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 3, 2022

Aurinia Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Canada	**001-36421**	**98-1231763**
(State or Other Jurisdiction of Incorporation)	**(Commission File No.)**	**(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 November 3, 2022, Aurinia Pharmaceuticals Inc. ("Aurinia") issued a press release announcing its financial results for the quarter ended September 30, 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 November 3, 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: November 3, 2022

AURINIA PHARMACEUTICALS INC.

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

AURINIA REPORTS THIRD QUARTER AND NINE MONTHS 2022 FINANCIAL AND OPERATIONAL RESULTS

Net revenue of $55.8 million for Q3 2022; including $30.0 million milestone from Otsuka related to European Approval of LUPKYNIS® (voclosporin)

Adjusts net product revenue guidance to $100-105 million from sales of LUPKYNIS for 2022

Issues preliminary net product revenue guidance for 2023 in the range of $120-140 million from sales of LUPKYNIS

Approximately $400 million of cash, cash equivalents, restricted cash and investments as of October 31, 2022

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

VICTORIA, British Columbia – November 3, 2022 - Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today issued its financial results for the three months ended September 30, 2022. Amounts, unless specified otherwise, are expressed in U.S. dollars.

Total net revenue was $55.8 million for the three months ended September 30, 2022, compared to $14.7 million for the same period ended September 30, 2021. Revenues for the three months ended September 30, 2022 included net product revenues of $25.5 million and license and collaboration revenue of $30.3 million.

“During the third quarter, we demonstrated progress across many key commercial metrics for LUPKYNIS, including an increased total number of patients on therapy, improved patient start form conversion rates and processing speed, and sustained patient adherence, in comparison to the second quarter ended June 30, 2022. Unfortunately, we experienced a slight decline in new patient start forms over the second quarter ended June 30, 2022, which is potentially the result of reduced lupus nephritis diagnoses and patient visits in the quarter,” said Peter Greenleaf, President and Chief Executive Officer of Aurinia. “Given these current market dynamics, we are adjusting our net revenue guidance to $100-105 million from sales of LUPKYNIS for 2022. We are also providing preliminary net revenue guidance from product sales of LUPKYNIS for 2023 in the range of $120-140 million.”

Mr. Greenleaf continued, “In addition to our U.S. commercial efforts, we have also made meaningful advancement in our planned globalization for LUPKYNIS, highlighted by the European Commission Marketing Authorization for LUPKYNIS for the treatment of adults with active lupus nephritis in Europe in September 2022. Working with Otsuka, we expect to achieve continued important regulatory milestones in additional geographies in 2022 and 2023.”

Third Quarter 2022 and Recent Highlights

- There were approximately 1,354 patients on LUPKYNIS therapy at September 30, 2022, compared with 1,274 at June 30, 2022.
- Aurinia added 374 patient start forms (PSFs) during the third quarter 2022, as compared to 412 in the third quarter of 2021. As of Monday, October 31, 2022, the Company recorded 1,357 total PSFs since January 1, 2022.
- PSF conversion rates after 90 days, adherence rates and confirmed patient access remain at peak levels since launch.
- Persistency rates at 6 months and at 9 months remain reasonably consistent with prior periods, at approximately, 70% and 60%, respectively. At 12 months post-treatment-start, an average of approximately 50% of patients remain on treatment.
- The European Commission (EC) granted Marketing Authorization for LUPKYNIS to Otsuka for the treatment of adults with active lupus nephritis in Europe in September 2022. The centralized marketing authorization is valid in all European Union (EU) member states as well as in Iceland, Liechtenstein, Norway and Northern Ireland.
    - The Company recognized a one-time $30.0 million EC approval-related milestone in connection with its collaboration and licensing agreement with its partner Otsuka Pharmaceuticals Co., Ltd., during the quarter, which was subsequently received on October 31, 2022. In addition to the milestone, the Company began recognizing revenue for the supply of product and certain reimbursable collaboration activities under a cost-plus arrangement. Going forward the Company will be eligible to receive further payments tied to additional regulatory and reimbursement milestones, along with low double digit royalties on future net sales.
- Additional clinical data, including updates from AURORA 1 and AURORA 2, are expected to be presented at upcoming conferences, including LUPUS, the American College of Rheumatology Convergence 2022, and, the American Society of Nephrology.
- Key ongoing clinical updates for LUPKYNIS include the advancement of both the VOCAL pediatric study and the ENLIGHT-LN registry. With the registry, which we just initiated at the beginning of the year, we now have 38 activated sites toward our goal of having 75 sites total. As a reminder, we plan to leverage real-world data collected from this study to gain further knowledge about patients taking LUPKYNIS and help clinicians and payers to improve patient care and ensure access to therapy. We also remain on track to meet our post approval FDA commitments.

As previously reported, on July 26, 2022 the U.S. Patent Office Patent Trial and Appeal Board (PTAB) determined to institute an inter partes review (IPR) petition filed by Sun Pharmaceuticals. On October 20, 2022 the PTAB notified the Company that they have denied our rehearing appeal for the institution decision. This follows a prior denial of our precedential opinion panel appeal, which was received on October 5, 2022. The IPR is related to a patent claiming LUPKYNIS dosing protocol that extends patent protection on LUPKYNIS in the United States to 2037. The Company is diligently working on its defense to the IPR, which will be filed after market on November 4, 2022. The defense will address all challenges raised in the IPR process. A determination on patentability, relative to the IPR, is expected on or prior to July 26, 2023.

Financial Results for the Three and Nine Months Ended September 30, 2022

Total net revenue was $55.8 million and $14.7 million for the three months ended September 30, 2022 and September 30, 2021, respectively. Total net revenue was $105.6 million and $22.2 million for the nine months ended September 30, 2022 and September 30, 2021, respectively. The increase in both periods is primarily due to the recognition of a $30.0 million regulatory milestone from Otsuka following the EC marketing authorization of LUPKYNIS in September 2022, coupled with an increase in product sales to our two main customers for LUPKYNIS, which was driven predominantly by further penetration in the lupus nephritis market.

Total cost of sales and operating expenses for the three months ended September 30, 2022 and September 30, 2021 were $65.3 million and $65.0 million, respectively. Total cost of sales and operating expenses were $189.0 million and $170.2 million for the nine months ended September 30, 2022 and September 30, 2021, respectively. Further breakdown of operating expenses drivers and fluctuations are highlighted in the following paragraphs.

Cost of sales were $2.4 million and $0.3 million for the three months ended September 30, 2022 and September 30, 2021, respectively. Cost of sales were $4.3 million and $0.6 million for the nine months ended September 30, 2022 and September 30,

2021, respectively. The increase for both periods was primarily due to an increase in product related revenue, coupled with safety stock inventory reserves.

Gross margin for the three months ended September 30, 2022 and September 30, 2021 was approximately 96% and 98% respectively. Gross margin for the nine months ended September 30, 2022 and September 30, 2021 was approximately 96% and 97%, respectively.

Selling, general and administrative (SG&A) expenses, inclusive of share-based compensation, were $52.2 million and $44.6 million for the three months ended September 30, 2022 and September 30, 2021, respectively. For the nine months ended September 30, 2022 and September 30, 2021, SG&A expenses, inclusive of share-based compensation, were $148.9 million and $128.8 million, respectively. The primary drivers for the increase for both periods ended September 30, 2022 as compared to September 30, 2021 were an increase in professional fees and services related to corporate legal matters, and travel and sponsorships to support the commercialization of LUPKYNIS. For the nine months ended September 30, 2022, the primary drivers were salaries, incentive pay and employee benefits due to employee related expenses such as increased headcount, promotions and inflation, along with an increase in professional fees for corporate legal matters and travel related costs, which increased once the impacts from COVID started to normalize.

Non-cash SG&A share-based compensation expense included above for the three months ended September 30, 2022 and September 30, 2021 was $6.6 million and $6.0 million, respectively. Non-cash SG&A share-based compensation expense included above for the nine months ended September 30, 2022 and September 30, 2021 was $21.5 million and $19.2 million, respectively.

Research and Development (R&D) expenses, inclusive of share-based compensation, were $11.0 million and $20.1 million for the three months ended September 30, 2022 and September 30, 2021, respectively. For the nine months ended September 30, 2022 and September 30, 2021, R&D expenses, inclusive of share-based compensation expense, were $35.1 million and $40.0 million, respectively. The primary drivers for the decrease were the upfront license and accrued milestone expense for AUR300 from the periods ended September 30, 2021 offset year to date by additional developmental expenses related to AUR200 and AUR300 for the periods ended September 30, 2022. In accordance with U.S. GAAP, AUR300 was recorded as an asset acquisition during the period ended September 30, 2021 and expensed as R&D expense at the acquisition date.

Non-cash R&D share-based compensation expense included above for the three months ended September 30, 2022 and September 30, 2021 was $1.5 million and $1.0 million, respectively. Non-cash R&D share-based compensation expense included above for the nine months ended September 30, 2022 and September 30, 2021 was $3.5 million and $3.2 million, respectively.

Interest income was $1.5 million and $0.1 million for the three months ended September 30, 2022 and September 30, 2021, respectively. Interest income was $2.2 million and $0.4 million for the nine months ended September 30, 2022 and September 30, 2021, respectively. The increase in both periods is due to higher yields on our investments as a result of increasing interest rates.

For the three months ended September 30, 2022, Aurinia recorded a net loss of $9.0 million or $0.06 net loss per common share, as compared to a net loss of $50.3 million or $0.39 net loss per common share for the quarter ended September 30, 2021. For the nine months ended September 30, 2022, Aurinia recorded a net loss of $82.1 million or $0.58 net loss per common share, as compared to a net loss of $147.6 million or $1.15 net loss per common share for the nine months ended September 30, 2021.

Financial Liquidity at September 30, 2022

As of September 30, 2022, Aurinia had cash, cash equivalents and restricted cash and investments of $376.6 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, advancement of our pipeline 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 operations, which include funding commercial activities, including 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, 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 September 30, 2022 financial results today, Thursday, November 3, 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 (877) 407-9170 (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 manifestation of 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, LN can lead to permanent and irreversible tissue damage within the kidney. Black and Asian individuals with SLE are four times more likely to develop LN and individuals of 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 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 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 annual net revenue from sales of LUPKYNIS in the range of $100-$105 million in 2022; Aurinia's estimates as to net product revenue for 2023 in the range of $120-$140 million from the sales of LUPKYNIS in the United States; Aurinia's expectations to achieve important regulatory milestones in additional geographies in 2022 and 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; 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. 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; 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 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 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 and its other public available filings 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)

	September 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash, cash equivalents and restricted cash	**$ 86,052**	$ 231,900
Short-term investments	**290,592**	234,178
Accounts receivable, net	**41,771**	15,414
Inventories, net	**25,320**	19,326
Prepaid expenses	**12,159**	11,710
Other current assets	**3,808**	796
Total current assets	**459,702**	513,324
Non-current assets		
Other non-current assets	**13,049**	11,838
Property and equipment, net	**3,758**	4,418
Acquired intellectual property and other intangible assets, net	**6,839**	8,404
Right-of-use assets, net	**4,945**	5,383
Total assets	**488,293**	543,367
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	**40,123**	34,947
Other current liabilities	**724**	4,640
Operating lease liabilities	**918**	1,059
Total current liabilities	**41,765**	40,646
Non-current liabilities		
Deferred compensation and other non-current liabilities	**15,833**	15,950
Operating lease liabilities	**7,270**	7,680
Total liabilities	**64,868**	64,276
SHAREHOLDER'S EQUITY		
Common shares - no par value, unlimited shares authorized, 142,110 and 141,600 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	**1,184,020**	1,177,051
Additional paid-in capital	**79,188**	59,014
Accumulated other comprehensive loss	**(1,527)**	(852)
Accumulated deficit	**(838,256)**	(756,122)
Total shareholders' equity	**423,425**	479,091
Total liabilities and shareholders' equity	**$ 488,293**	$ 543,367

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,	
	2022	**2021**	**2022**	**2021**
	(unaudited)		**(unaudited)**	
Revenue				
Product revenue, net	**$ 25,502**	$ 14,638	**$ 75,142**	$ 22,113
License and collaboration revenue	**30,277**	29	**30,453**	88
Total revenue, net	**55,779**	14,667	**105,595**	**22,201**
Operating expenses				
Cost of sales	**2,447**	254	**4,302**	610
Selling, general and administrative	**52,169**	44,645	**148,898**	128,772
Research and development	**10,973**	20,066	**35,118**	39,990
Other (income) expense, net	**(311)**	55	**647**	859
Total cost of sales and operating expenses	**65,278**	65,020	**188,965**	170,231
Loss from operations	**(9,499)**	(50,353)	**(83,370)**	(148,030)
Interest income	**1,464**	106	**2,209**	420
Net loss before income taxes	**(8,035)**	(50,247)	**(81,161)**	(147,610)
Income tax expense	**954**	8	**973**	34
Net loss	**(8,989)**	(50,255)	**$ (82,134)**	$ (147,644)
Basic and diluted loss per share	**$ (0.06)**	$ (0.39)	**$ (0.58)**	$ (1.15)
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	**141,856**	128,443	**141,831**	128,084