

**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): November 2, 2023**

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.)

**#140, 14315 - 118 Avenue
Edmonton, Alberta
T5L 4S6
(250) 744-2487**

(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 November 2, 2023, Aurinia Pharmaceuticals Inc. ("Aurinia") issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 November 2, 2023
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: November 1, 2023

AURINIA PHARMACEUTICALS INC.

By: /s/ Joseph Miller

Name: Joseph Miller

Title: Chief Financial Officer



AURINIA PHARMACEUTICALS REPORTS THIRD QUARTER AND NINE MONTHS 2023 FINANCIAL AND OPERATIONAL RESULTS

Net product revenue of \$40.8 million for the third quarter of 2023; an increase of 60% over the prior year third quarter

Total net revenue of \$130.4 million for the nine months ended September 30, 2023, an increase of 24% over prior year

Achieved European pricing and reimbursement milestone triggering \$10 million payment from Otsuka Pharmaceutical Co. Ltd.

Narrowing 2023 net product revenue guidance range to \$155 - \$160 million from net product sales of LUPKYNIS® (voclosporin)

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

ROCKVILLE, Maryland and EDMONTON, Alberta – November 2, 2023 - Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today issued its financial results for the three and nine months ended September 30, 2023. Amounts are expressed in U.S. dollars.

Net product revenue was \$40.8 million for the three months ended September 30, 2023 and \$25.5 million for the same period in 2022, representing growth of approximately 60%. Net product revenue was \$116.2 million for the nine months ended September 30, 2023 and \$75.1 million for the same period ended 2022, representing growth of approximately 55%.

Total net revenue was \$54.5 million for the three months ended September 30, 2023 and \$55.8 million for the same period in 2022. Total net revenue was \$130.4 million for the nine months ended September 30, 2023 and \$105.6 million for the same period in 2022.

“We are very pleased with our overall results for the first nine months of the year. Reporting another strong quarter of results reinforces our ability to execute and deliver against key metrics. Our team continues to focus on business fundamentals and steady performance,” said Peter Greenleaf, President, and Chief Executive Officer of Aurinia. “We continue to deliver new data on LUPKYNIS and grow the overall LN market. In addition, we received a \$10.0 million milestone from our collaboration partner outside the U.S. as a result of securing pricing and reimbursement approvals in three of the five major European markets.”

For the fiscal year 2023, the Company is narrowing its net product revenue guidance to a range of \$155 - \$160 million for net product sales of LUPKYNIS. This guidance range is based on assumptions regarding PSF run rates, consistent conversion rates, time to convert, persistency and pricing.

Third Quarter 2023 and Recent Highlights

- Full results from AURORA 2 (the long-term extension study of the Phase 3 AURORA trial) were published in *Arthritis & Rheumatology*, the official peer-reviewed journal of the American College of Rheumatology, demonstrating kidney preservation over the 3-year study period as measured by eGFR (estimated glomerular filtration rate) along with additional efficacy, safety, and tolerability of LUPKYNIS over the study duration.

- A total of 14 LUPKYNIS clinical abstracts were accepted for presentation at the upcoming American Society of Nephrology and the American College of Rheumatology being held in November 2023. Led by several leading experts in nephrology and rheumatology, these presentations reinforce the long-term safety and efficacy profile of LUPKYNIS for the treatment of adults with active lupus nephritis (LN), a serious complication of systemic lupus erythematosus (SLE). The robust set of data demonstrates Aurinia's deep commitment to sustained research in autoimmune diseases, including lupus.
- Received notification that the pricing and reimbursement milestone was secured. As a result, this triggered a \$10 million milestone from Otsuka Pharmaceutical Co. Ltd (Otsuka). Additionally, LUPKYNIS received marketing acceptance in Scotland by the Scottish Medicines Consortium.
- Appointed three new directors to the Board of Directors - Dr. Karen Smith, Jeffrey Bailey, and Dr. Robert Foster.

LUPKYNIS Product Performance Highlights

- There were approximately 1,939 patients on LUPKYNIS therapy at September 30, 2023, compared with 1,354 at September 30, 2022, representing an increase of approximately 43% year over year.
- Aurinia added 436 patient start forms (PSFs) during the three months ended September 30, 2023, compared to 374 during the three months ended September 30, 2022, representing an increase of approximately 17% over the same period last year.
- Through the end of October 2023, the Company recorded approximately 1,510 PSFs since January 1, 2023.
- Conversion rates remain consistent with approximately 90% of PSFs converted to patients on therapy.
- Time to convert has improved to an all-time high with the large majority (64%) of patients on therapy by 20 days.
- Adherence improved from 84% at September 30, 2022 to 87% at September 30, 2023.
- Persistency at 12 months has maintained at 54%; and remained stable at further months on therapy: 48% at 15 months and 43% at 18 months.

Financial Results for the Three and Nine Months Ended September 30, 2023

Total net revenue was \$54.5 million and \$55.8 million for the three months ended September 30, 2023 and September 30, 2022, respectively. Total net revenue was \$130.4 million and \$105.6 million for the nine months ended September 30, 2023 and September 30, 2022, respectively.

Net product revenue was \$40.8 million and \$25.5 million for the three months ended September 30, 2023 and September 30, 2022, respectively. Net product revenue was \$116.2 million and \$75.1 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. The increase for both periods is primarily due to an increase in product sales to our two main customers for LUPKYNIS, driven predominantly by further penetration of the LN market.

License, royalty and collaboration revenue was \$13.7 million and \$30.3 million for the three months ended September 30, 2023 and September 30, 2022, respectively. License, royalty and collaboration revenue was \$14.2 million and \$30.5 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. The decrease for both periods is due to the recognition of a \$30.0 million regulatory milestone from Otsuka following the EC marketing authorization of LUPKYNIS in September 2022 partially offset by the recognition of a \$10.0 million pricing and reimbursement milestone as well as recognition of collaboration revenue from Otsuka in the quarter ended September 2023.

Total cost of sales and operating expenses were \$70.8 million and \$65.3 million for the three months ended September 30, 2023 and September 30, 2022, respectively. Total cost of sales and operating expenses were \$192.4 million and \$189.0 million for

the nine months ended September 30, 2023 and September 30, 2022, respectively. Further breakdown of cost of sales and operating expense drivers and fluctuations are highlighted in the following paragraphs.

Cost of sales were \$6.8 million and \$2.4 million for the three months ended September 30, 2023 and September 30, 2022, respectively. The increase is primarily due to increased sales of LUPKYNIS, coupled with the amortization of the monoplant finance right of use asset, which was placed into service in late June 2023.

Cost of sales were \$8.8 million and \$4.3 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. The increase is primarily due to increased sales of LUPKYNIS coupled with the amortization of the monoplant finance right of use asset, partially offset by higher inventory reserves in 2022 due to the write-down of FDA validation batches.

Gross margin for the three months ended September 30, 2023 and September 30, 2022 was approximately 88% and 96%, respectively. Gross margin for the nine months ended September 30, 2023 and September 30, 2022 was approximately 93% and 96% respectively.

Selling, general and administrative (SG&A) expenses, inclusive of share-based compensation, were \$47.8 million and \$52.2 million for the three months ended September 30, 2023 and September 30, 2022, respectively. The decrease is primarily due to a decrease in professional fees and services (including legal fees with respect to litigation matters that occurred during the three months ended September 30, 2022), partially offset by an increase in share-based compensation expense.

SG&A expenses, inclusive of share-based compensation, were \$145.0 million and \$148.9 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. The decrease was primarily due to a decrease in professional fees and services (including legal fees) and other corporate costs (including rent and insurance), partially offset by an increase in share-based compensation expense.

Non-cash SG&A share-based compensation expense included within SG&A expenses was \$9.6 million and \$6.6 million for the three months ended September 30, 2023 and September 30, 2022, respectively. Non-cash SG&A share-based compensation expense included within SG&A expenses, was \$27.0 million and \$21.5 million for the nine months ended September 30, 2023 and September 30, 2022, respectively.

Research and development (R&D) expenses, inclusive of share-based compensation, were \$13.6 million and \$11.0 million for the three months ended September 30, 2023 and September 30, 2022, respectively. The primary drivers for the increase were due to an increase in CRO and developmental costs as the Company advances its preclinical assets.

R&D expenses, inclusive of share-based compensation expense, were \$39.4 million and \$35.1 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. The increase was primarily due to an increase in costs to advance the Company's preclinical assets coupled with an increase in share-based compensation expense partially offset by the decrease in costs associated with the completion of the AURORA 2 continuation study and drug interaction study, which were substantially completed in 2022.

Non-cash R&D share-based compensation expense included with R&D expense was \$2.0 million and \$1.5 million for the three months ended September 30, 2023 and September 30, 2022, respectively. Non-cash R&D share-based compensation expense included with R&D expenses was \$5.7 million and \$3.5 million for the nine months ended September 30, 2023 and September 30, 2022, respectively.

Other (income) expense, net was \$2.6 million and \$(0.3) million for the three months ended September 30, 2023 and September 30, 2022, respectively. The change is primarily related to expenses incurred for shareholder matters partially offset by foreign exchange gain related to the revaluation of the monoplant finance lease liability.

Other (income) expense, net was \$(0.7) million and \$0.6 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. The change is primarily related to change in fair value assumptions driven predominantly by

rising interest rates related to our deferred compensation liability and foreign exchange gain on revaluation of the monoplant finance lease liability, partially offset by expenses incurred for shareholder matters.

Interest income was \$4.5 million and \$1.5 million for the three months ended September 30, 2023 and September 30, 2022, respectively. Interest income was \$12.4 million and \$2.2 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. The increase for both periods is due to higher yields on our investments as a result of increased interest rates.

For the three months ended September 30, 2023, Aurinia recorded a net loss of \$13.4 million or \$0.09 net loss per common share, as compared to a net loss of \$9.0 million or \$0.06 net loss per common share for the three months ended September 30, 2022. For the nine months ended September 30, 2023, Aurinia recorded a net loss of \$51.1 million or \$0.36 net loss per common share, as compared to a net loss of \$82.1 million or \$0.58 net loss per common share for the nine months ended September 30, 2022.

Financial Liquidity at September 30, 2023

As of September 30, 2023, Aurinia had cash, cash equivalents and restricted cash and investments of \$338.5 million compared to \$389.4 million at December 31, 2022. The decrease is primarily related to the continued investment in commercialization activities and post approval commitments of our approved drug, LUPKYNIS, inventory purchases, advancement of our pipeline and monoplant payments, partially offset by an increase in cash receipts from sales of LUPKYNIS.

Aurinia believes that it has sufficient financial resources to fund its operations, which include funding commercial activities, such as FDA related post approval commitments, manufacturing and packaging of commercial drug supply, funding its supporting commercial infrastructure, advancing its R&D programs and funding its working capital obligations for at least the next few years.

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 September 30, 2023 in the Company's Quarterly Report on Form 10-Q and the Company's Annual Report on Form 10-K for the year ended December 31, 2022, including risk factors disclosed therein, which will be accessible on Aurinia's website at www.auriniapharma.com, on SEDAR at www.sedarplus.ca or on EDGAR at www.sec.gov/edgar.

Conference Call Details

Aurinia will host a conference call and webcast to discuss the quarter ended September 30, 2023 financial results today, Thursday, November 2, 2023 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 the corrected call-in number for participants +1 (877) 407-9170 / + 1 201-493-6756 (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

Lupus Nephritis is a serious manifestation 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 about one-third of these people are diagnosed with lupus nephritis at the time of their SLE diagnosis. About 50 percent of all people with SLE may develop lupus nephritis. If poorly controlled, lupus nephritis can lead to permanent and irreversible tissue damage within the kidney. Black and Asian people with SLE are four times more likely to develop lupus nephritis and Hispanic people are approximately twice as likely to develop the disease compared to White people with SLE. Black and Hispanic people with SLE also tend to develop lupus nephritis earlier and have poorer outcomes, compared to White people with SLE.

About Aurinia

Aurinia Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations with a high unmet medical need that are impacted by autoimmune, kidney and rare diseases. In January 2021, the Company introduced LUPKYNIS® (voclosporin), the first FDA-approved oral therapy for the treatment of adult patients with active lupus nephritis (LN). The Company's head office is in Edmonton, Alberta, 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 annual net product revenue from sales of LUPKYNIS in the range of \$155 - \$160 million in 2023; 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; and Aurinia's belief that it has sufficient financial resources to fund its operations for at least the next few years. 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; assumptions relating to pricing for LUPKYNIS and patient persistency on the product; 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; 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 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: 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 widespread health concerns 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 and its other public available filings available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at

www.sedarplus.ca 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.

Investor/Media Contact:

ir@auriniapharma.com

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

(unaudited)	September 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash, cash equivalents and restricted cash	\$ 46,397	\$ 94,172
Short-term investments	291,503	295,218
Accounts receivable, net	37,946	13,483
Inventories, net	32,820	24,752
Prepaid expenses	16,158	13,580
Other current assets	1,645	1,334
Total current assets	<u>426,469</u>	<u>442,539</u>
Non-current assets		
Long-term investments	591	—
Other non-current assets	1,518	13,339
Property and equipment, net	3,496	3,650
Acquired intellectual property and other intangible assets, net	5,261	6,425
Finance right-of-use asset, net	113,069	—
Operating right-of-use assets, net	4,609	4,907
Total assets	<u>\$ 555,013</u>	<u>\$ 470,860</u>
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	52,309	39,990
Deferred revenue	4,662	3,148
Other current liabilities	2,611	2,033
Finance lease liability	13,328	—
Operating lease liabilities	980	936
Total current liabilities	<u>73,890</u>	<u>46,107</u>
Non-current liabilities		
Finance lease liability	72,193	—
Operating lease liabilities	6,713	7,152
Deferred compensation and other non-current liabilities	10,340	12,166
Total liabilities	<u>163,136</u>	<u>65,425</u>
SHAREHOLDER'S EQUITY		
Common shares - no par value, unlimited shares authorized, 143,605 and 142,268 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1,198,560	1,185,309
Additional paid-in capital	109,711	85,489
Accumulated other comprehensive loss	(947)	(1,061)
Accumulated deficit	(915,447)	(864,302)
Total shareholders' equity	<u>391,877</u>	<u>405,435</u>
Total liabilities and shareholders' equity	<u>\$ 555,013</u>	<u>\$ 470,860</u>

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
	(unaudited)			
Revenue				
Product revenue, net	\$ 40,781	\$ 25,502	\$ 116,218	\$ 75,142
License, royalty and collaboration revenue	13,734	30,277	14,200	30,453
Total revenue, net	<u>54,515</u>	<u>55,779</u>	<u>130,418</u>	<u>105,595</u>
Operating expenses				
Cost of sales	6,769	2,447	8,753	4,302
Selling, general and administrative	47,759	52,169	144,964	148,898
Research and development	13,605	10,973	39,413	35,118
Other (income) expense, net	2,645	(311)	(695)	647
Total cost of sales and operating expenses	<u>70,778</u>	<u>65,278</u>	<u>192,435</u>	<u>188,965</u>
Loss from operations	<u>(16,263)</u>	<u>(9,499)</u>	<u>(62,017)</u>	<u>(83,370)</u>
Interest expense	(1,400)	—	(1,465)	—
Interest income	4,514	1,464	12,429	2,209
Net loss before income taxes	<u>(13,149)</u>	<u>(8,035)</u>	<u>(51,053)</u>	<u>(81,161)</u>
Income tax expense	298	954	92	973
Net loss	<u>\$ (13,447)</u>	<u>\$ (8,989)</u>	<u>\$ (51,145)</u>	<u>\$ (82,134)</u>
Basic and diluted loss per share	<u>\$ (0.09)</u>	<u>\$ (0.06)</u>	<u>\$ (0.36)</u>	<u>\$ (0.58)</u>
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	<u>142,847</u>	<u>141,856</u>	<u>143,085</u>	<u>141,831</u>