

**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, 2021

Aurinia Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Canada
(State or Other Jurisdiction of Incorporation)

001-36421
(Commission File No.)

46-4129078
(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, 2021, Aurinia Pharmaceuticals Inc. ("Aurinia") issued a press release announcing its financial results for the quarter ended September 30, 2021. 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, 2021
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, 2021

AURINIA PHARMACEUTICALS INC.

By: /s/ Joseph Miller

Name: Joseph Miller

Title: Chief Financial Officer



AURINIA REPORTS THIRD QUARTER AND NINE MONTHS 2021 FINANCIAL RESULTS AND COMPANY UPDATES

\$14.7 million in net revenue for the third quarter 2021 (122% increase from second quarter 2021)

Steady increases in LUPKYNIS Patient Start Forms, Conversion Rates and Payer Coverage

Addition of two preclinical assets with potential in rare autoimmune conditions to grow and diversify the pipeline

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

VICTORIA, British Columbia – November 3, 2021 - Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (“Aurinia” or the “Company”) today issued its financial results for the third quarter ended September 30, 2021. Amounts, unless specified otherwise, are expressed in U.S. dollars.

Aurinia achieved third quarter revenue of \$14.7 million, with nine months ended September 30, 2021 revenue of \$22.2 million and maintains its previously stated annual revenue estimate in the range of \$40 to \$50 million for 2021.

“We are very pleased with Q3 results as we continue to execute on our LUPKYNIS commercialization strategies,” said Peter Greenleaf, President and Chief Executive Officer of Aurinia. “Despite the challenge of the COVID-19 Delta variant and a slight seasonal slowdown, we saw steady increases in patient start forms and patients on treatment toward the end of the quarter and continue to see this upward momentum through October.”

“Data presentations at key medical meetings this week, including additional interim results from the AURORA 2 continuation study, will help bolster awareness of and confidence in the efficacy and safety of LUPKYNIS and we expect final results of the continuation study to be announced by the end of 2021,” Greenleaf added.

“Finally, while our commercial team focused on increasing adoption of LUPKYNIS, Aurinia recently added two exciting preclinical assets – AUR200 and AUR300”, said Greenleaf. “We are eager to leverage our expertise and capabilities to advance these compounds for the treatment of rare autoimmune diseases with high unmet needs.”

Third Quarter 2021 Highlights & Upcoming Milestones:

- Aurinia has secured 412 patient start forms (PSFs) in the third quarter and as of November 3, 2021, Aurinia has secured a total of more than 1,265 PSFs.
- PSF conversion rates continue to increase with more than 68% of PSFs converted to patients on therapy. Q2 conversion rates were 50%. Time to convert continues to decrease since launch: 30- and 60-day conversion rates have improved each month.
- As of early October, Aurinia has confirmed coverage for LUPKYNIS through published payer policies for 65% of total lives in the market. Through patients gaining access to LUPKYNIS, the company now has confirmed coverage in plans covering 87% of total lives.
- On August 17, 2021, Aurinia announced the addition of two novel pipeline assets: AUR200, an Fc protein targeting BAFF/APRIL (B-cell Activating Factor, known as BAFF, and A Proliferation-Inducing Ligand known as APRIL) and AUR300, a novel peptide therapeutic that modulates M2 macrophages via the macrophage mannose receptor CD206. For the acquisitions, an Investigational New Drug Application (IND) filing for AUR200 is expected by the end of 2022 and an AUR300 IND filing is expected during the first half of 2023.
- On October 1, 2021, Aurinia’s licensing partner, Otsuka Pharmaceutical Co., Ltd., filed an initial marketing authorization application (MAA) with the Swiss Agency for Therapeutic Products (Swissmedic) seeking approval for

the use of voclosporin for the treatment of adult patients with active LN. The Swiss filing was based on the June 24, 2021 MAA submission to the European Medicines Agency (EMA).

- Regulatory review of the EMA MAA remains on track with a Committee for Medicinal Products for Human Use (CHMP) opinion expected around mid-2022 followed by an EMA decision expected sometime in the third quarter of 2022. Additionally, Otsuka continues to work to finalize the timeline for the Japanese New Drug Application (JNDA) regulatory filing with Pharmaceutical and Medical Device Agency (PMDA) to seek approval of voclosporin for the treatment of LN in Japan.
- This week, Aurinia will present efficacy, safety and tolerability data for LUPKYNIS at two key medical meetings. The American College of Rheumatology (ACR) Convergence 2021 meeting (November 3-6) will feature an updated analysis of the AURORA 2 continuation study and two poster presentations on the efficacy of LUPKYNIS (from AURORA 1 data) across biopsy classes as well as in recent onset LN. The AURORA 2 updated interim analysis showed patients treated with LUPKYNIS maintained meaningful reductions in proteinuria with no change in mean eGFR at 30 months of treatment. At the American Society of Nephrology (ASN) Kidney Week 2021 (November 2-7) two Aurinia abstracts were accepted including an oral presentation on the efficacy of LUPKYNIS in achieving complete renal response in severe lupus nephritis.
- Data from the full AURORA 2 two-year continuation study is expected to be announced late in the fourth quarter of 2021.

Financial Liquidity at September 30, 2021

As of September 30, 2021, Aurinia had cash and cash equivalents and investments of \$286.4 million compared to \$422.7 million at December 31, 2020. The decrease was primarily related to the commercial infrastructure spend to support the launch of LUPKYNIS, payments for inventory, an upfront payment made as part of a collaborative agreement with Lonza to build a dedicated manufacturing capability (or monoplant) and an upfront license payment related to our recently acquired developmental program.

Net cash used in operating activities was \$131.8 million for the nine months ended September 30, 2021 compared to \$73.1 million for the nine months ended September 30, 2020. The increase was primarily due to the commercial infrastructure spend to support the launch of LUPKYNIS, payments for inventory and a one-time payment to a related party upon achievement of specific milestones partially offset by an increase in cash receipts. In the prior year, the Company was still in the development phase of LUPKYNIS.

The Company believes that it has sufficient financial resources to fund its current plans, which include funding commercial activities, including FDA related post approval commitments, manufacturing and packaging of commercial drug supply, funding our supporting commercial infrastructure, conducting planned research and development (R&D) programs, investing in our pipeline and operating activities into at least 2023.

Financial Results for the Quarter and Year Ended September 30, 2021

For the quarter ended September 30, 2021, Aurinia recorded a net loss of \$50.3 million or \$0.39 net loss per common share, as compared to a net loss of \$42.1 million or \$0.34 net loss per common share for the quarter ended September 30, 2020. For the nine months ended September 30, 2021, Aurinia recorded a net loss of \$147.6 million or \$1.15 net loss per common share as compared to a net loss of \$94.6 million or \$0.82 net loss per common share for the previous period.

Total revenue was \$14.7 million and \$29 thousand for the quarters ended September 30, 2021 and September 30, 2020, respectively. Total revenue was \$22.2 million and \$88 thousand for the nine months ended September 30, 2021 and September 30, 2020, respectively. Our revenues primarily consisted of product revenue, net of adjustments for LUPKYNIS, following FDA approval in January of 2021.

Cost of sales were \$254 thousand and nil for the quarters ended September 30, 2021 and September 30, 2020, respectively. Cost of sales were \$610 thousand and nil for the nine months ended September 30, 2021 and September 30, 2020, respectively. The increase for both periods was primarily the result of commercial sales of LUPKYNIS. Gross margin for the three and nine months ended September 30, 2021 was approximately 98% and 97% respectively.

Selling, general and administrative (SG&A) expenses were \$44.1 million and \$30.7 million for the quarters ended September 30, 2021 and September 30, 2020, respectively. For the nine months ended September 30, 2021 and September 30, 2020, SG&A expenses were \$127.2 million and \$57.2 million, respectively. The increase for both periods was due to the increase in salaries, incentive pay and employee benefits related to the expansion of the commercial and administrative functions to support the launch of LUPKYNIS which ramped up during the third quarter of 2020. Also contributing was an increase in professional fees for activities such as patient assistance programs, consulting, recruiting, legal, market research and marketing.

Non-cash SG&A share-based compensation expense for the three and nine months ended September 30, 2021 was \$6.0 million and \$19.2 million as compared to \$3.8 million and \$9.2 million for the same periods of 2020.

Research and Development (R&D) expenses were \$20.1 million and \$12.2 million for the quarters ended September 30, 2021 and September 30, 2020, respectively. For the nine months ended September 30, 2021 and September 30, 2020, R&D expenses were \$40.0 million and \$37.2 million, respectively. The primary driver for the increase for the three months ended September 30, 2021 as compared to the same period of 2020 was the upfront license and accrued milestone expense related to our recently acquired developmental programs, AUR200 and AUR300. In accordance with U.S. GAAP, these transactions did not meet the definition of a business combination and therefore, were recorded as asset acquisitions. We expensed the cost of the assets as R&D expense at the acquisition dates. The increase was partially offset by a decrease in clinical supply and distribution costs due to our new drug application and voclosporin related clinical trial expenditures in 2020 not recurring in 2021. Also contributing was a decrease in salaries, incentive pay and employee benefits due to the allocation of costs related to post approval support of LUPKYNIS to SG&A.

The primary drivers for the increase for the nine months ended September 30, 2021 as compared to the same period of 2020 were due to the upfront license and accrued milestone expense related to our recently acquired developmental programs, AUR200 and AUR300, and higher CRO expenses related to our new clinical programs offset by a decrease in clinical supply and distribution costs following the approval of LUPKYNIS, including a reduction in new drug application preparation costs and termination of the dry eye trial during the fourth quarter of 2020.

Non-cash R&D share-based compensation expense for the three and nine months ended September 30, 2021 was \$1.0 million and \$3.2 million as compared to \$0.8 million and \$3.1 million for the same periods of 2020.

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, 2021 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 and year ended September 30, 2021 financial results today, Wednesday, November 3, 2021 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 progression of systemic lupus erythematosus (SLE), a chronic and complex autoimmune disease. About 200,000-300,000 people live with SLE in the U.S. and approximately one out of three of these individuals have already developed LN at the time of SLE diagnosis. If poorly controlled, LN can lead to permanent and irreversible tissue damage within the kidney, resulting in kidney failure. Black and Asian individuals with SLE are four times more likely to develop LN and individuals with Hispanic ancestry are approximately twice as likely to develop the disease when compared with Caucasian

individuals. Black and Hispanic individuals with SLE also tend to develop LN earlier and have poorer outcomes when compared to Caucasian individuals.

About Aurinia

Aurinia Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company has introduced LUPKYNIS (voclosporin), the first FDA-approved oral therapy dedicated for the treatment of adult patients with active LN. The Company's head office is in Victoria, British Columbia, its U.S. commercial 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 in the range of \$40-\$50 million in 2021; Aurinia's estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who will develop LN; Aurinia being confident that it is well-poised for growth; Aurinia's belief that it has sufficient financial resources to fund its current plans until 2023; the expected timing for the EMA CHMP opinion and EMA decision relating to the EMA MAA; and the planned timing for reporting top-line results from the ongoing AURORA-2 continuation study. 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 into 2023; the assumption that Aurinia's current good relationships with its suppliers, service providers and other third parties will be maintained; assumptions relating to the burn rate of Aurinia's cash for operations; 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 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, or on Aurinia's website at www.auriniapharma.com.

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	<u>(unaudited)</u>	
ASSETS		
<i>Current assets</i>		
Cash and cash equivalents	\$ 57,587	\$ 272,350
Short-term investments	228,813	125,979
Accounts receivable, net	9,814	—
Inventories, net	19,293	13,927
Prepaid expenses and other current assets	13,712	7,171
Total current assets	<u>329,219</u>	<u>419,427</u>
<i>Non-current assets</i>		
Long-term investments	—	24,380
Other non-current assets	11,838	247
Property and equipment, net	4,551	4,786
Acquired intellectual property and other intangible assets, net	8,926	9,332
Right-of-use assets	5,532	5,489
Total assets	<u>360,066</u>	<u>463,661</u>
LIABILITIES		
<i>Current liabilities</i>		
Accounts payable and accrued liabilities	29,970	24,797
Other current liabilities (of which \$2,000 and \$6,000, due to related party in 2021 and 2020, respectively)	6,456	6,412
Operating lease liabilities	1,111	788
Total current liabilities	<u>37,537</u>	<u>31,997</u>
<i>Non-current liabilities</i>		
Other non-current liabilities	16,562	16,295
Operating lease liabilities	7,795	7,619
Total liabilities	<u>61,894</u>	<u>55,911</u>
SHAREHOLDER'S EQUITY		
Common shares - no par value, unlimited shares authorized, 129,570 and 126,725 shares issued and outstanding as at September 30, 2021 and December 31, 2020, respectively	967,159	944,328
Additional paid-in capital	54,607	39,383
Accumulated other comprehensive loss	(794)	(805)
Accumulated deficit	(722,800)	(575,156)
Total shareholder's equity	<u>298,172</u>	<u>407,750</u>
Total liabilities and shareholders' equity	<u>\$ 360,066</u>	<u>\$ 463,661</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,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Revenue				
Product revenue, net	\$ 14,638	\$ —	\$ 22,113	\$ —
License revenue	29	29	88	88
Total revenue	14,667	29	22,201	88
Operating expenses:				
Cost of sales	254	—	610	—
Selling, general and administrative	44,128	30,702	127,196	57,204
Research and development	20,066	12,243	39,990	37,154
Amortization of intangible assets	517	316	1,576	902
Other (income) expense, net	55	(917)	859	1,066
Total cost of sales and operating expenses	65,020	42,344	170,231	96,326
Loss from operations	(50,353)	(42,315)	(148,030)	(96,238)
Interest income	106	170	420	1,381
Net loss before income taxes	(50,247)	(42,145)	(147,610)	(94,857)
Income tax expense (benefit)	8	(15)	34	(251)
Net loss	\$ (50,255)	\$ (42,130)	\$ (147,644)	\$ (94,606)
Basic and diluted loss per share	\$ (0.39)	\$ (0.34)	\$ (1.15)	\$ (0.82)
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	128,443	122,357	128,084	115,738