

May 14, 2020



Aurinia Reports First Quarter 2020 Financial Results and Recent Operational Highlights

- *Cash and cash equivalents totaled approximately \$286 million at March 31, 2020 -*
- *Rolling submission of voclosporin New Drug Application to the U.S. Food & Drug Administration remains on track for completion by the end of the second quarter 2020 –*
- *Continued evolution into commercial-stage organization highlighted by the appointments of Timothy P Walbert to the Board, Max Colao as Chief Commercial Officer, and Joe Miller as Chief Financial Officer –*
- *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 first quarter ended March 31, 2020 and provided an update on recent operational highlights. Amounts, unless specified otherwise, are expressed in U.S. dollars.

“We are fortunate that the global COVID-19 pandemic has had minimal impact on Aurinia’s operations, and we have maintained our timelines to ensure the filing of the voclosporin NDA by the end of the second quarter and hopefully obtain approval in early 2021,” commented Peter Greenleaf, President and Chief Executive Officer of Aurinia. “Following the positive AURORA data reported last December we have strengthened the balance sheet, added world-class commercial expertise including the appointments of Timothy, Max, and Joe, and on-boarded a group of extraordinarily talented commercial leaders and additional staff.”

Mr. Greenleaf further stated, “With the establishment of our commercial hub in Maryland, we’re building and preparing for the U.S. launch of voclosporin as the first FDA-approved treatment for lupus nephritis. In addition, the VOS development program remains on target, and we anticipate reporting out top-line results from the Phase 2/3 AUDREY dose-ranging trial of VOS during the fourth quarter of this year.”

Dr. Neil Solomons, Chief Medical Officer of Aurinia commented, “With respect to FSGS, our exploratory study has been open for an extended period and due to the continued difficulty identifying and enrolling primary FSGS patients, we’ve decided to adjust our approach. We are preparing to evaluate voclosporin in other proteinuric kidney diseases, while continuing to support patients who have participated in the FSGS exploratory study. As we work to incorporate these broader populations further updates will be available later this year.”

First Quarter 2020 Highlights

Pre-NDA Meeting with the U.S. Food & Drug Administration (“FDA”) and Rolling New Drug Application (“NDA”) Submission

- Aurinia held a positive and successful Pre-NDA meeting with the FDA 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.
- In March 2020, Aurinia filed the non-clinical module to the FDA followed by the chemistry, manufacturing and controls module in April 2020.
- Aurinia remains on track to file the complete NDA to the FDA by the end of the second quarter of 2020.

Recent Director and Officer Appointments

Appointment of Timothy P. Walbert to the Board

On April 20, 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. Mr. Bourgeault will remain an advisor to the Company to assist with the transition.

Appointment of Max Colao as Chief Commercial Officer and build out of world-class 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 responsible for key commercial functions including sales, marketing, market access, and commercial operations.

Financial Liquidity at March 31, 2020

As of March 31, 2020, Aurinia had cash, cash equivalents and short-term investments of \$286.1 million compared to \$306 million as at December 31, 2019. Net cash used in operating activities was \$22.7 million for the first quarter ended March 31, 2020 compared to \$13.1 million for the first quarter ended March 31, 2019.

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 First Quarter Ended March 31, 2020

The Company reported a consolidated net loss of \$16.5 million or \$0.15 per common share for the first quarter ended March 31, 2020, as compared to a consolidated net loss of \$12.4 million or \$0.14 per common share for the first quarter ended March 31, 2019.

The loss for the first quarter ended March 31, 2020 reflected a reduction of \$9.8 million in the estimated fair value of derivative warrant liabilities compared to a reduction of \$1.7 million in the estimated fair value of derivative warrant liabilities for the first quarter ended March 31, 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 first quarter ended March 31, 2020 compared to \$14.1 million for the same period in 2019.

R&D expenses increased to \$13.8 million for the first quarter ended March 31, 2020 compared to \$10.6 million for the first quarter ended March 31, 2019. The increase 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. Non-cash stock compensation expense charged to R&D also increased to \$1.2 million for the first quarter ended March 31, 2020 compared to \$862,000 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 \$11.1 million for the first quarter of 2020 compared to \$3.9 million for the first 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 first quarter of 2020. Non-cash stock compensation expense charged to corporate, administration and business development also increased to \$2.3 million for the first quarter ended March 31, 2020 compared to \$742,000 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.

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 first quarter ended March 31, 2020 which are accessible on Aurinia's website at www.auriniapharma.com, on SEDAR at www.sedar.com or on EDGAR at www.sec.gov/edgar.

Aurinia will host a conference call and webcast to discuss the first quarter ended March 31, 2020 financial results today, Thursday, May 14, 2020 at 4:30 p.m. ET. The webcast can be accessed on the investor section of the Aurinia website at 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"), dry eye syndrome ("DES") and proteinuric kidney diseases. 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 second 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 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, 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; 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 or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at 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)

	March	December
	31,	31,
	2020	2019
	\$	\$
Assets		
Cash, cash equivalents and short-term investments	286,120	306,019
Accrued interest and other receivables	3,511	368
Prepaid expenses, deposits and other	8,266	8,750
	<u>297,897</u>	<u>315,137</u>
Clinical trial contract deposits	209	209
Acquired intellectual property and other intangible assets	10,944	11,244
Property and equipment	5,922	93
	<u>314,972</u>	<u>326,683</u>
Liabilities and Shareholders' Equity		
Accounts payable and accrued liabilities	12,411	11,177
Other current liabilities	1,767	118
	<u>14,178</u>	<u>11,295</u>
Derivative warrant liabilities	19,499	29,353
Other non-current liabilities	17,887	12,519
	<u>51,564</u>	<u>53,167</u>
Shareholders' equity	263,408	273,516
Total liabilities and shareholders' equity	<u>314,972</u>	<u>326,683</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 March 31, 2020 \$	Three months ended March 31, 2019 \$
Revenue		
Licensing revenue	30	30
Expenses		
Research and development	13,835	10,631
Corporate, administration and business development	11,061	3,901
Amortization of acquired intellectual property and other intangible assets	348	346
Amortization of property and equipment	55	37
Other expenses	2,212	55
	<u>27,511</u>	<u>14,970</u>
Loss before interest income, finance costs, change in estimated fair value of derivative warrant liabilities and income taxes	(27,481)	(14,940)
Interest income	891	811
Finance costs	(25)	(11)
Loss before change in estimated fair value of derivative warrant liabilities and income taxes	(26,615)	(14,140)
Change in estimated fair value of derivative warrant liabilities	9,845	1,725
Loss before income taxes	(16,770)	(12,415)
Income tax (recovery) expense	(236)	13
Net loss and comprehensive loss for the period	<u>(16,534)</u>	<u>(12,428)</u>
Net loss per common share (expressed in \$ per share)		
Basic and diluted loss per common share	(0.15)	(0.14)
Weighted average number of common shares outstanding	<u>112,209</u>	<u>90,146</u>

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20200514005720/en/>

Investor & Media Contacts:

Glenn Schulman, PharmD, MPH

Corporate Communications

gschulman@auriniapharma.com

Joseph Miller

Chief Financial Officer

jmiller@auriniapharma.com

Source: Aurinia Pharmaceuticals Inc.