

November 10, 2020



# Aurinia Reports Third 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 investments totaled approximately \$421 million at September 30, 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 third quarter ended September 30, 2020 and provided an update on recent operational highlights. Amounts, unless specified otherwise, are expressed in U.S. dollars.

“Throughout the course of 2020, Aurinia has evolved significantly as an organization as we ready the organization for our next potential phase of growth. With the voclosporin NDA undergoing Priority Review for LN, we are focused as an organization to being fully prepared for a potential launch by year-end as the January 22, 2021 PDUFA date approaches,” commented Peter Greenleaf, President and Chief Executive Officer of Aurinia. “In addition to preparing for commercialization, we continue to evaluate opportunities to strengthen the development pipeline and look forward to providing updates on our efforts in the coming months.”

Max Colao, Chief Commercial Officer of Aurinia commented, “Over the past few months, we have onboarded and deployed an amazingly talented commercial team that shares our passion for making a difference for patients. As our potential PDUFA date approaches, the team is focused on launch readiness by year-end in order to maximize the potential launch of voclosporin.”

## Recent Highlights

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

In July 2020, the Company announced that the U.S. Food and Drug Administration (FDA) has accepted the NDA filing for voclosporin, as a potential treatment for lupus nephritis (LN). The FDA has granted Priority Review for the NDA, which provides an expedited six-month review, and has assigned a 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.

**Appointment of Stephen Robertson as Executive Vice President, General Counsel, Corporate Secretary & Chief Compliance Officer**

On November 2, Aurinia appointed Mr. Robertson as Executive Vice President, General Counsel, Corporate Secretary & Chief Compliance Officer, following the departure of Dr. Erik Eglite, who served as General Counsel since 2017. Mr. Robertson brings more than 13 years of corporate law experience across various roles with the law firm Borden Ladner Gervais LLP, where he has been a Partner since 2014. He has focused on advising clients on securities, corporate and commercial legal matters, including extensive experience with mergers and acquisitions and commercial agreements. Mr. Robertson has served as Corporate Secretary for Aurinia since 2014.

## **July 27, 2020 Public Offering**

On July 27, 2020 the Company completed an underwritten public offering of 13.33 million Common Shares (the “July 2020 Offering”).

The Common Shares were sold at a public offering price of \$15.00 per share. The gross proceeds from the July 2020 Offering were \$200 million before deducting the 6% underwriting commission and other offering expenses which totaled an estimated aggregate \$12.3 million. Jefferies and SVB Leerink acted as joint book-running managers for the July 2020 Offering. Cantor acted as lead manager and Oppenheimer & Co and H.C. Wainwright & Co. acted as co-managers for the July 2020 Offering. We intend to use the net proceeds of the July 2020 Offering for pre-commercialization and launch activities, research and development (R&D), as well as working capital and general corporate purposes.

## **Financial Liquidity at September 30, 2020**

As of September 30, 2020, Aurinia had cash, cash equivalents and investments of \$421 million compared to \$306 million at December 31, 2019. Net cash used in operating activities was \$30.3 million for the third quarter ended September 30, 2020 compared to \$11.8 million for the third quarter ended September 30, 2019.

The Company believes that it has sufficient financial resources to fund its current plans, which include conducting its ongoing R&D programs, obtaining approval of voclosporin for the potential treatment of LN, 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 September 30, 2020**

The Company reported a consolidated net loss of \$34.1 million or \$0.28 per Common Share for the third quarter ended September 30, 2020, as compared to a consolidated net loss of \$19.0 million or \$0.21 per Common Share for the third quarter ended September 30, 2019.

The net loss for the third quarter ended September 30, 2020 reflected a non-cash decrease of \$2.6 million in the estimated fair value of derivative warrant liabilities compared to a non-cash decrease of \$4.5 million in the estimated fair value of derivative warrant liabilities for the same period in 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 \$36.7 million for the third quarter ended September 30, 2020 compared to \$23.5 million for the same period in 2019.

R&D expenses decreased to \$4.8 million for the third quarter ended September 30, 2020 compared to \$17.8 million for the same period in 2019. The decrease is due to a decrease in activities related to clinical trials and exploratory development work and the capitalization of inventory and internal development costs as management believes that approval by the FDA of voclosporin as a treatment for LN was reasonably assured.

Non-cash stock compensation expense charged to R&D increased to \$814,000 for the third

quarter ended September 30, 2020 compared to \$596,000 for the same period in 2019. The increase in stock option compensation expense for the three months ended September 30, 2020 reflected higher stock option grants resulting from the hiring of new employees and an increase in the fair value of the stock options granted due to the significant increase in our share price.

Corporate, administration and business development expenses increased to \$31.1 million for the third quarter of 2020 compared to \$6.1 million for the same period in 2019. The increase reflects the investment incurred to build out our organization to support the launch of voclosporin as a treatment for LN which is planned for early 2021, subject to FDA regulatory approval being granted. Since the release of the positive results of our AURORA trial in December of 2019 we have moved quickly to develop our commercial capabilities across the organization including the expansion of the commercial team headed by our new Chief Commercial Officer.

Non-cash stock compensation expense charged to corporate, administration and business development increased to \$3.8 million for the third quarter ended September 30, 2020 compared to \$1.4 million for the same period in 2019. The increase in stock option compensation expense for the three months ended September 30, 2020 reflected higher stock option grants resulting from the hiring of new employees and an increase in the fair value of the stock options granted due to the significant increase in our share price.

## Financial Results for Nine Months Ended September 30, 2020

For the nine months ended September 30, 2020, Aurinia reported a consolidated net loss of \$80.1 million or \$0.69 per Common Share compared to a consolidated net loss of \$47.4 million or \$0.52 per common share for the same period in 2019.

R&D expenses were \$29.7 million for the nine months ended September 30, 2020 compared to \$39.6 million for the same period in 2019. The decrease in these expenses is due to a decrease in activities related to clinical trials and exploratory development work and the capitalization of inventory and internal development costs as management believes that approval by the FDA of voclosporin as a treatment for LN was reasonably assured.

Corporate, administration and business development expenses were \$57.7 million for the nine months ended September 30, 2020 compared to \$14.9 million for the same period in 2019. The increase reflects the investment incurred to build out our organization to support the launch of voclosporin as a treatment for LN which is planned for early 2021, subject to FDA regulatory approval being granted. Since the release of the positive results of our AURORA trial in December of 2019 we have moved quickly to develop our commercial capabilities across the organization including the expansion of the commercial team headed by our new Chief Commercial Officer.

Non-cash stock compensation expense totaled \$12.3 million for the nine months ended September 30, 2020 compared with \$5.6 million for the same period in 2019 and is included in both R&D and corporate, general and business development expenses.

For the nine months ended September 30, 2020 Aurinia recorded a non-cash decrease of \$9.5 million in the estimated fair value of derivative warrant liabilities compared to a non-cash decrease of \$6.9 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 third quarter ended September 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 third quarter ended September 30, 2020 financial results today, Tuesday, November 10, 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 developing the investigational drug voclosporin for the treatment of lupus nephritis (“LN”). The Company’s head office is in Victoria, British Columbia and focuses its development efforts globally. The Company’s US commercial office is located in Rockville, Maryland.

## ***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 anticipated NDA filing by the end of the third quarter of 2020 and potential 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 belief that it has sufficient cash resources to adequately fund its plans which include conducting its ongoing 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; 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 programs; 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; 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 market; 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 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>September 30, 2020 \$</b>	<b>December 31, 2019 \$</b>
<b>Assets</b>		
Cash, cash equivalents and short term investments	392,042	306,019
Accrued interest and other receivables	1,127	368
Inventories	6,757	-
Prepaid expenses and deposits	11,714	8,750
	<u>411,640</u>	<u>315,137</u>
Long term investments	28,797	-
Clinical trial contract deposits	209	209
Property and equipment	9,663	93
Acquired intellectual property and other intangible assets	11,441	11,244
	<u><b>461,750</b></u>	<u><b>326,683</b></u>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	20,189	11,177
Other current liabilities	3,700	118
	<u>23,889</u>	<u>11,295</u>
Derivative warrant liabilities	19,852	29,353
Other non-current liabilities	19,166	12,519
	<u>62,907</u>	<u>53,167</u>
Shareholders' equity	398,843	273,516
<b>Total liabilities and shareholders' equity</b>	<u><b>461,750</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)

	Three months ended		Nine months ended	
	Sept. 30, 2020	Sept. 30, 2019	Sept. 30, 2020	Sept. 30, 2019
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing revenue	29	230	88	289
<b>Expenses</b>				
Research and development	4,800	17,791	29,711	39,574
Corporate, administration and business development	31,068	6,061	57,670	14,908
Amortization of acquired intellectual property and other intangible assets	348	348	1,044	1,041
Amortization of property and equipment	154	41	354	116
Other expenses	426	140	2,351	1,028
	<u>36,796</u>	<u>24,381</u>	<u>91,130</u>	<u>56,667</u>
<b>Loss before interest income, finance costs, change in estimated fair value of derivative warrant liabilities and income taxes</b>	<b>(36,767)</b>	<b>(24,151)</b>	<b>(91,042)</b>	<b>(56,378)</b>
Interest income	170	636	1,381	2,234
Finance costs	(101)	(9)	(204)	(30)
<b>Loss before change in estimated fair value of derivative warrant liabilities and income taxes</b>	<b>(36,698)</b>	<b>(23,524)</b>	<b>(89,865)</b>	<b>(54,174)</b>
Change in estimated fair value of derivative warrant liabilities	2,599	4,512	9,492	6,862
<b>Loss before income taxes</b>	<b>(34,099)</b>	<b>(19,012)</b>	<b>(80,373)</b>	<b>(47,312)</b>
Income tax (recovery) expense	(35)	25	(249)	54
<b>Net loss and comprehensive loss for the period</b>	<b>(34,064)</b>	<b>(19,037)</b>	<b>(80,124)</b>	<b>(47,366)</b>
<b>Net loss per Common Share (expressed in \$ per share)</b>				
Basic and diluted loss per Common Share	(0.28)	(0.21)	(0.69)	(0.52)
Weighted average number of Common Shares outstanding	122,357	92,169	115,738	91,368

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20201110006074/en/>

**Investor & Media Contacts:**

Glenn Schulman, PharmD, MPH

Corporate Communications

[gschulman@auriniapharma.com](mailto:gschulman@auriniapharma.com)

Joseph Miller

Chief Financial Officer

[jmiller@auriniapharma.com](mailto:jmiller@auriniapharma.com)

Source: Aurinia Pharmaceuticals Inc.