

February 24, 2021



# Aurinia Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Operational Highlights

*- LUPKYNIS<sup>TM</sup> is the first FDA-approved oral therapy for lupus nephritis (LN), a condition that causes irreversible kidney damage and increases the risk of kidney failure, cardiac events, and death -*

*- Cash, cash equivalents, and investments of \$423 million at December 31, 2020 –*

*- Conference call to be hosted today at 4:30 p.m. ET -*

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, 2020. Amounts, unless specified otherwise, are expressed in U.S. dollars.

“Over the past year, Aurinia matured into a fully-integrated biopharmaceutical company with capabilities spanning R&D, clinical, regulatory, CMC, and commercial. The recent FDA approval and immediate launch of LUPKYNIS underscores the exemplary performance and expertise of the Aurinia team,” commented Peter Greenleaf, President and Chief Executive Officer of Aurinia. “During 2020, we made calculated investments following the positive AURORA clinical trial results by building out a world-class commercial team, signing a major ex-US partnership with Otsuka, and ensuring we can meet future market demand for LUPKYNIS by securing our supply chain by expanding our manufacturing agreement with Lonza. After just 30 days, we are pleased by the uptake of LUPKYNIS by the healthcare community and believe we are on track to meet our internal expectations.”

“Launching LUPKYNIS within hours of our approval allows us to focus on getting LN patients who need intervention onto therapy as soon as possible,” said Max Colao, Chief Commercial Officer at Aurinia. “We look forward to translating years of innovation and development work, and our early preparation and planning for launch, into commercial success for LUPKYNIS.”

## Recent Highlights

### ***FDA Approval and Commercial Launch of LUPKYNIS<sup>TM</sup>***

On January 22, 2021, the FDA approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN. LUPKYNIS was approved by the FDA under Priority Review and was previously granted Fast Track designation from the Agency in 2016.

### ***Collaboration and Licensing Agreement with Otsuka Pharmaceutical Co., Ltd.***

On December 17, 2020, Aurinia announced it had entered into a collaboration and licensing agreement with Otsuka Pharmaceutical Co., Ltd., for the development and commercialization of oral LUPKYNIS for the treatment of LN in the European Union (EU), Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein, and Ukraine.

As part of the agreement, Aurinia received an upfront cash payment of \$50 million for the license agreement, and has the potential to receive up to an additional \$50 million in regulatory milestones. Aurinia will receive tiered royalties on future sales ranging from 10 to 20 percent on net sales upon commercialization, along with additional milestone payments based on the attainment of certain annual sales by Otsuka. In addition, Aurinia will provide LUPKYNIS to Otsuka via a supply agreement under a cost plus arrangement.

### ***Agreement for Dedicated LUPKYNIS Manufacturing Capacity***

On December 15, 2020, Aurinia entered into a collaborative agreement with Lonza Ltd. (Lonza) to build a dedicated manufacturing capacity within Lonza's existing small molecule facility in Visp, Switzerland. The dedicated facility (also referred to as "monoplant") will be equipped with state-of-the-art manufacturing equipment to provide cost and production efficiency for the manufacture of LUPKYNIS, while expanding existing capacity and providing supply security to meet future commercial demand. Upon completion of the monoplant, Aurinia will have the right to maintain exclusive use of the monoplant by paying a quarterly fixed facility fee. The first capital expenditure payment was made in February 2021.

### **Financial Liquidity at December 31, 2020**

As of December 31, 2020, Aurinia had cash, cash equivalents and investments of \$423 million compared to \$306 million at December 31, 2019. Net cash used in operating activities was \$69.9 million for the year ended December 31, 2020 compared to \$63.6 million for the year ended December 31, 2019.

The Company believes that it has sufficient financial resources to fund its current plans, which include funding commercial launch activities, manufacturing and packaging of commercial drug supply, conducting our planned R&D programs, and operating activities into at least 2023.

### **Financial Results for the Year Ended December 31, 2020**

For the year ended December 31, 2020, Aurinia recorded a consolidated net loss of \$102.7 million or \$0.87 per common share.

Revenues were \$50.1 million and \$0.3 million for the years ended December 31, 2020 and 2019, respectively. The increase of \$49.8 million in 2020 was due to the upfront license payment received from Otsuka of \$50 million, recorded as licensing revenue in the fourth quarter of 2020.

Research and development (R&D) expenses decreased to \$50.3 million for the year ended December 31, 2020 compared to \$52.9 million for the year ended December 31, 2019. The primary driver for the decrease of \$2.5 million in R&D spend in 2020 was a decrease in drug manufacturing and supply costs, lower Contract Research Organization (CRO) expenses

and other third party clinical trial expenses, partially offset by an increase in regulatory related costs as Aurinia prepared for FDA approval.

Corporate, administration and business development expenses increased to \$96 million for the year ended December 31, 2020 compared to \$22.3 million for the year ended December 31, 2019. The primary driver for the increase of \$73.6 million was the build out of commercial infrastructure in advance of approval, which included an increase in salaries and employee benefits, share based compensation expense and professional fees incurred during the year.

### **Financial Results for the Fourth Quarter Ended December 31, 2020**

For the three months ended December 31, 2020, Aurinia recorded a consolidated net loss of \$8.1 million or \$0.05 per common share.

Revenues were \$50 million and \$0.03 million for the three months ended December 31, 2020 and 2019, respectively. The increase of \$50 million in 2020 was due to the upfront payment from Otsuka of \$50 million recorded as licensing revenue.

R&D expenses decreased to \$13.2 million for the three months ended December 31, 2020 compared to \$13.3 million for the three months ended December 31, 2019. The primary drivers for the slight decrease in R&D spend in 2020 was a decrease in drug manufacturing and supply costs, lower CRO expenses and other third party clinical trial expenses, partially offset by an increase in regulatory related costs as Aurinia prepared for FDA approval.

Corporate, administration and business development expenses increased to \$38.8 million for the three months ended December 31, 2020 compared to \$7.3 million for the three months ended December 31, 2019. The primary driver for the increase of \$31.5 million in 2020 was the build out of commercial infrastructure in advance of approval, which included an increase in salaries and employee benefits, share based compensation expense and professional fees incurred during the quarter.

This press release is intended to be read in conjunction with the Company's audited financial statements and the Management's Discussion and Analysis for the year ended December 31, 2020 in the Company's Annual Report on Form 10-K, which is 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, 2020 financial results today, Wednesday, February 24, 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 Lupus Nephritis**

LN is a serious progression of systemic lupus erythematosus (SLE), a chronic and complex autoimmune disease. About 200,000-300,000 people live with SLE in the U.S. and approximately one out of three of these individuals have already developed LN at the time of SLE diagnosis. If poorly controlled, LN can lead to permanent and irreversible tissue damage within the kidney, resulting in kidney failure. Black and Asian individuals with SLE are four times more likely to develop LN and individuals with Hispanic ancestry are approximately

twice as likely to develop the disease when compared with Caucasian individuals. Black and Hispanic individuals with SLE also tend to develop LN earlier and have poorer outcomes when compared to Caucasian individuals.

## **About Aurinia**

Aurinia Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company has introduced LUPKYNIS (voclosporin), the first FDA-approved oral therapy dedicated for the treatment of adult patients with active LN. The Company's head office is in Victoria, British Columbia, its U.S. commercial hub is in Rockville, Maryland, and the Company 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: Aurinia's estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who will develop LN; Aurinia's belief that it is on track to meet its internal expectations for the prescribing of LUPKYNIS; Aurinia will receive certain payments (including royalties and milestones) from its agreement with Otsuka; that operational qualification of the monoplant facility is expected in 2023; Aurinia's belief that it has sufficient financial resources to fund its current plans until 2023. 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 accuracy of reported data from third party studies and reports; that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of third parties; Aurinia's assumptions relating to the capital required to fund operations into 2023; the assumption that Aurinia's current good relationships with its suppliers, service providers and other third parties will be maintained; assumptions relating to the burn rate of Aurinia's cash for operations; that Aurinia's third party service providers will comply with their contractual obligations. 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 Aurinia may experience in completing the commercialization of voclosporin; the market for the LN business may not be as estimated;

Aurinia may have to pay unanticipated expenses; 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 Aurinia's business operations including nonclinical, clinical, regulatory and commercial activities; the results from Aurinia's clinical studies and from third party studies and reports may not be accurate; Aurinia's third party service providers may not, or may not be able to, comply with their obligations under their agreements with Aurinia; and Aurinia's assets or business activities may be subject to disputes that may result in litigation or other legal claims. Although Aurinia has 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 Aurinia's 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.

All forward-looking information contained in this presentation 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 Report on Form 10-K 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), or on Aurinia's website at [www.auriniapharma.com](http://www.auriniapharma.com).

**Aurinia Pharmaceuticals Inc.**  
**Condensed Consolidated Balance Sheets**  
**(unaudited – amounts in thousands of U.S. dollars)**

	December 31, 2020	December 31, 2019
	\$	\$
<b>Assets</b>		
Cash, cash equivalents and short term investments	\$ 398,329	\$ 306,019
Accrued interest and other receivables	1,018	368
Inventories	13,927	—
Prepaid expenses and deposits	6,153	8,750
<b>Total current assets</b>	<b>419,427</b>	<b>315,137</b>
Long term investments	24,380	—
Other non-current assets	247	209
Property and equipment	4,786	93
Acquired intellectual property and other intangible assets	9,332	8,862
Right of use asset	5,489	—

<b>Total assets</b>	<b>\$ 463,661</b>	<b>\$ 324,301</b>
<b>Liabilities and Shareholders' Equity</b>		
Accounts payable and accrued liabilities	24,797	11,177
Other current liabilities	7,200	118
<b>Total current liabilities</b>	<b>31,997</b>	<b>11,295</b>
Other non-current liabilities	23,914	14,406
<b>Total liabilities</b>	<b>55,911</b>	<b>25,701</b>
Shareholders' equity	407,750	298,600
<b>Total liabilities and shareholders' equity</b>	<b>\$ 463,661</b>	<b>\$ 324,301</b>

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

	Three months ended		Years ended	
	Dec. 31, 2020	Dec. 31, 2019	Dec. 31, 2020	Dec. 31, 2019
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing revenue	\$ 50,030	\$ 29	\$ 50,118	\$ 318
<b>Expenses</b>				
Research and development	13,173	13,292	50,327	52,866
Corporate, administration and business development	38,779	7,294	95,983	22,338
Amortization of intangible assets	387	284	1,289	1,138
Other expenses, net	5,743	14,000	6,809	14,919
<b>Total operating expenses</b>	<b>58,082</b>	<b>34,870</b>	<b>154,408</b>	<b>91,261</b>
<b>Loss from operations</b>	<b>(8,052)</b>	<b>(34,841)</b>	<b>(104,290)</b>	<b>(90,943)</b>
<b>Interest income</b>	<b>135</b>	<b>467</b>	<b>1,516</b>	<b>2,702</b>
<b>Loss before income taxes</b>	<b>(7,917)</b>	<b>(34,374)</b>	<b>(102,774)</b>	<b>(88,241)</b>
Income tax benefit (expense)	(157)	(85)	94	(144)
<b>Net loss and comprehensive loss</b>	<b>(8,074)</b>	<b>(34,459)</b>	<b>(102,680)</b>	<b>(88,385)</b>
<b>Net loss (expressed in \$ per share)</b>				
Basic and diluted loss per Common Share	\$ (0.05)	\$ (0.36)	\$ (0.87)	\$ (0.95)

Weighted average number of Common Shares outstanding	<b>126,618</b>	97,936	<b>118,473</b>	93,024
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**Investor Contact:**

Glenn Schulman, PharmD, MPH  
Corporate Communications, Aurinia  
[gschulman@auriniapharma.com](mailto:gschulman@auriniapharma.com)

**Corporate Contact:**

Dana Lynch  
Corporate Communications, Aurinia  
[dlynch@auriniapharma.com](mailto:dlynch@auriniapharma.com)

**Media Contact:**

Stefan Riley  
Ten Bridge Communications  
[stefan@tenbridgecommunications.com](mailto:stefan@tenbridgecommunications.com)

Source: Aurinia Pharmaceuticals Inc.