

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): May 10, 2022**

Aurinia Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Canada
(State or Other Jurisdiction of Incorporation)

001-36421
(Commission File No.)

98-1231763
(IRS Employer Identification No.)

#1203-4464 Markham Street
Victoria, British Columbia
V8Z 7X8
(250) 708-4272
(Address and telephone number of registrant's principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Shares, without par value	AUPH	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2022, Aurinia Pharmaceuticals Inc. ("Aurinia") issued a press release announcing its financial results for the quarter ended March 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Current Report on Form 8-K and the exhibit hereto are being furnished pursuant to this Item 2.02 and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Current Report on Form 8-K and the exhibit hereto that is furnished pursuant to this Item 2.02 shall not be incorporated by reference in any of Aurinia's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated May 10, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 10, 2022

AURINIA PHARMACEUTICALS INC.

By: /s/ Joseph Miller
Name: Joseph Miller
Title: Chief Financial Officer



AURINIA REPORTS FIRST QUARTER 2022 FINANCIAL AND OPERATIONAL RESULTS

\$21.6 million in net revenue for Q1 2022; Maintains net revenue guidance range of \$115-\$135 million from sales of LUPKYNIS for 2022

Continued increases in LUPKYNIS™ (voclosporin) Patients on Treatment and Patient Start Forms; Steady Conversion Rates and Payor Coverage

EMA review of LUPKYNIS remains on track with decision expected in 2H 2022

Conference call to be hosted today at 8:30 a.m. ET

VICTORIA, British Columbia – May 10, 2022 - Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today issued its financial results for the first quarter ended March 31, 2022. Amounts, unless specified otherwise, are expressed in U.S. dollars.

Net product revenues were \$21.6 million for the quarter ended March 31, 2022, compared to \$914 thousand in the prior year period, reflecting FDA approval of LUPKYNIS in late January 2021.

“As previously reported on our fourth quarter call, LUPKYNIS revenues in the first quarter were impacted by care disruptions to both patients and the healthcare system caused by the COVID-19 Omicron variant. We are quite pleased that exiting the quarter, as Omicron abated, we began to see a significant increase in prescribing, patient starts, and refills, leading to a monthly record for received patient start forms and patient starts in March,” said Peter Greenleaf, President and Chief Executive Officer of Aurinia. “Heading into the second half of the year, in addition to expected growth in LUPKYNIS revenues, we look forward to multiple expected corporate milestones, including potential European LUPKYNIS approval, the presentation of additional clinical data sets and continued development progress with our pipeline products, AUR200 and AUR300.”

For fiscal year 2022, the Company maintains its net revenue guidance of \$115 million to \$135 million from sales of LUPKYNIS. This range is based on assumptions regarding the impact of COVID-19 on the current business environment and represents an increase of more than 150 to 200% in net revenue from sales of LUPKYNIS compared to fiscal year 2021. Aurinia’s guidance does not include any potential milestone payments, royalties or contract manufacturing revenue related to the Company’s licensing agreement with Otsuka Pharmaceutical or associated with the marketing of voclosporin in the European Union or Japan.

First Quarter 2022 and Recent Highlights & Upcoming Milestones:

- Aurinia added 461 patient start forms (PSFs) during the first quarter 2022, as compared to 257 in the first quarter 2021.
- As of Friday, May 6, 2022, the Company recorded 647 total PSFs since January 1, 2022.
- PSF conversion rates are now at 80% after 90 days; confirmed patient access to LUPKYNIS through payors and plans remains steady representing about 90% of U.S. total lives.
- There were approximately 1,071 patients on LUPKYNIS therapy at March 31, 2022, compared with 884 at the end of 2021. At 6 months post-treatment-start, an average of approximately 70% of patients remain on treatment.
- Per recent healthcare provider (HCP) surveys, unaided brand awareness of LUPKYNIS is over 70% while aided brand awareness is over 90% and intent to use in the next 3 months is over 70%, the highest level since launch.

- The first presentations of final AURORA 2 continuation study data are expected at the 59th European Renal Association (ERA) Congress and at the European Congress of Rheumatology at the end of May 2022 and at the European Alliance of Associations for Rheumatology (EULAR) 2022 in June. Submission of a manuscript with the full results is expected in the second half of 2022.
- With the start of the year, the Aurinia commercial team initiated several new HCP and patient-targeted marketing programs that include the AURORA 2 data and patient brand ambassadors.
- Regulatory review of the European Medicines Agency (EMA) marketing authorization application (MAA) remains on track with a European Commission (EC) approval decision expected in second half of 2022.
- Recruitment of patients and initiation of new sites into both the VOCAL pediatric study and the ENLIGHT-LN registry is continuing.

Financial Liquidity at March 31, 2022

As of March 31, 2022, Aurinia had cash, cash equivalents and restricted cash and investments of \$418.8 million compared to \$466.1 million at December 31, 2021. The decrease in cash, cash equivalents and restricted cash and investments is primarily related to the continued investment in commercialization activities, payments made for our ongoing post approval obligations and advancement of our pipeline, payments associated with inventory purchases to ensure adequate supply to meet forecasted demand and a payment for the achievement of a one-time milestone, partially offset by an increase in cash receipts from sales of LUPKYNIS.

Aurinia believes that it has sufficient financial resources to fund its current operations, which include funding commercial activities, including FDA related post approval commitments, manufacturing and packaging of commercial drug supply, funding its supporting commercial infrastructure, conducting planned research and development (R&D) programs, investing in its pipeline and operating activities for at least the next few years.

Financial Results for the Quarter Ended March 31, 2022

Total net revenue was \$21.6 million and \$914 thousand for the quarters ended March 31, 2022 and March 31, 2021, respectively. Net revenues primarily consisted of product revenue, net of adjustments for LUPKYNIS, following FDA approval in late January 2021. Quarter over quarter revenue growth is attributed to continued progress in the launch of LUPKYNIS, driven predominantly by further penetration into the LN market.

Total cost of sales and operating expenses for the quarter ended March 31, 2022 were \$59.5 million in comparison to \$51.5 million for the quarter ended March 31, 2021.

Cost of sales were \$256 thousand and \$48 thousand for the quarters ended March 31, 2022 and March 31, 2021, respectively. The increase was primarily due to the growth of LUPKYNIS sales, in comparison to the prior year period.

Gross margin for the quarters ended March 31, 2022 and March 31, 2021 was approximately 99% and 95% respectively. The fluctuation in gross margin is driven primarily by fixed specialty pharmacy costs in the first quarter of 2021, as a larger percentage of the overall cost of sales in the quarter.

Selling, general and administrative (SG&A) expenses were \$45.2 million and \$39.8 million for the quarters ended March 31, 2022 and March 31, 2021, respectively, which is consistent with the prior quarter and represents a fully burdened quarter, as the Company did not have approval until late January 2021. The increase was primarily due to an increase in employee related expenses, professional fees related to various corporate matters, pharmacovigilance costs and consulting related expenses tied to the increased investment in back office infrastructure to support the commercialization of LUPKYNIS.

Non-cash SG&A share-based compensation expense for the quarters ended March 31, 2022 and March 31, 2021 was \$6.0 million and \$6.6 million, respectively.

R&D expenses were \$12.6 million and \$9.8 million for the quarters ended March 31, 2022 and March 31, 2021, respectively. The primary driver for the increase quarter over quarter was due to an increase in expenses related to AUR200 and AUR300 development, partially offset by a decrease in expenses related to the AURORA 2 continuation study which was completed during the fourth quarter of 2021 but had wind down activities ongoing in the quarter ended March 31, 2022.

Non-cash R&D share-based compensation expense for the quarters ended March 31, 2022 and March 31, 2021 was \$1.0 million compared to \$1.1 million, respectively.

For the quarter ended March 31, 2022, Aurinia recorded a net loss of \$37.6 million or \$0.27 net loss per common share, as compared to a net loss of \$50.4 million or \$0.40 net loss per common share for the quarter ended March 31, 2021.

This press release is intended to be read in conjunction with the Company's unaudited condensed consolidated financial statements and Management's Discussion and Analysis for the quarter ended March 31, 2022 in the Company's Quarterly Report on Form 10-Q, which will be accessible on Aurinia's website at www.auriniapharma.com, on SEDAR at www.sedar.com or on EDGAR at www.sec.gov/edgar.

Conference Call Details

Aurinia will host a conference call and webcast to discuss the quarter ended March 31, 2022 financial results today, Tuesday, May 10, 2022 at 8:30 a.m. ET. The audio webcast can be accessed under "News/Events" through the "Investors" section of the Aurinia corporate website at www.auriniapharma.com. In order to participate in the conference call, please dial +1 (866) 682-6100 / (862) 298-0702 (Toll-free U.S. & Canada). An audio webcast can be accessed under "News/Events" through the "Investors" section of the Aurinia corporate website at www.auriniapharma.com. A replay of the webcast will be available on Aurinia's website.

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. In January 2021, 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 office is in Rockville, Maryland. 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 annual net revenue from sales of LUPKYNIS in the range of \$115-\$135 million in 2022; Aurinia's estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who have developed LN at time of SLE diagnosis; Aurinia being confident that it is poised for growth and success; Aurinia's belief that it has sufficient financial resources to fund its current plans for at least the next few years; and the expected timing for the EMA CHMP opinion and EC

decision relating to the EMA MAA. It is possible that such results or conclusions may change. 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; the number, and timing of receipt, of PSFs and their rate of conversion into patients on therapy; 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; 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; the relationship between COVID vaccinations and patient treatment; assumptions related to timing of interactions with regulatory bodies; and 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 or 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: Aurinia’s actual future financial and operational results may differ from its expectations; 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; regulatory bodies may not grant approvals on conditions acceptable to Aurinia and its business partners, or at all; 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 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 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 or the U.S. Securities and Exchange Commission’s Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar, and on Aurinia’s website at www.auriniapharma.com.

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AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets		
Cash, cash equivalents and restricted cash	\$ 132,542	\$ 231,900
Short-term investments	286,210	234,178
Accounts receivable, net	20,401	15,414
Inventories, net	26,266	19,326
Prepaid expenses and other current assets	12,199	12,506
Total current assets	<u>477,618</u>	<u>513,324</u>
Non-current assets		
Other non-current assets	11,838	11,838
Property and equipment, net	4,332	4,418
Acquired intellectual property and other intangible assets, net	7,882	8,404
Right-of-use assets	5,232	5,383
Total assets	<u>506,902</u>	<u>543,367</u>
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	32,327	34,947
Other current liabilities	502	4,640
Operating lease liabilities	1,009	1,059
Total current liabilities	<u>33,838</u>	<u>40,646</u>
Non-current liabilities		
Deferred compensation and other non-current liabilities	17,379	15,950
Operating lease liabilities	7,562	7,680
Total liabilities	<u>58,779</u>	<u>64,276</u>
SHAREHOLDER'S EQUITY		
Common shares - no par value, unlimited shares authorized, 141,742 and 141,600 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	1,178,807	1,177,051
Additional paid-in capital	64,686	59,014
Accumulated other comprehensive loss	(1,618)	(852)
Accumulated deficit	(793,752)	(756,122)
Total shareholders' equity	<u>448,123</u>	<u>479,091</u>
Total liabilities and shareholders' equity	<u>\$ 506,902</u>	<u>\$ 543,367</u>

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Three months ended	
	March 31,	
	2022	2021
	(unaudited)	
Revenue		
Product revenue, net	\$ 21,492	\$ 884
License and collaboration revenue	133	30
Total revenue, net	<u>21,625</u>	<u>914</u>
Operating expenses		
Cost of sales	256	48
Selling, general and administrative	45,197	39,805
Research and development	12,620	9,833
Other expense, net	1,434	1,771
Total cost of sales and operating expenses	<u>59,507</u>	<u>51,457</u>
Loss from operations	<u>(37,882)</u>	<u>(50,543)</u>
Interest income	262	172
Net loss before income taxes	<u>(37,620)</u>	<u>(50,371)</u>
Income tax expense	10	8
Net loss	<u>\$ (37,630)</u>	<u>\$ (50,379)</u>
Basic and diluted loss per share	<u>\$ (0.27)</u>	<u>\$ (0.40)</u>
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	<u>141,675</u>	<u>127,401</u>