plc. He also served as President, Chief Executive Officer and Director of IDM Pharma, Inc., a public biopharmaceutical company which was acquired by Takeda.

### **Appointment of Joe Miller as Chief Financial Officer**

On April 27, Aurinia appointed Mr. Miller as Chief Financial Officer following the retirement of Mr. Dennis Bourgeault, who served in that role since 1998. Mr. Miller will be responsible for developing and leading the Company's financial operations to effectively support the Company's rapid growth.

## **Financial Liquidity at June 30, 2020 and July Public Offering of Common Shares**

All amounts in this press release, unless specified otherwise, are expressed in U.S. dollars.

As of June 30, 2020, Aurinia had cash, cash equivalents and short-term investments of \$264.4 million compared to \$286.1 million at March 31, 2020 and \$306 million at December 31, 2019. Net cash used in operating activities was \$22.6 million for the second quarter ended June 30, 2020 compared to \$13.3 million for the second quarter ended June 30, 2019.

Following the recently completed \$200 million public offering, which closed on July 27, 2020, the Company's cash, cash equivalents and short term investments totaled approximately \$442.06 million at July 31, 2020. 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 the end of 2022.

### **Financial Results for Three Months Ended June 30, 2020**

The Company reported a consolidated net loss of \$29.5 million or \$0.26 per Common Share for the second quarter ended June 30, 2020, as compared to a consolidated net loss of \$15.9 million or \$0.17 per Common Share for the second quarter ended June 30, 2019.

The loss for the second quarter ended June 30, 2020 reflected an increase of \$3.0 million in the estimated fair value of derivative warrant liabilities compared to a reduction of \$625,000 in the estimated fair value of derivative warrant liabilities for the second quarter ended June 30, 2019. 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 outstanding warrants expire on December 28, 2021.

The loss before the change in estimated fair value of derivative warrant liabilities and income taxes was \$26.6 million for the second quarter ended June 30, 2020 compared to \$16.5 million for the same period in 2019.

R&D expenses decreased to \$11.1 million for the second quarter ended June 30, 2020 compared to \$11.2 million for the second quarter ended June 30, 2019. The decrease in these expenses primarily reflected higher costs related to the preparation of the NDA submission and related supporting activities, the ongoing VOS Phase 2/3 AUDREY™ trial, the AURORA 2 extension trial and the expansion of the medical affairs team to support the launch of voclosporin partially offset by lower AURORA trial costs as this trial is now complete. Non-cash stock compensation expense charged to R&D also increased to \$1.1 million for the second quarter ended June 30, 2020 compared to \$749,000 for the comparable period in 2019 reflecting the hiring of a significant number of personnel in 2020 and an increase in the fair value of the stock options granted due to the increase in the Company's share price.

Corporate, administration and business development expenses increased to \$15.5 million for the second quarter of 2020 compared to \$4.9 million for the second quarter of 2019. These expenses included the expansion of the commercial team, higher consulting and professional fees, insurance costs, and personnel compensation costs as the corporate organization buildout continued in the second quarter of 2020. Non-cash stock compensation expense charged to corporate, administration and business development also increased to \$3.1 million for the second quarter ended June 30, 2020 compared to \$1.2 million for the comparable period in 2019 reflecting the hiring of a significant number of personnel in 2020 and an increase in the fair value of the stock options granted due to the increase in the Company's share price.

### **Financial Results for Six Months Ended June 30, 2020**

For the six months ended June 30, 2020, Aurinia reported a consolidated net loss of \$46.1 million or \$0.41 per Common Share compared to a consolidated net loss of \$28.3 million or \$0.31 per common share for the comparable period in 2019.

R&D expenses were \$24.9 million for the six months ended June 30, 2020 compared to \$21.8 million for the same period in 2019. The increase in these expenses reflected higher costs incurred for the AURORA 2 extension trial, and preparation costs associated with the LN NDA submission partially offset by lower AURORA trial costs as this trial is now complete.

Corporate, administration and business development expenses were \$26.6 million for the six months ended June 30, 2020 compared to \$8.8 million for the same period in 2019. The increase reflects the same items as noted in the second quarter corporate, administration and business development expenses.

Non-cash stock compensation expense totaled \$7.7 million for the six months ended June 30, 2020 as compared with \$3.6 million for the same period in 2019 and is included in both research and development and corporate, general and business development expenses.

For the six months ended June 30, 2020 Aurinia recorded a decrease of \$6.9 million in the estimated fair value of derivative warrant liabilities compared to a decrease of \$2.4 million

for the comparable period in 2019.

This press release should be read in conjunction with our unaudited interim condensed consolidated financial statements and the Management's Discussion and Analysis for the second quarter ended June 30, 2020 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 the second quarter ended June 30, 2020 financial results today, Tuesday, August 11, 2020 at 4:30 p.m. ET. The webcast can be accessed on the investor section of the Aurinia website at [www.auriniapharma.com](http://www.auriniapharma.com). To participate in the teleconference please dial +1-877-407-9170 (Toll-free U.S. & Canada).

### **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. Voclosporin may result in 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 patent extension laws in other countries 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-stage clinical 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 seeking FDA approval of voclosporin for the potential treatment of lupus nephritis (Anticipated PDUFA date: January 22, 2021) and evaluating voclosporin ophthalmic solution (VOS) in a Phase 2/3 study for the treatment of dry eye syndrome. The Company's head office is in Victoria, British Columbia, its U.S. commercial hub in Rockville, Maryland, 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: the potential FDA approval in early 2021; the Company's continued evolution into a commercial-stage organization; the anticipated U.S. launch of Voclosporin as the first FDA-approved treatment for LN; the Company's expectation that is tracking well for launch readiness in advance of the Company's PDUFA date of January 22, 2021; the Company's anticipated PDUFA date of January 22, 2021; the Company's expectation that the top-line results from the Phase 2/3 AUDREY™ dose-ranging trial of VOS will be released during the fourth quarter of 2020; the Company's belief that it has sufficient cash resources to adequately fund its plans which include conducting its ongoing R&D programs, 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 the end of 2022; 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 with anticipated pediatric extension; and 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. 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 and DES programs; that another company will not create a substantial competitive product for Aurinia's LN and DES 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; that Aurinia will successfully complete its clinical programs on a timely basis; the planned studies achieving positive results; Aurinia being able to extend and protect its patents on terms acceptable to Aurinia; the size of the LN or DES 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 including approval of marketing authorization applications and new drug

approvals, as well as favourable product labeling; 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 and DES 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; unknown impact and difficulties imposed by the COVID-19 pandemic on our business operations including nonclinical, clinical, regulatory and commercial activities; and our assets or business activities may be subject to disputes that may result in litigation or other legal claims. 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.**  
**Interim Condensed Consolidated Statements of Financial**  
**Position**  
(unaudited – amounts in thousands of U.S. dollars)

	<b>June 30, 2020 \$</b>	<b>December 31, 2019 \$</b>
<b>Assets</b>		
Cash, cash equivalents and short-term investments	264,350	306,019
Accrued interest and other receivables	508	368
Prepaid expenses, deposits and other	13,161	8,750
	<u>278,019</u>	<u>315,137</u>
Clinical trial contract deposits	209	209
Acquired intellectual property and other intangible assets	10,627	11,244
Property and equipment	6,423	93
	<u><b>295,278</b></u>	<u><b>326,683</b></u>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	13,641	11,177
Other current liabilities	3,502	118
	<u>17,143</u>	<u>11,295</u>
Derivative warrant liabilities	22,451	29,353
Other non-current liabilities	16,645	12,519
	<u>56,239</u>	<u>53,167</u>
Shareholders' equity	<u>239,039</u>	<u>273,516</u>
<b>Total liabilities and shareholders' equity</b>	<u><b>295,278</b></u>	<u><b>326,683</b></u>

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

	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>June 30, 2020</b>	<b>June 30, 2019</b>	<b>June 30, 2020</b>	<b>June 30, 2019</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Revenue</b>				
Licensing revenue	29	29	59	59
<b>Expenses</b>				
Research and development	11,076	11,152	24,911	21,783
Corporate, administration and business development	15,541	4,946	26,602	8,847
Amortization of acquired intellectual property and other intangible assets	348	347	696	693
Amortization of property and equipment	145	38	200	75
Other expenses	(287)	833	1,925	888
	<u>26,823</u>	<u>17,316</u>	<u>54,334</u>	<u>32,286</u>
<b>Loss before interest income, finance costs, change in estimated fair value of derivative warrant liabilities and income taxes</b>	<b>(26,794)</b>	<b>(17,287)</b>	<b>(54,275)</b>	<b>(32,227)</b>
Interest income	320	787	1,211	1,598
Finance costs	(78)	(10)	(103)	(21)
<b>Loss before change in estimated fair value of derivative warrant liabilities and income taxes</b>	<b>(26,552)</b>	<b>(16,510)</b>	<b>(53,167)</b>	<b>(30,650)</b>
Change in estimated fair value of derivative warrant liabilities	(2,952)	625	6,893	2,350
<b>Loss before income taxes</b>	<b>(29,504)</b>	<b>(15,885)</b>	<b>(46,274)</b>	<b>(28,300)</b>
Income tax expense (recovery)	22	16	(214)	29
<b>Net loss and comprehensive loss for the period</b>	<b>(29,526)</b>	<b>(15,901)</b>	<b>(46,060)</b>	<b>(28,329)</b>
<b>Net loss per Common Share (expressed in \$ per share)</b>				
Basic and diluted loss per Common Share	(0.26)	(0.17)	(0.41)	(0.31)
Weighted average number of Common Shares outstanding	112,576	91,768	112,392	90,961

View source version on [businesswire.com](http://businesswire.com):

<https://www.businesswire.com/news/home/20200811005762/en/>

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Source: Aurinia Pharmaceuticals Inc.